

Sanofi  
Form 20-F  
March 03, 2017  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 20-F**

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

or

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016

Or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Or

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-31368

**Sanofi**

(Exact name of registrant as specified in its charter)

N/A

(Translation of registrant's name into English)

Edgar Filing: Sanofi - Form 20-F

France

(Jurisdiction of incorporation or organization)

54, Rue La Boétie, 75008 Paris, France

(Address of principal executive offices)

Karen Linehan, Executive Vice President Legal Affairs and General Counsel

54, Rue La Boétie, 75008 Paris, France. Fax: 011 + 33 1 53 77 43 03. Tel: 011 + 33 1 53 77 40 00

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of each exchange on which registered:
American Depositary Shares, each representing one half of one ordinary share, par value 2 per share	New York Stock Exchange
Ordinary shares, par value 2 per share	New York Stock Exchange (for listing purposes only)
Contingent Value Rights	NASDAQ Global Market
Securities registered pursuant to Section 12(g) of the Act: None	

The number of outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2016 was:

Ordinary shares: 1,292,022,324

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO .

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. YES NO .

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

# Edgar Filing: Sanofi - Form 20-F

U.S. GAAP

International Financial Reporting Standards as issued by  
the International Accounting Standards Board

Other

If **Other** has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17                      Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  
No .

---

## **Table of Contents**

### **Presentation of financial and other information**

The consolidated financial statements contained in this annual report on Form 20-F have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS as adopted by the European Union, as of December 31, 2016.

Unless the context requires otherwise, the terms Sanofi, the Company, the Group, we, our or us refer to Sanofi and its consolidated subsidiaries.

All references herein to United States or US are to the United States of America, references to dollars or \$ are to the currency of the United States, references to France are to the Republic of France, and references to euro and € are to the currency of the European Union member states (including France) participating in the European Monetary Union.

Brand names appearing in this annual report are trademarks of Sanofi and/or its affiliates, with the exception of:

· trademarks used or that may be or have been used under license by Sanofi and/or its affiliates, such as Actonel<sup>®</sup>, a trademark of Actavis; Afrezza<sup>®</sup>, a trademark of Mannkind Corporation; Aldurazyme<sup>®</sup>, a trademark of the Joint Venture Biomarin/Genzyme LLC; Avilomics<sup>®</sup>, a trademark of Avila Therapeutics, Inc.; Cialis<sup>®</sup> OTC, a trademark of Eli Lilly; Copaxone<sup>®</sup>, a trademark of Teva Pharmaceuticals Industries; Cortizone-10<sup>®</sup>, a trademark of Johnson & Johnson (except in the United States where it is a Sanofi trademark); Fludara<sup>®</sup> and Leukine<sup>®</sup>, trademarks of Alcafleu; Flutiform<sup>®</sup>, a trademark of Jagotec AG; Gardasil<sup>®</sup> and Zostavax<sup>®</sup>, trademarks of Merck & Co.; Hexyon<sup>®</sup> and Repevax<sup>®</sup>, trademarks of Sanofi Pasteur MSD; RetinoStat<sup>®</sup> and UshStat<sup>®</sup>, trademarks of Oxford Biomedica; Spedra<sup>®</sup> and Stendra<sup>®</sup>, trademarks of Vivus Inc.; and Zaltrap<sup>®</sup> a trademark of Regeneron in the United States;

· trademarks sold by Sanofi and/or its affiliates to a third party, such as Altace<sup>®</sup>, a trademark of King Pharmaceuticals in the United States; Hyalgan<sup>®</sup>, a trademark of Fidia Farmaceutici S.p.A.; Liberty<sup>®</sup>, Liberty<sup>®</sup> Herbicide, LibertyLink<sup>®</sup> Rice 601, LibertyLink<sup>®</sup> Rice 604 and StarLink<sup>®</sup>, trademarks of Bayer; Maalox<sup>®</sup>, a trademark of Novartis in the United States, Canada and Puerto Rico; and Sculptra<sup>®</sup> a trademark of Valeant; and

· other third party trademarks such as Advantage<sup>®</sup> and Advantix<sup>®</sup>, trademarks of Bayer; Atelvia<sup>®</sup>, a trademark of Actavis in the United States; DDAVP<sup>®</sup>, a trademark of Ferring (except in the United States where it is a Sanofi trademark); Enbrel<sup>®</sup>, a trademark of Immunex in the United States and of Wyeth in other geographical areas; GLAAS<sup>®</sup>, a trademark of Immune Design; Humalog<sup>®</sup>, Humulin<sup>®</sup>, Miriopeñ<sup>®</sup>, Basaglar<sup>®</sup> and Kwikpen<sup>®</sup>, trademarks of Eli Lilly; iPhone<sup>®</sup> and iPod Touch<sup>®</sup>, trademarks of Apple Inc.; Lactacyd<sup>®</sup>, a trademark of Omega Pharma NV in the EU and several other European countries; Rituxan<sup>®</sup>, a trademark of Biogen Idec, Inc. in the United States and Canada, and Genentech in Japan; Squarekids<sup>®</sup>, a trademark of Kitasato Daiichi Sankyo Vaccine Co., Ltd.; Unisom<sup>®</sup> a trademark of Johnson & Johnson in certain geographical areas (except in the United States and Israel where it is a Sanofi trademark and Canada where it is a trademark of Paladin Labs, Inc.); and Yosprala<sup>®</sup>, a trademark of Pozen, Inc.

Not all trademarks related to investigational agents have been authorized as of the date of this annual report by the relevant health authorities; for instance, the Lyxumia<sup>®</sup> trade name has not been approved by the FDA.

The data relating to market shares and ranking information for pharmaceutical products, in particular as presented in Item 4. Information on the Company B. Business Overview B.6. Markets B.6.1. Marketing and distribution, are based mainly on sales data from QuintilesIMS (MIDAS) on Moving Annual Total September 2016, in constant euros (unless otherwise indicated), supplemented by country-specific sources.

While we believe that the IMS sales data we present below are generally useful comparative indicators for our industry, they may not precisely match the sales figures published by the companies that sell the products (including our company and other pharmaceutical companies). In particular, the rules used by IMS to attribute the sales of a product covered by an alliance or license agreement do not always exactly match the rules of the agreement.

In order to allow a reconciliation with our basis of consolidation as defined in Item 5. Operating and Financial Review and Prospects Presentation of Net Sales, IMS data shown in the present document have been adjusted and include:

## Edgar Filing: Sanofi - Form 20-F

(i) sales as published by IMS excluding Sanofi sales generated by the vaccines business, equating to the scope of our pharmaceutical operations;

(ii) IMS sales of products sold under alliance or license agreements which we recognize in our consolidated net sales but which are not attributed to us in the reports published by IMS; and

(iii) adjustments related to the exclusion of IMS sales for products which we do not recognize in our consolidated net sales but which are attributed to us by IMS.

Data relating to market shares and ranking information presented herein for our Consumer Healthcare products are based on sales data from Nicholas Hall.

Data relating to market shares and ranking information presented herein for our vaccines business are based on internal estimates unless stated otherwise.

---

## **Table of Contents**

Product indications described in this annual report are composite summaries of the major indications approved in the product's principal markets. Not all indications are necessarily available in each of the markets in which the products are approved. The summaries presented herein for the purpose of financial reporting do not substitute for careful consideration of the full labeling approved in each market.

### **Cautionary statement regarding forward-looking statements**

This annual report contains forward-looking statements. We may also make written or oral forward-looking statements in our periodic reports to the Securities and Exchange Commission on Form 6-K, in our annual report to shareholders, in our offering circulars and prospectuses, in press releases and other written materials and in oral statements made by our officers, directors or employees to third parties. Examples of such forward-looking statements include:

- projections of operating revenues, net income, business net income, earnings per share, business earnings per share, capital expenditures, cost savings, restructuring costs, positive or negative synergies, dividends, capital structure or other financial items or ratios;
- statements of our profit forecasts, trends, plans, objectives or goals, including those relating to products, clinical trials, regulatory approvals and competition; and
- statements about our future events and economic performance or that of France, the United States or any other countries in which we operate.

This information is based on data, assumptions and estimates considered as reasonable by Sanofi as at the date of this annual report and undue reliance should not be placed on such statements.

Words such as believe, anticipate, plan, expect, intend, target, estimate, project, predict, forecast, guideline, should and intended to identify forward-looking statements but are not the exclusive means of identifying such statements.

Forward-looking statements involve inherent, known and unknown, risks and uncertainties associated with the regulatory, economic, financial and competitive environment, and other factors that could cause future results and objectives to differ materially from those expressed or implied in the forward-looking statements.

Risk factors which could affect future results and cause actual results to differ materially from those contained in any forward-looking statements are discussed under Item 3. Key Information D. Risk Factors. Additional risks, not currently known or considered immaterial by the Group, may have the same unfavorable effect and investors may lose all or part of their investment.

Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

**Table of Contents****ABBREVIATIONS****Principal abbreviations used in the Annual Report on Form 20-F**

<b>ADR</b>	American Depositary Receipt
<b>ADS</b>	American Depositary Share
<b>AFEP</b>	<i>Association française des entreprises privées</i> (French Association of Large Companies)
<b>AMF</b>	<i>Autorité des marchés financiers</i> (the French market regulator)
<b>ANDA</b>	Abbreviated New Drug Application
<b>BLA</b>	Biologic License Application
<b>BMS</b>	Bristol-Myers Squibb
<b>CEO</b>	Chief Executive Officer
<b>CER</b>	Constant exchange rates
<b>CGU</b>	Cash generating unit
<b>CHC</b>	Consumer Healthcare
<b>CHMP</b>	Committee for Medicinal Products for Human Use
<b>CVR</b>	Contingent value right
<b>ECB</b>	European Central Bank
<b>EMA</b>	European Medicines Agency
<b>EU</b>	European Union
<b>FDA</b>	US Food and Drug Administration
<b>GAVI</b>	Global Alliance for Vaccines and Immunisation
<b>GBU</b>	Global Business Unit
<b>GLP-1</b>	Glucagon-like peptide-1
<b>GMP</b>	Good manufacturing practice
<b>Hib</b>	Haemophilus influenzae type b
<b>HSE</b>	Health, Safety and Environment
<b>IASB</b>	International Accounting Standards Board
<b>ICH</b>	International Council for Harmonization
<b>IFRS</b>	International Financial Reporting Standards
<b>IPV</b>	Inactivated polio vaccine
<b>ISIN</b>	International Securities Identification Number
<b>J-MHLW</b>	Japanese Ministry of Health, Labor and Welfare
<b>LSD</b>	Lysosomal storage disorder
<b>MEDEF</b>	<i>Mouvement des entreprises de France</i> (French business confederation)
<b>MS</b>	Multiple sclerosis
<b>NASDAQ</b>	National Association of Securities Dealers Automated Quotations
<b>NDA</b>	New Drug Application
<b>NHI</b>	National Health Insurance (Japan)
<b>NYSE</b>	New York Stock Exchange
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>OPV</b>	Oral polio vaccine
<b>OTC</b>	Over the counter
<b>PMDA</b>	Pharmaceuticals and Medical Devices Agency (Japan)
<b>PRV</b>	Priority Review Voucher
<b>PTE</b>	Patent Term Extension
<b>QIV</b>	Quadrivalent influenza vaccine
<b>R&amp;D</b>	Research and development
<b>ROA</b>	Return on assets
<b>SA</b>	<i>Société anonyme</i> (French public limited corporation)
<b>SEC</b>	US Securities and Exchange Commission
<b>SPC</b>	Supplementary Protection Certificate
<b>TSR</b>	Total shareholder return
<b>UNICEF</b>	United Nations Children's Fund
<b>US</b>	United States of America
<b>WHO</b>	World Health Organization



**Table of Contents***Table of contents*

Item 1.	<b><u>IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS</u></b>	1
Item 2.	<b><u>OFFER STATISTICS AND EXPECTED TIMETABLE</u></b>	1
Item 3.	<b><u>KEY INFORMATION</u></b>	1
	<b><u>A. Selected Financial Data</u></b>	1
	<b><u>B. Capitalization and Indebtedness</u></b>	3
	<b><u>C. Reasons for Offer and Use of Proceeds</u></b>	3
	<b><u>D. Risk Factors</u></b>	4
Item 4.	<b><u>INFORMATION ON THE COMPANY</u></b>	19
	<b><u>A. History and Development of the Company</u></b>	20
	<b><u>B. Business Overview</u></b>	20
	<b><u>C. Organizational Structure</u></b>	73
	<b><u>D. Property, Plant and Equipment</u></b>	74
Item 4A.	<b><u>UNRESOLVED STAFF COMMENTS</u></b>	77
Item 5.	<b><u>OPERATING AND FINANCIAL REVIEW AND PROSPECTS</u></b>	78
	<b><u>A. Operating results</u></b>	78
	<b><u>B. Liquidity and Capital Resources</u></b>	126
	<b><u>C. Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments</u></b>	129
Item 6.	<b><u>DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES</u></b>	132
	<b><u>A. Directors and Senior Management</u></b>	132
	<b><u>B. Compensation</u></b>	152
	<b><u>C. Board Practices</u></b>	168
	<b><u>D. Employees</u></b>	173
	<b><u>E. Share Ownership</u></b>	175
Item 7.	<b><u>MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS</u></b>	179
	<b><u>A. Major Shareholders</u></b>	179
	<b><u>B. Related Party Transactions</u></b>	180
	<b><u>C. Interests of Experts and Counsel</u></b>	180
Item 8.	<b><u>FINANCIAL INFORMATION</u></b>	181
	<b><u>A. Consolidated Financial Statements and Other Financial Information</u></b>	181
	<b><u>B. Significant Changes</u></b>	184
Item 9.	<b><u>THE OFFER AND LISTING</u></b>	185
	<b><u>A. Offer and Listing Details</u></b>	185
	<b><u>B. Plan of Distribution</u></b>	186
	<b><u>C. Markets</u></b>	186
	<b><u>D. Selling Shareholders</u></b>	186

	<u>E. Dilution</u>	186
	<u>F. Expenses of the Issue</u>	186
Item 10.	<u>ADDITIONAL INFORMATION</u>	187
	<u>A. Share Capital</u>	187
	<u>B. Memorandum and Articles of Association</u>	187
	<u>C. Material Contracts</u>	200
	<u>D. Exchange Controls</u>	200
	<u>E. Taxation</u>	201
	<u>F. Dividends and Paving Agents</u>	205
	<u>G. Statement by Experts</u>	205
	<u>H. Documents on Display</u>	205
	<u>I. Subsidiary Information</u>	205
Item 11.	<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	206
Item 12.	<u>DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES</u>	210
Item 13.	<u>DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES</u>	216
Item 14.	<u>MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS</u>	216
Item 15.	<u>CONTROLS AND PROCEDURES</u>	216
Item 16.	<u>[Reserved]</u>	216
Item 16A.	<u>AUDIT COMMITTEE FINANCIAL EXPERT</u>	217
Item 16B.	<u>CODE OF ETHICS</u>	217
Item 16C.	<u>PRINCIPAL ACCOUNTANTS FEES AND SERVICES</u>	217
Item 16D.	<u>EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES</u>	217
Item 16E.	<u>PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS</u>	217
Item 16F.	<u>CHANGE IN REGISTRANT S CERTIFYING ACCOUNTANT</u>	218
Item 16G.	<u>CORPORATE GOVERNANCE</u>	218
Item 16H.	<u>MINE SAFETY DISCLOSURE</u>	219
Item 17.	<u>FINANCIAL STATEMENTS</u>	220
Item 18.	<u>FINANCIAL STATEMENTS</u>	220
Item 19.	<u>EXHIBITS</u>	220

**Table of Contents**

**ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS**

**PART I**

**Item 1. Identity of Directors, Senior Management and Advisers**

N/A

**Item 2. Offer Statistics and Expected Timetable**

N/A

**Item 3. Key Information**

**A. Selected Financial Data**

**SUMMARY OF SELECTED FINANCIAL DATA**

The tables below set forth selected consolidated financial data for Sanofi. These financial data are derived from the Sanofi consolidated financial statements. The Sanofi consolidated financial statements for the years ended December 31, 2016, 2015 and 2014 are included in Item 18 of this annual report.

## Edgar Filing: Sanofi - Form 20-F

The consolidated financial statements of Sanofi for the years ended December 31, 2016, 2015 and 2014 have been

prepared in compliance with IFRS issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2016. The term "IFRS" refers collectively to international accounting and financial reporting standards (IAS and IFRS) and to interpretations of the interpretations committees (SIC and IFRIC) mandatorily applicable as of December 31, 2016.

Sanofi reports its financial results in euros.

**Table of Contents****ITEM 3. KEY INFORMATION****SELECTED CONDENSED FINANCIAL INFORMATION**

( million, except per share data)	As of and for the year ended December 31,				
	2016	2015	2014	2013	2012 <sup>(a)</sup>
<b>IFRS Income statement data</b>					
Net sales <sup>(b)</sup>	33,821	34,060	31,380	30,693	34,743
Gross profit	24,006	23,942	21,769	20,989	24,859
Operating income	6,534	5,624	6,064	4,982	6,430
Net income excluding the held-for-exchange Animal Health business	4,486	4,512	4,392	3,797	-
Net income attributable to equity holders of Sanofi	4,709	4,287	4,390	3,716	4,888
<b>Basic earnings per share ( <sup>(g)</sup> ):</b>					
Net income excluding the held-for-exchange Animal Health business	3.42	3.38	3.25	2.75	-(a)
Net income attributable to equity holders of Sanofi	3.66	3.28	3.34	2.81	3.70
<b>Diluted earnings per share ( <sup>(g)</sup> ):</b>					
Net income attributable to equity holders of Sanofi	3.63	3.25	3.30	2.77	3.68
<b>IFRS Balance sheet data</b>					
Goodwill and other intangible assets	51,166 <sup>(e)</sup>	51,583 <sup>(e)</sup>	53,740	52,529	58,265
Total assets	104,672	102,321	97,392	96,055	100,399
Outstanding share capital	2,544	2,603	2,620	2,641	2,646
Equity attributable to equity holders of Sanofi	57,554	58,049	56,120	56,904	57,352
Long term debt	16,815 <sup>(e)</sup>	13,118 <sup>(e)</sup>	13,276	10,414	10,719
Cash dividend paid per share ( <sup>(g)</sup> )	2.96 <sup>(g)</sup>	2.93	2.85	2.80	2.77
Cash dividend paid per share ( \$ ) <sup>(f)(h)</sup>	3.12 <sup>(g)</sup>	3.19	3.46	3.86	3.65

(a) For 2012, the lines **Net sales**, **Gross profit**, and **Operating Income** include the Animal Health business. For the other periods (2013 to 2016), the net results of the Animal Health business are presented in a separate line item, **Net income/(loss) of the held-for-exchange Animal Health business**, in the consolidated income statements.

(b) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards (see Notes A.5. and B.14.). The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).

(c) Based on the weighted average number of shares outstanding in each period used to compute basic earnings per share, equal to 1,286.6 million shares in 2016, 1,306.2 million shares in 2015, 1,315.8 million shares in 2014, 1,323.1 million shares in 2013 and 1,319.5 million shares in 2012.

(d) Based on the weighted average in each period of the number of shares outstanding plus stock options and restricted shares with a potentially dilutive effect; i.e., 1,296.0 million shares in 2016, 1,320.7 million shares in 2015, 1,331.1 million shares in 2014, 1,339.1 million shares in 2013 and 1,329.6 million shares in 2012.

(e) As reported, excluding the Animal Health business clarified in the line item, **Assets held for sale or exchange and liabilities related to assets held for sale or exchange** as of December 31, 2015 and December 31, 2016.

(f) Each American Depositary Share, or ADS, represents one half of one share.

(g) Dividends for 2016 will be proposed for approval at the annual general meeting scheduled for May 10, 2017.

(h) Based on the relevant year-end exchange rate.



**Table of Contents****ITEM 3. KEY INFORMATION****SELECTED EXCHANGE RATE INFORMATION**

The following table sets forth, for the periods and dates indicated, certain information concerning the exchange rates for the euro from 2011 through March 2017 expressed in US dollars per euro. The information concerning the US dollar exchange rate is based on the noon buying rate in New York City for cable transfers in foreign currencies as certified for customs purposes by the Federal Reserve Bank of New York (the Noon Buying Rate). We provide the

exchange rates below solely for your convenience. We do not represent that euros were, could have been, or could be, converted into US dollars at these rates or at any other rate. For information regarding the effect of currency fluctuations on our results of operations, see Item 5. Operating and Financial Review and Prospects and Item 11. Quantitative and Qualitative Disclosures about Market Risk.

<i>(U.S. dollar per euro)</i>	<b>Period-end Rate</b>	<b>Average Rate<sup>(a)</sup></b>	<b>High</b>	<b>Low</b>
2011	1.30	1.40	1.49	1.29
2012	1.32	1.29	1.35	1.21
2013	1.38	1.33	1.38	1.28
2014	1.21	1.32	1.39	1.21
2015	1.09	1.10	1.20	1.05
2016	1.06	1.10	1.15	1.04
Last 6 months				
2016				
September	1.12	1.12	1.13	1.12
October	1.10	1.10	1.12	1.09
November	1.06	1.08	1.11	1.09
December	1.06	1.05	1.08	1.04
2017				
January	1.08	1.06	1.08	1.04
February	1.06	1.07	1.08	1.06
March <sup>(b)</sup>	1.05	1.05	1.05	1.05

(a) The average of the Noon Buying Rates on the last business day of each month during the relevant period for the full year average, and on each business day of the month for the monthly average. The latest available Noon Buying Rate being February 24, 2017, we have used European Central Bank Rates for the period from February 27, 2017 through March 2, 2017.

(b) In each case, measured through March 2, 2017.

On March 2, 2017 the European Central Bank Rate was 1.05 per euro.

*B. Capitalization and Indebtedness*

N/A

*C. Reasons for Offer and Use of Proceeds*

N/A

---

**Table of Contents****ITEM 3. KEY INFORMATION****D. Risk Factors**

*Important factors that could cause actual financial, business, research or operating results to differ materially from expectations are disclosed in this annual report, including without limitation the following risk factors. Investors should carefully consider all the information set forth in the following risk factors before deciding to invest in any of the Company's securities. In addition to the risks listed below, we may be subject to other material risks that as of the date of this report are not currently known to us or that we deem immaterial at this time.*

**Risks Relating to Legal and Regulatory Matters**

**We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected.**

Through patent and other proprietary rights such as data exclusivity or supplementary protection certificates in Europe, we hold exclusivity rights for a number of our research-based products. However, the protection that we are able to obtain varies in its duration and scope from product to product and country to country. This protection may not be sufficient to maintain effective product exclusivity because of local differences in the patents, in national laws or applicable legal systems, or developments in law or jurisprudence, which may give rise to inconsistent judgments when we assert or defend our patents.

Moreover, patent and other proprietary rights do not always provide effective protection for our products. Manufacturers of generic products or biosimilars are increasingly seeking to challenge patent validity or coverage before the patents expire, and manufacturers of biosimilars or interchangeable versions of the products are seeking to have their version of the product approved before the exclusivity period ends. Furthermore, in an infringement suit against a third party, we may not prevail and the decision rendered may not conclude that our patent or other proprietary rights are valid, enforceable or infringed. Our competitors may also successfully avoid patents, for example, through design innovation, and we may not hold sufficient evidence of infringement to bring suit.

In addition, if we lose patent protection in patent litigation as a result of an adverse court decision or a settlement, we face the risk that government and private third-party payers and purchasers of pharmaceutical products may claim damages alleging they have over-reimbursed or paid a drug. For example, in Australia, our patent on clopidogrel was ultimately held invalid. Following this decision, the Australian Government is seeking damages for its alleged over-reimbursement of clopidogrel drugs due to the preliminary injunction we had obtained against the sale of generic clopidogrel during the course of the litigation.

In certain cases, to terminate or avoid patent litigation, we or our partners may be required to obtain licenses from the holders of third-party intellectual property rights that cover aspects of our existing and future products in order to manufacture, use and/or sell them. Any payments under these licenses may reduce our profits from such products and we may not be able to obtain these licenses on favorable terms or at all. We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. Typically, biological therapeutics face third party intellectual property rights, otherwise known as freedom to operate (FTO) issues, more than small molecule therapeutics because of the types of patents allowed by national patent offices. Further, our ability to successfully challenge third party patent rights is dependent on the laws of national courts. Certain countries have laws that provide stronger bases for challenging third party patent rights compared to the laws that are available to challenge patents in other countries. Therefore, we may be able to invalidate a certain third party patent in one country but not invalidate counterpart patents in other countries. Third parties may also request a preliminary or a permanent injunction in a country from a court of law to prevent us from marketing a product if they consider that we infringe their patent rights in that country. For example, Sanofi is currently party to patent infringement proceedings in several countries initiated against us and Regeneron by Amgen relating to Praluent® in which Amgen has requested injunctive relief (see Note D.22.b) to the consolidated financial statements

## Edgar Filing: Sanofi - Form 20-F

included at Item 18 of this annual report and Item 8 B. of this annual report for more information). If third parties obtain a preliminary or permanent injunction from a court of law or if we fail to obtain a required license for a country where the valid third-party intellectual property right, as confirmed by a court of law, exists or if we are unable to alter the design of our technology to fall outside the scope of third-party intellectual property rights, we may be unable to market some of our products in certain countries, which may limit our profitability.

Also, some countries may consider granting a compulsory license to a third party to use patents protecting an innovator's product, which limits the value of the patent protection granted to such products.

We are involved in litigation worldwide to enforce certain of our patent rights against generics, proposed generics and biosimilars of our small molecule and biological pharmaceutical products (see Item 8. Financial Information - A. Consolidated Financial Statements and Other Financial Information - Information on Legal or Arbitration Proceedings for additional information). Even in cases where we ultimately prevail in an infringement claim, legal remedies available for harm caused to us by infringing products may be inadequate to make us whole. A competitor may launch a generic or a biosimilar product at risk before the initiation or completion of the court proceedings, and the court may decline to grant us a preliminary injunction to halt

---

**Table of Contents**

**ITEM 3. KEY INFORMATION**

further at risk sales and order removal of the infringing product from the market. Additionally, while we would be entitled to obtain damages in such a case, the amount that we may ultimately be awarded and able to collect may be insufficient to compensate all harm caused to us. A successful result against a competing product for a given patent or in a specific country is not necessarily predictive of our future success against another competing product or in another country because of local variations in the patents and patent laws.

We have increased the proportion of biological therapeutics in our pipeline relative to traditional small molecule pharmaceutical products. We expect to face increasing competition from biosimilars in the future. With the accelerated regulatory pathways provided in the US and Europe for biosimilar drug approval, biosimilars can be a threat to the exclusivity of any biological therapeutics we sell or may market in the future and can pose the same issues as the small molecule generic threat described above. Governments may adopt more permissive approval frameworks (for example, shortening the duration of data exclusivity, or narrowing the scope of new products receiving data exclusivity) which could allow competitors to obtain broader marketing approval for biosimilars including as a substitutable product, increasing competition for our products (see also Changes in the laws or regulations that apply to us could affect our business, results of operations and financial condition below). If a biosimilar version of one of our products were approved, it could reduce our sales and/or profitability of that product.

However, with our presence as a manufacturer of generics and biosimilars, we will utilize patent challenge strategies against other innovators patents, similar to those of long-established generic companies, but there is no assurance that these strategies will be successful.

If our patents and/or proprietary rights to our products were limited or circumvented, our financial results could be materially and adversely affected.

**Product liability claims could adversely affect our business, results of operations and financial condition.**

Product liability is a significant risk for any pharmaceutical company, and our product liability exposure could increase given that liability claims relating to our businesses may differ with regards to their nature, scope and level, from the types of product liability claims that we have handled in the past. Substantial damage awards and/or settlements have been handed down notably in the United States and other common law jurisdictions against pharmaceutical companies based on claims for injuries allegedly caused by the use of their products. Such claims can also be accompanied by consumer fraud claims by customers or third-party payers seeking reimbursement of the cost of the product.

We are currently defending a number of product liability claims (see Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report) and there can be no assurance that the Company will be successful in defending against these claims or will not face additional claims in the future.

Often, establishing the full side effect profile of a pharmaceutical drug goes beyond data derived from preapproval clinical studies which may only involve several hundred to several thousand patients. Routine review and analysis of the continually growing body of post-marketing safety surveillance and clinical trials provide additional information for example, potential evidence of rare, population-specific or long-term adverse reactions or of drug interactions that were not observed in preapproval clinical studies and may cause product labeling to evolve over time following interactions with regulatory authorities, including restrictions of therapeutic indications, new contraindications, warnings or precautions, and occasionally even the suspension or withdrawal of a product marketing authorization. Following any of these events, pharmaceutical companies can face significant product liability claims.

Furthermore, we commercialize several devices (some of which use new technologies) which, if they malfunction, could cause unexpected damage and lead to product liability claims (see Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm. ).

## Edgar Filing: Sanofi - Form 20-F

Although we continue to insure a portion of our product liability with third-party carriers, product liability coverage is increasingly difficult and costly to obtain, particularly in the United States. In the future, it is possible that self-insurance may become the sole commercially reasonable means available for managing the product liability financial risk of our pharmaceutical and vaccines businesses (see Item 4. Information on the Company B. Business Overview B.9. Insurance and Risk Coverage ). In cases where we self-insure, the legal costs that we would bear for handling such claims and potential indemnifications to be paid to claimants could have a negative impact on our financial condition.

Due to insurance conditions, even when the Company has insurance coverage, recoveries from insurers may not be totally successful. Moreover, insolvency of an insurer could affect our ability to recover claims on policies for which we have already paid a premium.

Product liability claims, regardless of their merits or the ultimate success of the Company's defense, are costly, divert management's attention, may harm our reputation and can impact the demand for our products. Substantial product liability claims could materially adversely affect our business, results of operations and financial condition.

---

**Table of Contents**

**ITEM 3. KEY INFORMATION**

**Our products and manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to anticipate the regulations, comply with them and/or maintain the required approvals.**

Obtaining marketing authorization is a long and highly regulated process requiring us to present extensive documentation and data to the regulatory authorities. Regulatory processes differ from one authority to another. Either at the time of the filing of the application for a marketing authorization or later during its review, each regulatory authority may impose its own requirements which can evolve over time, including requiring local clinical studies, and it may delay or refuse to grant approval, even though a product has already been approved in another country. For example, in August 2016, Sanofi submitted at the FDA's request updated information on the pen delivery device of Soliqua 100/33, based on feedback received from the FDA during its review of the New Drug Application for this product. This resulted in a three-month delay of the approval date.

Health authorities are increasingly focusing on product safety and on the risk/benefit profile of pharmaceutical products. In particular, the FDA and the EMA have increased their requirements, particularly in terms of the volume of data needed to demonstrate a product's efficacy and safety. Even after regulatory approval, marketed products are subject to continual review, risk evaluations or comparative effectiveness studies including post-marketing studies to which at times we have committed as a condition of approval. In addition, following the implementation of European pharmacovigilance legislation in 2012, the Company and the European Regulatory Agencies (under the supervision of the PRAC (Pharmacovigilance Risk Assessment Committee)) have reinforced their systematic and intensive safety signal detection systems, which may detect safety issues even with mature products that have been on the market for a considerable time. This system may result in additional market authorization suspensions or withdrawals. All of these requirements have increased the costs associated with maintaining regulatory approvals and achieving reimbursement for our products. Post-regulatory approval reviews and data analyses can lead to the issuance of recommendations by government agencies, health professional and patient or other specialized organizations regarding the use of products; for example, a recommendation to limit the patient population of a drug's indication, impose marketing restrictions, or suspend or withdraw the product can result in a reduction in sales volume, as well as an increased risk of litigation.

Moreover, to monitor our compliance with applicable regulations, the FDA, the EMA and comparable agencies in other jurisdictions routinely conduct inspections of our facilities and may identify potential deficiencies. We have received FDA Warning Letters in the past following the

inspection of some of our facilities and may receive such letters in the future. In 2016, manufacturing deficiencies were observed by the FDA at our fill and finish facility specialized in biologics in Le Trait, France, during a routine CGMP inspection, and the FDA issued a form 483 (Inspectional Observations) listing manufacturing deficiencies. These CGMP deficiencies led the FDA to issue a Complete Response Letter in October 2016, delaying the approval of sarilumab (Kevzara). More generally, if we fail to adequately respond to warning letters identifying a deficiency following an inspection, or fail to comply with applicable regulatory requirements at all or within the targeted timeline, we could be subject to enforcement, remedial and/or punitive actions by the FDA, the EMA or other regulatory authorities. In addition, in order to comply with our duty to report adverse safety signals to regulatory authorities, we must regularly train our employees and third parties (such as external sales forces and distributor employees) on regulatory matters. If we fail to train these people, or fail to train them appropriately, we may be exposed to the risk that safety events are not reported or not reported in a timely manner in breach of our reporting obligations.

To the extent that new regulations raise the costs of obtaining and maintaining product authorizations, or limit the economic value of a new product to its originator, the growth prospects of our industry and of Sanofi would be diminished. Approximately 60% of our current development portfolio consists of biological products that may in the future bring new therapeutic responses to current unmet medical needs, but that may also lead to more regulatory and technical constraints and/or costly investments from an industrial standpoint as biological products are complex to produce. These constraints and costs could adversely affect our business, results of operations and financial condition.

**Claims and investigations relating to compliance, competition law, marketing practices, pricing and other legal matters could adversely affect our business, results of operations and financial condition.**

The marketing of our products is heavily regulated. Sanofi's business covers an extremely wide range of activities worldwide and involves numerous partners. We have adopted a Code of Ethics that calls for employees to comply with applicable legislation and regulations, as well as with the specific principles and rules of conduct set forth in that Code. We also have policies and procedures designed to help ensure that we, our employees, officers, agents, intermediaries and other third parties comply with applicable laws and regulations (including the US Foreign Corrupt Practices Act (FCPA), the UK Bribery Act, the OECD Anti-Bribery Convention and other anti-bribery laws and regulations).

Notwithstanding these efforts, deviations may occur and there can be no assurance that we, our officers and/or our

**Table of Contents**

**ITEM 3. KEY INFORMATION**

directors will not face liability under laws and regulations for actions taken with respect to our business.

Any failure to comply directly or indirectly (including as a result of a business partner's breach) with the laws and regulations applicable to us, including new regulations, could lead to substantial liabilities and harm the Company's reputation. Governments and regulatory authorities around the world have been strengthening implementation and enforcement activities in recent years, including in relation to anti-bribery, anti-corruption, and data privacy legislation. Sanofi and certain of its subsidiaries are under investigation or could become the subject of additional investigations by various government entities and the Company is defending a number of lawsuits relating to pricing and marketing practices (including, for example, whistleblower litigation in the United States). The Company also faces litigation and government investigations or audits, including allegations of corruption, claims related to employment matters, patent and intellectual property disputes, consumer law claims and tax audits. See Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings and Note D.22. to our consolidated financial statements included at Item 18 of this annual report. Responding to such investigations is costly and distracts management's attention from our business.

Unfavorable outcomes in any of these matters, or in similar matters to be faced in the future, could preclude the commercialization of products, harm our reputation, negatively affect the profitability of existing products and subject us to substantial fines (including treble damages and fines based on our sales), punitive damages, penalties and injunctive or administrative remedies, potentially leading to the imposition of additional regulatory controls, monitoring or self-reporting obligations, or exclusion from government reimbursement programs or markets. All of this could have a material adverse effect on our business, results of operations or financial condition.

These risks may encourage us to enter into settlement agreements and those settlements may involve significant monetary payments and/or criminal penalties and may include admissions of wrongdoing. Settlement of healthcare fraud cases in the United States may require companies to enter into a Corporate Integrity Agreement, which is intended to regulate company behavior for a specified period of years. For example in 2015 we entered into such an agreement as part of settlements relating to the Septrafilm® and Hyalgan® products.

**Changes in the laws or regulations that apply to us could affect our business, results of operations and financial condition.**

All aspects of our business, including research and development, manufacturing, marketing, pricing and sales, are subject to extensive legislation and governmental regulation.

Changes in applicable laws, or in their application, could have a material adverse effect on our business.

For example, governmental authorities are increasingly looking to facilitate generic and biosimilar competition to existing products through new regulatory proposals intended to achieve, or resulting in, changes to the scope of patent or data exclusivity rights and use of accelerated regulatory pathways for generic and biosimilar drug approvals. Such regulatory proposals could make patent prosecution for new products more difficult and time consuming or could adversely affect the exclusivity period for our products (see We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected above).

This new competitive environment and the potential regulatory changes may further limit the exclusivity enjoyed by innovative products on the market and directly impact pricing, access and reimbursement levels, which may adversely affect our business and future results. See Item 4. Information on the Company B. Business Overview B.6. Markets B.6.2. Competition and B.6.3. Regulatory framework .

In addition to international tax law and regulatory changes such as the OECD BEPS initiatives and EU directives still to be adopted, changes in tax frameworks, tax reforms and other changes to the way existing tax laws are applied in jurisdictions and major countries where Sanofi and its subsidiaries and affiliates operate could affect our income, our effective tax rate, and consequently our future net income. These changes may

cover matters such as taxable income, tax rates, indirect taxation, transfer pricing, dividend taxation, controlled companies or a restriction in certain forms of tax relief. Any of these changes could have a material adverse effect on our business and future results. Additionally, due to the complexity of the fiscal environment, the ultimate resolution of any tax matters may result in payments greater or lesser than amounts accrued.

For information regarding risks related to changes in environmental rules and regulations, see Environmental liabilities and costs related to compliance with applicable regulations may have a significant adverse effect on our results of operations below.

### **Risks Relating to Our Business**

#### **Our research and development efforts may not succeed in adequately renewing our product portfolio.**

Discovering and developing a new product is a costly, lengthy and uncertain process. To be successful in the highly competitive pharmaceutical industry, we must commit substantial resources each year to research and development in order to develop new products to compensate for the decreasing sales of our products facing expiry of patents and regulatory data exclusivity or competition from new products of

---

**Table of Contents**

**ITEM 3. KEY INFORMATION**

competitors that are perceived as being superior or equivalent. In 2016, we spent 5,172 million on research and development (excluding Animal Health), amounting to 15.3% of our net sales.

Our industry is driven by the need for constant innovation, but we may spread ourselves across too many areas of inquiry to be successful and may not be able to improve internal research productivity sufficiently to sustain our pipeline. We may also fail to invest in the right technology platforms, therapeutic areas, and product classes to build a robust pipeline and fulfill unmet medical needs. Fields of discovery, particularly biotechnology, are highly competitive and characterized by significant and rapid technological changes. Numerous companies are working on the same targets and a product considered as promising at the very beginning of its development may become less attractive if a competitor addressing the same unmet need reaches the market earlier.

The research and development process can take up to 15 years from discovery to commercial product launch. This process is conducted in various stages in order to test, along with other features, the efficacy, effectiveness and safety of a product. There can be no assurance that any of these product candidates will be proven safe or effective. See Item 4. Information on the Company B. Business Overview B.5. Global Research & Development . Accordingly, there is a substantial risk at each stage of development including clinical studies that we will not achieve our goals of safety and/or efficacy and that we will have to abandon a product in which we have invested substantial amounts of money and human resources, even in late stage development (Phase III). More and more trials are designed with clinical endpoints of superiority; failure to achieve those endpoints could damage the product's reputation and our overall program. Decisions concerning the studies to be carried out can have a significant impact on the marketing strategy for a given product. Multiple in-depth studies can demonstrate that a product has additional benefits, facilitating the product's marketing, but such studies are expensive and time consuming and may delay the product's submission to health authorities for approval. Our ongoing investments in new product launches and research and development for future products could therefore result in increased costs without a proportionate increase in revenues, which would negatively affect our operating results and profitability.

In 2015 we announced that we had up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020, including six key launches. As of the end of 2016, four of those six key products have already been approved or launched: Toujeo<sup>®</sup>, Praluent<sup>®</sup>, Dengvaxia<sup>®</sup> and Soliqua 100/33 / Suliqua . However, there can be no assurance that all (or any) of the other products will be approved, or with the targeted indications, and/or within the expected timeline, or that all the products approved will achieve commercial success.

Following each product marketing approval, the medical need served by the product and the corresponding reimbursement are evaluated by governmental agencies and/or third party payers, requiring in some cases additional studies, including comparative studies, which may effectively delay marketing, change the population which the new product treats, and add to its development costs.

After marketing approval of our products, other companies or investigators, whether independently or with our authorization, may conduct studies or analysis beyond our control that may ultimately report results negatively affecting our sales either permanently or temporarily and it may take time for Sanofi to address the reported findings, leading among other things to a material adverse impact on sales.

**The pricing and reimbursement of our products is increasingly affected by decisions of governments and other third parties and cost reduction initiatives.**

The commercial success of our existing products and our product candidates depends in part on their pricing and the conditions under which our products are reimbursed. Our products continue to be subject to increasing price and reimbursement pressure due inter alia to:

## Edgar Filing: Sanofi - Form 20-F

- price controls imposed by governments in many countries;
- increased public attention to the price of drugs and particularly price increases, limiting our ability to set the price, or to manage or increase the price of our products based upon their value;
- removal of a number of drugs from government reimbursement schemes (for example products determined to be less cost-effective than alternatives);
- partial reimbursement of patient populations within a labelled indication;
- increased difficulty in obtaining and maintaining satisfactory drug reimbursement rates;
- increase in cost containment policies (including budget limitations) related to health expenses;
- governmental and private health care provider policies that favor prescription of generic medicines or substitution of branded products with generic medicines;
- more demanding evaluation criteria applied by Health Technology Assessment (HTA) agencies when considering whether to cover new drugs at a certain price level;
- more governments using international reference pricing to set or manage the price of drugs based on an external benchmark of a product's price in other countries; and
- aggressive pricing strategies by some of our competitors.

**Table of Contents**

**ITEM 3. KEY INFORMATION**

In addition to the pricing pressures they exert, governmental and private third-party payers and purchasers of pharmaceutical products may reduce volumes of sales by restricting access to formularies (including exclusive formularies), managing prescribing via various conditions (including prior authorisations and step edits) or otherwise discouraging physicians from prescribing our products (see also [The concentration of the US payer market exposes us to greater pricing pressure](#) below).

In the United States, the federal Affordable Care Act has increased the government's role with respect to price, reimbursement, and coverage levels for healthcare services and products within the large government healthcare sector. This law also imposed rebates and fees on pharmaceutical companies. Some US states are also considering legislation that could affect transparency practices, the marketing and prices of, and access to, drugs. US federal and state officials will continue to focus on healthcare reform in the future, creating multiple risks for the sector.

Government price reporting obligations are complex, and we face risks related to the reporting of pricing data that could affect the reimbursement of and discount provided for our products to US government healthcare programs.

We encounter similar cost containment issues in countries outside the United States. In certain countries, including countries in the European Union, China and Canada, the coverage of prescription drugs, and pricing and levels of reimbursement, are subject to governmental control. For example, in Europe various authorities are developing the use of tenders for expensive products and are considering joint procurement mechanisms to negotiate lower prices. See also below [Global economic conditions and an unfavorable financial environment could have negative consequences for our business](#).

We are also unable to predict the availability or level of reimbursement and related restrictions for our product candidates.

Price negotiations in a country may result in a price that is incompatible with the global price positioning of our products, which may lead us not to launch the product in that country, damaging our image and resulting in a decrease in initially anticipated sales.

Finally, our operating results may also be affected by parallel imports, particularly within the European Union, whereby distributors engage in arbitrage based on national price differences to buy products in low cost markets for resale in higher cost markets.

**[The concentration of the US market exposes us to greater pricing pressure.](#)**

In the United States, price is increasingly important to managed care organizations (MCOs) and pharmacy benefit managers (PBMs), and as the MCOs/PBMs grow in size

following market consolidation, pharmaceutical companies have faced increased pressure in pricing and usage negotiations, and competition among pharmaceutical companies to have their products included in the care providers' formulary is robust. This can lead to price discounts or rebates in connection with the placement of products. Exclusion of one of our drugs from a formulary can significantly reduce sales in the MCO/PBM patient population. For example, since 2014, we have increased the level of rebates granted for Lantus® in order to maintain favorable formulary positions with key payers in the US. Despite these efforts, in 2016, CVS and UnitedHealthcare (a PBM and MCO, respectively) decided that effective January 1, 2017 and April 1, 2017, respectively, Lantus®/Toujeo® will be excluded from the formulary across the commercial and MMC (Medicaid Managed Care) template formularies covering several million people, thus reducing the potential patient populations to whom Lantus® may be prescribed.

Also, some payers in the United States have put in place significant restrictions on the usage of Praluent®, which has resulted in significant out-of-pocket expenditures for Medicare patients.

## Edgar Filing: Sanofi - Form 20-F

In addition, distributors have increased their capacity to negotiate price and other terms as a consequence of the growing number of mergers of retail chains and distributors, resulting in consolidation of the distribution channel.

Due to these pressures on our prices, our revenues and margins are, and could continue to be, negatively affected.

### **We may lose market share to competing therapeutic options, biosimilar or generic products.**

We are faced with intense competition from generic products, biosimilars and brand-name drugs including from retail chains and distributors.

Doctors or patients may choose competitors' products over ours or alternative therapeutic options such as surgery if they perceive them to be safer, more reliable, more effective, easier to administer or less expensive, which could cause our revenues to decline and adversely affect our results of operations.

The success of any product also depends on our ability to educate patients when permissible and promote our products to healthcare providers by providing them with innovative data about the product and its uses including through the use of digital tools. If these education efforts are not effective, we may not be able to increase the sales of our products or realize the full value of our investment in their development.

We may not be able to anticipate precisely the date of market entry of generics or biosimilars or the potential impact on our sales, both of which depend on numerous parameters. The introduction of a generic version of a

**Table of Contents****ITEM 3. KEY INFORMATION**

branded medicine typically results in a significant and rapid reduction in net sales for the branded product because generic manufacturers typically offer their unbranded versions at significantly lower prices, resulting in adverse price and volume effects for our genericized products. Also mandatory price regulations apply in certain countries to off-patent products and classes of products, and generics prices are taken into account for international reference pricing and tenders. Substitution is often permitted for generic products that are considered to be interchangeable or clinically identical. With respect to biosimilars, in the United States only biosimilars that refer to an innovator drug that was approved under a Biologics License Application may be designated as interchangeable with the original biologic and only in circumstances where specific criteria are met. In many European countries, automatic substitution of biologics is officially prohibited or not recommended. Nevertheless, competition including from non-substitutable biosimilars would likely result in a decrease in prices, additional rebates, increased promotion efforts and lower margins.

Approval of a generic or biosimilar that is substitutable for one of our products would increase the risk of accelerated market penetration by that generic or biosimilar to a greater extent than would be the case for a non-substitutable product.

These trends are exacerbated by applicable legislation which encourages the use of generic products to reduce spending on prescription drugs in many countries such as the United States, France and Germany. Therefore, the market for our products could also be affected if a competitor's innovative drug in the same market were to become available as a generic because a certain number of patients can be expected to switch to a lower-cost alternative therapy. We expect this generic competition to continue and to affect more of our products, including those with relatively modest sales.

**A substantial share of the revenue and income of Sanofi continues to depend on the performance of certain flagship products.**

We generate a substantial share of our revenues from the sale of certain key products (see Item 5. Operating and Financial Review and Prospects Results of Operations Year ended December 31, 2016 compared with year ended December 31, 2015 Net Sales Pharmaceuticals segment). Lantus® is particularly important; it was Sanofi's leading product with revenues of 5,714 million in 2016, representing 16.9% of Sanofi's net sales for the year. Lantus® is a flagship product of the Diabetes franchise. Accounting for market trends, we announced in October 2015 that we project global diabetes sales over the period from 2015 to 2018 to decline at an average annualized rate of between 4% and 8% at constant exchange rate (CER). Nevertheless our actual sales may differ from these expectations given the numerous underlying assumptions

(for example the outlook for insulin glargine sales, the introduction of one or several biosimilar glargines and their penetration of the market or the market uptake of our new products).

Furthermore, the launch of new medicines and vaccines in other therapeutic areas and the performance of our other businesses may not be sufficient to reduce the relative contribution of Lantus® to our overall performance.

Our flagship products benefit from certain intellectual property protections such as patents and exclusivity periods but patent and proprietary rights, even if they are not challenged, are subject to expiration dates. Expiration of effective intellectual property protections for our products typically results in the entry of one or more lower-priced generic competitors, often leading to a rapid and severe decline in revenues on those products (for information on the expected impact of biosimilar entry on the market see We may lose market share to competing therapeutic options, biosimilar or generic products above).

Furthermore, in general, if one or more of our flagship products were to encounter problems such as material product liability litigation, unexpected side effects, recall, regulatory proceedings, publicity affecting doctor or patient confidence, pressure from existing competitive products, changes in labeling, or if a new, more effective treatment were introduced, or if there were a reduction in sales of one or more of our flagship products or in their growth, the adverse impact on our business, results of operations and financial condition could be significant.

**The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image.**

Many of our products are manufactured using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. Third parties supply us with a substantial portion of our raw materials, active ingredients and medical devices, which exposes us to the risk of a supply shortage or interruption in the event that these suppliers are unable to manufacture our products to Sanofi quality standards or if they experience financial difficulties. Further, some raw materials essential to the manufacture of our products are not widely available from sources we consider reliable; for example, we have approved only a limited number of suppliers of heparins for use in the manufacture of Lovenox<sup>®</sup>. Any of these factors could adversely affect our business, operating results or financial condition. See Item 4. Information on the Company B. Business Overview B.8. Production and Raw Materials for a description of these outsourcing arrangements.

**Table of Contents****ITEM 3. KEY INFORMATION**

Our products are also increasingly reliant on the use of product-specific devices for administration which may result in technical issues. For example in October 2015, we voluntarily recalled all Auvi-Q® (epinephrine injection, USP) marketed in the US and Canada as the product was found to potentially have inaccurate dosage delivery, which may include failure to deliver the drug. Sanofi ultimately decided to return all US and Canadian rights to the developer of Auvi-Q®. One of our newly launched products, Praluent®, is administered with an auto-injector manufactured by a third party. The success of this product will depend partially on the performance of this device.

We must also be able to produce sufficient quantities of our products to satisfy demand. We may have difficulties transforming and adapting our existing plants to manufacture new products, including biologics, and scaling up production of our products currently under development once they are approved. Our biological products, in particular, are subject to the risk of manufacturing stoppages or the risk of loss of inventory because of the difficulties inherent in the processing of biological materials and the potential difficulties in accessing adequate amounts of raw materials meeting required standards. Effective insurance coverage for biological products in the event of contaminated batches may also be difficult to obtain as the cause of the contamination can be difficult to ascertain (for the impact on our financial statements see Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on the Company's results of operations and financial results. below)

For example, in the US we have encountered production issues for several years which caused delays in the supply of Pentacel® vaccine starting from 2013. While the supply conditions have been improving since the end of 2016, there can be no guarantee that we will not face similar issues in the future or that we will successfully manage such issues when they arise.

Additionally, specific conditions must be respected both by Sanofi and our customers for the storage and distribution of many of our biological products. For example, cold storage for certain vaccines and insulin-based products is required. Failure to adhere to these requirements may result in lost product inventory.

The complexity of these processes, as well as strict internal and health authority standards for the manufacture of our products, subject us to risks because the investigation and remediation of any identified or suspected problems can cause production delays, substantial expense, product recalls, or lost sales and inventories and delay the launch of new products, which could adversely affect our operating results and financial condition, and cause reputational damage and the risk of product liability (see Product liability claims could adversely affect our business, results of operations and financial condition ).

When manufacturing disruptions occur, we may not have alternate manufacturing capacity, particularly for certain biologics. In the event of manufacturing disruptions, our ability to use backup facilities or set up new facilities is more limited because biologics are more complex to manufacture. Even though we aim to have backup sources of supply whenever possible, including by manufacturing backup supplies of our principal active ingredients at additional facilities when practicable, we cannot be certain they will be sufficient if our principal sources become unavailable. Switching sources and manufacturing facilities require significant time.

Supply shortages generate even greater negative reactions when they occur with respect to life saving medicines with limited or no viable therapeutic alternatives. Shortages of products can have a negative impact on the confidence of patients, customers and professional healthcare providers and the image of Sanofi and may lead to lower product revenues. Government authorities and regulators in the United States, in the European Union and other agencies worldwide are also considering measures to reduce these risks, such as Supply Risk Management Plans for some products with high medical need (e.g. the French decree of July 2016 concerning the preparation of shortage management plans ( *plans de gestion des pénuries* ). It cannot be ruled out that these ongoing initiatives may generate additional costs for Sanofi if they result in a requirement to establish backup supply channels or to increase inventory levels to avoid shortages.

We are sometimes required to use animals to test our products in the development phase and our vaccines before distributing them. Animal testing activities have been the subject of controversy and adverse publicity. Testing on animals can be vital for the development or

commercialization of a product. If applicable regulations were to ban this practice, or if, due to pressure from animal welfare groups, we were no longer able to source animals to perform such tests, it would be difficult and in some cases impossible to develop or distribute our products in certain jurisdictions under the applicable marketing authorizations. In addition, negative publicity regarding our use, or the industry's use, of animal subjects could harm our reputation.

**We rely on third parties for the discovery, manufacture and marketing of some of our products.**

Our industry is highly collaborative, whether in the discovery and development of new products, in-licensing, the marketing and distribution of approved products, or manufacturing activities. We expect that we will continue to rely on third parties for key aspects of our business.

We conduct a number of significant research and development programs and market some of our products in collaboration with other biotechnology and pharmaceutical companies. For example, we currently have a global

---

**Table of Contents**

**ITEM 3. KEY INFORMATION**

strategic collaboration with Regeneron for the discovery, development, commercialization and manufacturing of therapies based on monoclonal antibodies. With Alnylam, we have an agreement to develop and commercialize treatments for rare genetic diseases (See Item 4. Information on the Company B. Business Overview B.2. Main pharmaceutical products ). In addition we may also rely on partners to design and manufacture medical devices, notably for the administration of our products.

If disruptions or quality concerns were to arise in the third-party supply of raw materials, active ingredients or medical devices or if our partners were unable to manufacture a product, this could also adversely affect our ability to sell our products in the quantities demanded by the market and could damage our reputation and relationships with our customers. See also The manufacture of our products is technically complex, and supply interruptions, product recalls or inventory losses caused by unforeseen events may reduce sales, adversely affect our operating results and financial condition, delay the launch of new products and negatively impact our image above.

When we research and market our products through collaboration arrangements, the performance of certain key tasks or functions are the responsibility of our collaboration partners. We are therefore subject to the risk that they do not perform effectively. We are also subject to the risk that decisions may be under the control of or subject to the approval of our collaboration partners, and we may have differing views. Failures in the development process or differing priorities may adversely affect the activities conducted through the collaboration arrangements. Any conflicts or difficulties that we may have with our partners during the course of these agreements or at the time of their renewal or renegotiation or any disruption in the relationships with our partners, may affect the development, the launch and/or the marketing of certain of our products or product candidates and may cause a decline in our revenues and negatively affect our results of operations.

**We are subject to the risk of non-payment by our customers<sup>(1)</sup>.**

We run the risk of delayed payments or even non-payment by our customers, which consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies. This risk is accentuated by recent concentrations among distributors, as well as by uncertainties around global credit and economic conditions, in particular in emerging markets. The United States poses particular customer credit risk issues because of the concentrated distribution system:

our three main customers represented respectively 12%, 7% and 6% of our consolidated net sales in 2016. We are also exposed to large wholesalers in other markets, particularly in Europe. An inability of one or more of these wholesalers to honor their debts to us would adversely affect our financial condition (see Note D.34. to our consolidated financial statements included at Item 18 of this annual report).

In some countries, some customers are public or subsidized health systems. The economic and credit conditions in these countries may lead to an increase in the average length of time needed to collect on accounts receivable or the ability to collect 100% of receivables outstanding. Because of this context, we may need to reassess the recoverable amount of our debts in these countries during the coming financial years (see also Item 5. Operating and Financial Review and Prospects Liquidity and Capital Resources Liquidity. ).

**Global economic conditions and an unfavorable financial environment could have negative consequences for our business<sup>(2)</sup>.**

Over the past several years, growth of the global pharmaceutical market has become increasingly tied to global economic growth. In this context, a substantial and lasting slowdown of the global economy, major national economies or emerging markets could negatively affect growth in the global pharmaceutical market and, as a result, adversely affect our business.

Unfavorable economic conditions have reduced the sources of funding for national social security systems, leading to austerity measures including heightened pressure on drug prices, increased substitution of generic drugs, and the exclusion of certain products from formularies.

## Edgar Filing: Sanofi - Form 20-F

Further, our net sales may be negatively impacted by the continuing challenging global economic environment, as high unemployment, increases in cost-sharing, and lack of developed third party payer systems in certain regions may lead some patients to switch to generic products, delay treatments, skip doses or use less effective treatments to reduce their costs. In the United States there has been an increase in the number of patients in the Medicaid program, under which sales of pharmaceuticals are subject to substantial rebates and, in many US states, to formulary restrictions limiting access to brand-name drugs, including ours. Also, as a result of the insurance coverage mandate that came into effect in the United States in 2015, some employers may seek to reduce costs by reducing or eliminating employer group healthcare plans or transferring a greater portion of healthcare costs to their employees.

- (1) Information in this section is supplementary to Notes B.8.8. (with respect to information required by IFRS 7), D.10 and D.34 to our consolidated financial statements included at Item 18 of this annual report.*
- (2) Information in this section is supplementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report, with respect to information required by IFRS 7.*

---

**Table of Contents**

**ITEM 3. KEY INFORMATION**

In certain emerging markets countries where the economy is highly dependent on oil, a decline in oil prices may impact the ability of those countries to sustain healthcare spending, which could adversely affect our sales in those countries.

Our Consumer HealthCare (CHC) business could also be adversely impacted by difficult economic conditions that limit the financial resources of our customers.

If economic conditions worsen, or in the event of default or failure of major players including wholesalers or public sector buyers financed by insolvent states, the financial situation of the Company, its results of operations and the distribution channels of its products may be adversely affected. See also We are subject to the risk of non-payment by our customers above.

Economic and financial difficulties may have an adverse impact on third parties who are important to our business, including collaboration partners and suppliers, which could cause such third parties to delay or disrupt performance of their obligations to us and could materially adversely affect our business or results of operations. See We rely on third parties for the discovery, manufacture and marketing of some of our products above. For more information see Item 5. Operating and Financial Review and Prospects Liquidity and Capital Resources Liquidity.

**Counterfeit versions of our products harm our business.**

Counterfeiting activities and the presence of counterfeit products in a number of markets and over the Internet continue to be a challenge for maintaining a safe drug supply. Counterfeit products are frequently unsafe or ineffective, and can be life-threatening. To distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs along with increased levels of counterfeiting could be mistakenly attributed to the authentic product, affect patient confidence in the authentic product and harm the business of companies such as Sanofi. If one of our products were to be the subject of counterfeits, we could incur substantial reputational and financial harm. See Item 4. Information on the Company B. Business Overview B.6. Markets B.6.2. Competition.

**Breaches of data security, disruptions of information technology systems and cyber threats could result in financial, legal, business or reputational harm.**

Our business depends heavily on the use of information technologies. Certain key areas such as research and development, production and sales are to a large extent dependent on our information systems, including cloud-based computing, or those of third party providers, including for the storage and transfer of critical, confidential or

sensitive information. We and our third-party service providers are implementing secure information technology systems for the protection of data and threat detection. However, there can be no assurance that our efforts or those of our third-party service providers to implement adequate security and control measures would be sufficient to protect against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm.

We commercialize a number of devices using new information technologies which, if they malfunction or are compromised could lead to a risk of harm to patients (see Product liability claims could adversely affect our business, results of operations and financial condition above), including the unavailability of our products.

**The expansion of social media platforms and new technologies present risks and challenges for our business and reputation.**

## Edgar Filing: Sanofi - Form 20-F

We increasingly rely on social media and new technologies to communicate about our products and diseases or to provide health services. The use of these media requires specific attention, monitoring programs and moderation of comments. For example, patients may use these channels to comment on the effectiveness of a product and to report an alleged adverse event. When such questions arise, the nature of evidence-based health care and restrictions on what pharmaceutical manufacturers may say about their products are not always well suited to rapidly defending Sanofi or the public's legitimate interests in the face of the political and market pressures generated by social media and rapid news cycles, and this may result in commercial harm, overly restrictive regulatory actions and erratic share price performance. In addition, unauthorized communications, such as press releases or posts on social media, purported to be issued by Sanofi, may contain information that is false or otherwise damaging and could have an adverse impact on our stock price. Negative or inaccurate posts or comments about Sanofi, our business, directors or officers on any social networking website could seriously damage our reputation. In addition, our employees and partners may use social media and mobile technologies inappropriately, which may give rise to liability for the Company, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information, including information about our employees, clinical trials or customers. Such uses of social media and mobile technologies could have a material adverse effect on our reputation, business, financial condition and results of operations.

## **Table of Contents**

### **ITEM 3. KEY INFORMATION**

#### **Impairment charges or write downs in our books and changes in accounting standards could have a significant adverse effect on Sanofi's results of operations and financial results.**

Substantial value is allocated to intangible assets and goodwill resulting from business combinations, as disclosed at Note D.4. to our consolidated financial statements included in this annual report at Item 18, which could be substantially written down in value upon indications of impairment (primarily relating to pharmacovigilance, discontinued research and development projects, patent litigation and the launch of competing products), with adverse effects on our financial condition and the value of our assets.

If any of our strategic equity investments decline in value and remain below cost for an extended period, we may be required to write down our investment. We own a significant stake in Regeneron Pharmaceuticals, Inc. (22.1% of its share capital as of December 31, 2016), which is listed on the NASDAQ and has been accounted for using the equity method since 2014. Any material deterioration in Regeneron's share price or financial performance would be an indicator that the value of our investment might have become impaired. This would require us to perform an impairment test, which could have a negative impact on our financial statements.

In addition, the inherent variability of biologics manufacturing increases the risk of write-offs of these products. Due to the value of the materials used, the carrying amount of biological products is much higher than that of small-molecule products.

The financial environment and in particular the economic difficulties affecting Russia, Venezuela, Brazil, China and the Middle East could also negatively affect the value of our assets (see Global economic conditions and an unfavorable financial environment could have negative consequences for our business above and Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition below).

Any new or revised accounting standards, rules and interpretations issued by the IASB (International Accounting Standards Board) could also result in changes to the recognition of income and expense that may materially and adversely affect Sanofi's financial results.

#### **Our pension liabilities are affected by factors such as the performance of plan assets, interest rates, actuarial data and experience and changes in laws and regulations.**

Our future funding obligations for our main defined-benefit pension plans depend on changes in the future performance of assets held in trust for these plans, the interest rates used to determine funding levels (or company liabilities), actuarial data and experience, inflation trends, the level of benefits

provided for by the plans, as well as changes in laws and regulations. Adverse changes in those factors could increase our unfunded obligations under such plans, which would require more funds to be contributed and hence negatively affect our cash flow and results (see Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report).

#### **Risks Relating to Sanofi's Structure and Strategy**

##### **Our strategic objectives for long-term growth may not be fully realized.**

In November 2015, we outlined our strategic roadmap for the period 2015-2020. Our long term strategy rests on four pillars: reshape our portfolio, deliver outstanding launches, sustain innovation in R&D and simplify our organization.

## Edgar Filing: Sanofi - Form 20-F

We may not be able to fully realize our strategic objectives and, even if we are able to do so, these strategic objectives may not deliver the expected benefits or within the expected timeline.

We will look to reshape our portfolio through acquisitions and divestitures and may not reach this objective if we are unable to identify opportunities, or enter into agreements in a timely manner or on sufficiently attractive terms. In addition, we may fail to (i) adopt the best strategy for our acquisitions/ divestitures or (ii) compete in an intensively competitive, increasingly focused market environment (see We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments below and Our research and development efforts may not succeed in adequately renewing our product portfolio above). We may also not have the necessary flexibility to appropriately reallocate resources towards our priority businesses.

The successful launch of a new pharmaceutical product involves substantial investment in sales and marketing activities. In 2015 we announced that we have up to 18 new medicines and vaccines on track to arrive on the market between 2014-2020. As of the end of 2016, four of those six key products have already been approved or launched: Toujeo<sup>®</sup>, Praluent<sup>®</sup>, Dengvaxia<sup>®</sup> and Soliqua 100/33 / Suliqua . However there can be no assurance that all of these products will be approved, or with the targeted indications, and/or within the expected timeline or that, if approved, they will achieve commercial success. For example, we announced in July 2016 that the overall uptake of Dengvaxia<sup>®</sup> had been delayed by recent political changes and economic volatility in Latin America. Also, the level of Praluent<sup>®</sup> sales reflects the implementation of management restrictions by payers in the United States and limited market access in Europe. The launch strategy we develop (in terms of timing, pricing, market access, marketing efforts and dedicated sales forces) may not deliver the benefits that we expect. The competitive environment for a given product may also have changed by the time of the actual launch,

**Table of Contents**

**ITEM 3. KEY INFORMATION**

modifying our initial expectations. The need to prioritize the allocation of resources may also cause delays in the expected launch of some of our products.

Sustaining innovation in R&D is inherently risky due to the high rate of failure and we may not be able to allocate our resources to obtain optimal results (see also Our research and development efforts may not succeed in adequately renewing our product portfolio above).

Our ongoing simplification of our global organization through the implementation, starting from January 2016, of five global business units (GBUs) to meet significant growth objectives requires substantial attention from our management. There is no guarantee that this new organization will enable Sanofi to concentrate its efforts around the businesses most likely to deliver growth, or that these GBUs will grow in line with anticipated growth rates or deliver the expected benefits.

Failure to successfully implement and meet our strategic objectives would have an adverse impact on our business, prospects and results of operations.

**We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments.**

We pursue a strategy of selective acquisitions, in-licensing and collaborations in order to reinforce our pipeline and portfolio. The implementation of this strategy depends on our ability to identify business development opportunities and execute them at reasonable cost and on acceptable financing terms. Moreover, entering into in-licensing or collaboration agreements generally requires the payment of significant milestones well before the relevant products reach the market, without any assurance that such investments will ultimately become profitable in the long term (see Note D.21.1. to the consolidated financial statements included at Item 18 of this annual report and also We rely on third parties for the discovery, manufacture and marketing of some of our products above).

For newly acquired activities or businesses our growth objectives could be delayed or ultimately not realized, and expected synergies could be adversely impacted if:

we are unable to quickly or efficiently integrate those activities or businesses;

integration takes longer than expected;

key employees leave; or

we have higher than anticipated integration costs.

In January 2017, we completed the acquisition of Boehringer Ingelheim's consumer healthcare (CHC) business in exchange for our animal health business (Merial), but we cannot guarantee that Boehringer Ingelheim's CHC business

will be successfully integrated with ours and that we will be able to retain key personnel. Also, the expected benefits of the transaction may never be fully realized or may take longer to realize than expected.

We may miscalculate the risks associated with business development transactions at the time they are made or not have the resources or ability to access all the relevant information to evaluate them properly, including with regards to the potential of research and development pipelines, manufacturing issues, compliance issues, or the outcome of ongoing legal and other proceedings. It may also take a considerable amount of time and be difficult to implement a risk analysis and risk mitigation plan after the acquisition of an activity or business is completed due to lack of historical data. As a result, risk management and coverage of such risks, particularly through insurance policies, may prove to be insufficient or ill-adapted.

Because of the active competition among pharmaceutical groups for such business development opportunities, there can be no assurance of our success in completing these transactions when such opportunities are identified.

**The globalization of our business exposes us to increased risks in specific areas.**

We continue to focus on emerging markets. However, difficulties in operating in emerging markets, a significant decline in the anticipated growth rate in these regions or an unfavorable movement of the exchange rates of these countries' currencies against the euro could impair our ability to take advantage of these growth opportunities and could affect our business, results of operations or financial condition (see also

Global economic conditions and an unfavorable financial environment could have negative consequences for our business above).

The expansion of our activities in emerging markets also exposes us to more volatile economic conditions, political instability, competition from multinational or locally based companies that are already well established in these markets, the inability to adequately respond to the unique characteristics of emerging markets (particularly with respect to their underdeveloped judicial systems and regulatory frameworks), difficulties in recruiting qualified personnel or maintaining the necessary internal control systems, potential exchange controls, weaker intellectual property protection, higher crime levels (particularly with respect to counterfeit products (see Counterfeit versions of our products harm our business above)), and compliance issues including corruption and fraud (see Claims and investigations relating to compliance, competition law, marketing practices, pricing and other legal matters could adversely affect our business, results of operations and financial condition above). We may also face compliance and internal control systems issues in mature markets due to increased competition and more complex and stringent regulations.

## **Table of Contents**

### **ITEM 3. KEY INFORMATION**

As a global healthcare leader, we are exposed to a number of risks inherent in sectors in which we were previously less active such as generics and consumer healthcare, whose business models and trade channels are different from our traditional pharmaceutical business, in particular regarding promotional efforts and trade terms.

#### **Our success depends in part on our senior management team and other key employees and our ability to attract, integrate and retain key personnel and qualified individuals in the face of intense competition.**

We depend on the expertise of our senior management team and other key employees. In addition, we rely heavily on recruiting and retaining talented people to help us meet our strategic objectives. We face intense competition for qualified individuals for senior management positions, or in specific geographic regions or in specialized fields such as clinical development, biosciences and devices. In addition, our ability to hire qualified personnel also depends in part on our ability to reward performance, incentivize our employees and to pay competitive compensation. Laws and regulations on executive compensation may restrict our ability to attract, motivate and retain the required level of talented people. The inability to attract, integrate and/or retain highly skilled personnel, in particular those in leadership positions, may weaken our succession plans, may materially adversely affect the implementation of our strategy and our ability to meet our strategic objectives and could ultimately impact our business or results of operations.

#### **Environmental Risks of Our Industrial Activities**

##### **Risks from the handling of hazardous materials could adversely affect our results of operations.**

Manufacturing activities, such as the chemical manufacturing of the active ingredients in our products and the related storage and transportation of raw materials, products and wastes, expose us to various risks, including:

fires and/or explosions;

storage tank leaks and ruptures; or

discharges or releases of toxic or pathogen substances.

These operating risks can cause personal injury, property damage and environmental contamination, and may result in the shutdown of affected facilities and/or the imposition of civil, administrative, criminal penalties and/or civil damages.

The occurrence of any of these events may significantly reduce the productivity and profitability of a particular manufacturing facility and adversely affect our operating results and reputation.

Although we maintain property, business interruption and casualty insurance that we believe is in accordance with

customary industry practices, this insurance may not be adequate to fully cover all potential hazards incidental to our business.

**Environmental liabilities and costs related to compliance with applicable regulations may have a significant adverse effect on our results of operations.**

The environmental laws of various jurisdictions impose actual and potential obligations on our Company to remediate contaminated sites. These obligations may relate to sites:

that we currently own or operate;

that we formerly owned or operated; or

where waste from our operations was disposed.

These environmental remediation obligations could significantly reduce our operating results. Sanofi accrues provisions for remediation when our management believes the need is probable and that it is reasonably possible to estimate the cost. See Item 4. Information on the Company Business Overview B.10. Health, Safety and Environment (HSE) for additional information regarding our environmental policies. In particular, our provisions for these obligations may be insufficient if the assumptions underlying these provisions prove incorrect or if we are held responsible for additional, currently undiscovered contamination. These judgments and estimates may later prove inaccurate, and any shortfalls could have a material adverse effect on our results of operations and financial condition.

We are or may become involved in claims, lawsuits and administrative proceedings relating to environmental matters. Some current and former Sanofi subsidiaries have been named as potentially responsible parties or the equivalent under the US Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (also known as Superfund), and similar statutes in France, Germany, Italy, Brazil and elsewhere. As a matter of statutory or contractual obligation, we and/or our subsidiaries may retain responsibility for environmental liabilities at some of the sites of our predecessor companies, or of subsidiaries that we demerged, divested or may divest. We have disputes outstanding regarding certain sites no longer owned by the Company. An adverse outcome in such disputes might have a significant adverse effect on our operating results. See Note D.22.e) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Information on Legal or Arbitration Proceedings.

Environmental regulations are evolving. For example, in Europe, new or evolving regulatory regimes include REACH, CLP/GHS, SEVESO, IPPC/IED, the Waste Framework

**Table of Contents****ITEM 3. KEY INFORMATION**

Directive, the Emission Trading Scheme Directive, the Water Framework Directive, the Directive on Taxation of Energy Products and Electricity and several other regulations aimed at preventing global warming. Stricter environmental, safety and health laws and enforcement policies could result in substantial costs and liabilities to our Company and could subject our handling, manufacture, use, reuse or disposal of substances or pollutants, site restoration and compliance to more rigorous scrutiny than is currently the case. Consequently, compliance with these laws could result in significant capital expenditures as well as other costs and liabilities, thereby adversely affecting our business, results of operations or financial condition. For more detailed information on environmental issues, see Item 4. Information on the Company B. Business Overview B.10. Health, Safety and Environment (HSE).

**Natural disasters prevalent in certain regions in which we do business could affect our operations.**

Some of our production sites are located in areas exposed to natural disasters, such as earthquakes, floods and hurricanes. In the event of a major disaster we could experience severe destruction or interruption of our operations and production capacity. As a result, our operations and our employees could suffer serious harm which could have a material adverse effect on our business, financial condition and results of operations.

**Risks Related to Financial Markets<sup>(1)</sup>****Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.**

Because we sell our products in numerous countries, our results of operations and financial condition could be adversely affected by fluctuations in currency exchange rates. We are particularly sensitive to movements in exchange rates between the euro and the US dollar, the Japanese yen, and to currencies in emerging markets. In 2016, 36.6% of our net sales were realized in the United States, 28.4% in Emerging Markets (including countries that are, or may in future become, subject to exchange controls or hyper-inflation), and 5% in Japan. While we incur expenses in those currencies, the impact of currency exchange rates on these expenses does not fully offset the impact of currency exchange rates on our revenues. As a result, currency exchange rate movements can have a considerable impact on our earnings. When deemed appropriate and when technically feasible, we enter into transactions to hedge our exposure to foreign exchange risks. These efforts, when undertaken, may fail to offset the effect of adverse currency exchange rate fluctuations on our results of operations or financial condition. For more information concerning our exchange rate exposure, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

**Risks Relating to an Investment in Our Shares or ADSs****Foreign exchange fluctuations may adversely affect the US dollar value of our ADSs and dividends (if any).**

Holders of ADSs face exchange rate risk. Our ADSs trade in US dollars and our shares trade in euros. The value of the ADSs and our shares could fluctuate as the exchange rates between these currencies fluctuate. If and when we pay dividends, they would be denominated in euros. Fluctuations in the exchange rate between the euro and the US dollar will affect the US dollar amounts received by owners of ADSs upon conversion by the depositary of cash dividends, if any. Moreover, these fluctuations may affect the US dollar price of the ADSs on the New York Stock Exchange (NYSE), whether or not we pay dividends in addition to any amounts that a holder would receive upon our liquidation or in the event of a sale of assets, merger, tender offer or similar transaction denominated in euros or any foreign currency other than US dollars.

**Persons holding ADSs rather than shares may have difficulty exercising certain rights as a shareholder.**

Holders of ADSs may have more difficulty exercising their rights as a shareholder than if they directly held shares. For example, if we issue new shares and existing shareholders have the right to subscribe for a portion of them, the depositary is allowed, at its own discretion, to sell for their benefit that right to subscribe for new shares instead of making it available to ADS holders. Also, holders of ADSs must instruct the depositary

how to vote their shares. Because of this extra procedural step involving the depository, the process for exercising voting rights will take longer for holders of ADSs than for holders of shares. ADSs for which the depository does not receive timely voting instructions will not be voted at any meeting.

**Our largest shareholder owns a significant percentage of the share capital and voting rights of Sanofi.**

As of December 31, 2016, L'Oréal held approximately 9.15% of our issued share capital, accounting for approximately 16.7% of the voting rights (excluding treasury shares) of Sanofi. See Item 7. Major Shareholders and Related Party Transactions A. Major Shareholders. Affiliates of L'Oréal currently serve on our Board of Directors. To the extent L'Oréal continues to hold a large percentage of our share capital and voting rights, it will remain in a position to exert greater influence in the appointment of the directors and officers of Sanofi and in other corporate actions that require shareholders' approval.

*(1) Information in this section is supplementary to Note B.8.8. to our consolidated financial statements included at Item 18 of this annual report with respect to information required by IFRS 7.*

---

**Table of Contents**

**ITEM 3. KEY INFORMATION**

**Sales of our shares may cause the market price of our shares or ADSs to decline.**

Sales of large numbers of our shares, or a perception that such sales may occur, could adversely affect the market price for our shares and ADSs. To our knowledge, L'Oréal, our largest shareholder, is not subject to any contractual restrictions on the sale of the shares it holds in our Company. L'Oréal does not consider its stake in our Company as strategic.

**Risks Relating to Our Contingent Value Rights (CVRs)**

**In addition to the risks relating to our shares, CVR holders are subject to additional risks.**

In connection with our acquisition of Genzyme, we issued CVRs under a CVR agreement entered into by and between us and American Stock Transfer & Trust Company, the trustee (see also Note D.18. to the consolidated financial statements included at Item 18 of this annual report). A copy of the form of the CVR agreement is on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed with the Securities and Exchange Commission on March 24, 2011. Pursuant to the CVR agreement, each holder of a CVR is entitled to receive cash payments upon the achievement of certain milestones, if any, based on the achievement of certain cumulative net sales thresholds by Lemtrada<sup>®</sup> (alemtuzumab for treatment of multiple sclerosis). See Item 10. Additional Information C. Material Contracts The Contingent Value Rights Agreement.

CVR holders are subject to additional risks, including:

- the public market for the CVRs may not be active or the CVRs may trade at low volumes, both of which could have an adverse effect on the resale price, if any, of the CVRs;
- the market price and trading volume of the CVRs may be volatile;
- no payment will be made on the CVRs without the achievement of certain agreed upon milestones. As such, it may be difficult to value the CVRs and accordingly it may be difficult or impossible to resell the CVRs;
- if net sales do not exceed the thresholds set forth in the CVR agreement for any reason within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire without value;
- since the US federal income tax treatment of the CVRs is unclear, any part of any CVR payment could be treated as ordinary income and required to be included in income prior to the receipt of the CVR payment;
- any payments in respect of the CVRs rank at parity with our other unsecured unsubordinated indebtedness;

## Edgar Filing: Sanofi - Form 20-F

we are not prohibited from acquiring the CVRs, whether in open market transactions, private transactions or otherwise and we have already purchased CVRs on several occasions (for more information see Item 5. Operating and Financial Review and Prospects Liquidity and Capital Resources Liquidity. );

we may, under certain circumstances, purchase and cancel all outstanding CVRs; and

while we have agreed to use diligent efforts (as defined in the CVR agreement), until the CVR agreement is terminated, to achieve each of the remaining Lemtrada® related CVR milestones set forth in the CVR agreement, we are not required to take all possible actions to achieve these goals. On July 5, 2016 Sanofi disclosed that, based upon actual sales trends to date, product sales milestone #1 has not been met. There can be no assurance that the other product sales milestones will be achieved. Failure to achieve the sales milestones would have an adverse effect on the value, if any, of the CVRs (see also Note D.22.d) to the consolidated financial statements included at Item 18 of the annual report regarding the ongoing CVR Trustee Claim).

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

## **Item 4. Information on the Company**

### **Introduction**

Sanofi is a leading global healthcare company, focused on patient needs and engaged in the research, development, manufacture and marketing of therapeutic solutions.

In 2016, our net sales were 33,821 million. This figure excludes the net sales of our Animal Health business.

In the remainder of this section:

- A product is referred to either by its international non-proprietary name (INN) or its brand name, which is generally exclusive to the company that markets it. In most cases, the brand names of our products, which may vary from country to country, are protected by specific registrations. In this document, products are identified by their brand names used in France and/or in the US.
- For our Pharmaceuticals activity, unless otherwise stated, all market share percentages and rankings are calculated based on consolidated national pharmaceutical sales data (excluding vaccines), in constant euros, on a September 2016 MAT (Moving Annual Total) basis. The data are mainly from Quintiles IMS (MIDAS), supplemented by country-specific sources: Knobloch (Mexico), GERS (France hospital channel), and HMR (Portugal). Market share data for the Consumer Healthcare business are from Nicholas Hall, June 2016 MAT.
- For our Human Vaccines (Vaccines) activity, market share percentages and rankings are based on our own estimates. These estimates have been made from information in the public domain collated from various sources, including statistical data collected by industry associations and information published by our competitors.

Sanofi has two principal activities: pharmaceuticals, and vaccines via Sanofi Pasteur. These activities are operating segments within the meaning of the IFRS 8 accounting standard (see Note D.35. to our consolidated financial statements included in Item 18 of this annual report). We exited the Animal Health business on January 1, 2017 when we closed a transaction with Boehringer Ingelheim (BI) in most markets to swap our Animal Health business for BI's Consumer Healthcare (CHC) business.

We invest in the following activities (see B. Business Overview B.1. Strategy below): Rare Diseases, Multiple Sclerosis, Oncology, Diabetes, Cardiovascular, Established

Prescription Products<sup>(1)</sup>, Consumer Healthcare, Generics, and Vaccines. Unlike our Vaccines activity, which is an operating segment within the meaning of IFRS 8, our Rare Diseases, Multiple Sclerosis, Oncology, Diabetes, Cardiovascular, Established Prescription Products, Consumer

## Edgar Filing: Sanofi - Form 20-F

Healthcare and Generics activities are franchises whose performance is monitored primarily on the basis of net sales; the products sold by each of those franchises are included in our Pharmaceuticals operating segment. We are also active in emerging markets selling products from both our activities (pharmaceuticals and vaccines); the performance of our Emerging Markets<sup>(2)</sup> operations is monitored primarily on the basis of net sales.

For a presentation of the net sales of our activities for the year ended December 31, 2016, refer to Item 5 Results of Operations Year Ended December 31, 2016 Compared with Year Ended December 31, 2015 .

Our pharmaceuticals activity generated net sales of 29,244 million in 2016. The most important pharmaceutical products marketed by us are described below.

- Rare Diseases: a portfolio of enzyme replacement therapies including Cerezyme<sup>®</sup> and Cerdelga<sup>®</sup> for Gaucher disease; Myozyme<sup>®</sup> and Lumizyme<sup>®</sup> for Pompe disease; Fabrazyme<sup>®</sup> for Fabry disease; and Aldurazyme<sup>®</sup> for mucopolysaccharidosis Type 1 (MPS 1).
- Multiple sclerosis: Aubagio<sup>®</sup>, a once-daily oral immunomodulator; and Lemtrada<sup>®</sup>, a monoclonal antibody. Both products were developed to treat patients with relapsing forms of multiple sclerosis.
- Oncology: Jevtana<sup>®</sup>, a taxane derivative, indicated for patients with prostate cancer; Taxotere<sup>®</sup>, a taxoid representing a cornerstone therapy for several cancer types; Eloxatin<sup>®</sup>, a platinum agent, which is a key treatment for colorectal cancer; Thymoglobulin<sup>®</sup>, a broad immunosuppressive and immunomodulating agent; Mozobil<sup>®</sup>, a hematopoietic stem cell mobilizer for patients with hematologic malignancies; and Zaltrap<sup>®</sup>, a recombinant fusion protein, indicated for patients with metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin-containing regimen.
- Diabetes: Lantus<sup>®</sup> (insulin glargine), a long-acting human insulin analog which is the world-leading brand in the insulin market; Toujeo<sup>®</sup> (insulin glargine 300 U/mL); Amaryl<sup>®</sup>, an oral once-daily sulfonylurea; Apidra<sup>®</sup>, a rapid-

<sup>(1)</sup> Established Prescription Products comprises mature products including Plavix<sup>®</sup>, Lovenox<sup>®</sup>, Aprovel<sup>®</sup>, Renage1<sup>®</sup> and Renvela<sup>®</sup>.

<sup>(2)</sup> All markets excluding the US, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, and New Zealand.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

acting human insulin analog; Insuman<sup>®</sup>, a range of rapid-acting or intermediate-acting human insulins; Lyxumia<sup>®</sup>/Adlyxin (lixisenatide), a once-daily GLP-1 receptor agonist; and Soliqua 100/33 / Suliqua, a once-daily combination of insulin glargine and lixisenatide.

Cardiovascular diseases: Praluent<sup>®</sup>, a cholesterol-lowering drug that inhibits PCSK9; and Multaq<sup>®</sup>, an anti-arrhythmic drug in atrial fibrillation.

Established Prescription Products: Plavix<sup>®</sup>, an anti-platelet agent indicated for a number of atherothrombotic conditions; Lovenox<sup>®</sup>, a low molecular weight heparin for the prophylaxis and treatment of venous thromboembolism and of acute coronary syndrome; Aprovel<sup>®</sup> and CoAprovel<sup>®</sup>, anti-hypertensives; Renagel<sup>®</sup> and Renvela<sup>®</sup>, oral phosphate binders for use in patients undergoing dialysis; Synvisc<sup>®</sup> and Synvisc-One<sup>®</sup>, viscosupplements used to reduce pain in patients suffering from osteoarthritis of certain joints; Stilnox<sup>®</sup>, for the short-term treatment of insomnia; and Allegra<sup>®</sup>, a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and uncomplicated hives.

Consumer Healthcare (CHC): our CHC sales are supported by a wide range of products. On January 1, 2017, we acquired BII's CHC business in most markets except China.

Generics: our pharmaceuticals portfolio also includes a wide range of generics. In October 2016, we announced our intention to initiate a carve-out process in order to divest our European Generics business.

Our Vaccines activity is operated through Sanofi Pasteur, and generated net sales of 4,577 million in 2016. We sell leading vaccines in five areas: pediatric vaccines, influenza vaccines, adult and adolescent booster vaccines, meningitis vaccines, and travel and endemic vaccines. At the end of December 2016, Sanofi Pasteur and MSD ended their vaccines joint venture in Europe and integrated their respective European vaccines business into their own operations.

We obtained regulatory approval for one new product in 2016: Soliqua 100/33 in the US. The product was also approved in the EU as Suliqua in January 2017.

Collaborations are essential to our business and a certain number of our products, whether on the market or under development, are in-licensed products relying on third-party rights or technologies.

**A. History and Development of the Company**

The current Sanofi corporation was incorporated under the laws of France in 1994 as a *société anonyme*, a form of limited liability company, for a term of 99 years. Since May 2011, we have operated under the commercial name Sanofi (formerly known as Sanofi-Aventis). Our registered

office is located at 54, rue La Boétie, 75008 Paris, France, and our main telephone number is +33 1 53 77 40 00. Our principal US subsidiary's office is located at 55 Corporate Drive, Bridgewater, NJ 08807; telephone: +1 (908) 981 5000.

**Main changes since 2011**

## Edgar Filing: Sanofi - Form 20-F

On April 4, 2011, following a tender offer, we acquired control of Genzyme, a US biotechnology group headquartered in Cambridge, Massachusetts.

At the end of December 2016, Sanofi Pasteur and MSD ended their vaccines joint venture in Europe and integrated their respective European vaccines business into their own operations.

On January 1, 2017, Sanofi and Boehringer Ingelheim (BI) successfully closed in most markets a transaction to swap Sanofi's Animal Health business for BI's CHC business.

### **B. Business overview**

#### **B.1. Strategy**

##### **The market context for Sanofi**

A number of fundamental trends point to a positive outlook for the pharmaceutical industry. The global population is growing and aging. Unmet medical needs remain high. The industry has increased R&D productivity, and has returned to consistently launching a high number of innovative medicines. Patients around the world, and a rising middle class in emerging markets, are demanding better care, empowered by access to new information. It is a particularly exciting time scientifically and technologically, with the promise of genomics being realized, immuno-oncology transforming cancer treatments, big data generating new insights into disease, and digital technologies helping to transform care delivery.

At the same time, the industry faces challenges. Economic growth in emerging markets has slowed. Affordability is a key concern globally. In 2016, patient, payer, and politicians' concerns about drug prices, reimbursement, and access reached new levels, generating headlines particularly in the US and Europe. The pricing of products as varied as insulin, generics, mature products, and new cholesterol-lowering biologics all have come under scrutiny, with patient activism and social media playing a new and distinctive role. Biosimilars are now firmly part of the competitive landscape in both the US and Europe. More focused competitors are building leadership positions in their priority therapy areas.

##### **Implementing the strategic roadmap**

To compete and win in this market, we are implementing our 2020 strategic roadmap, announced in November 2015. We have made real progress against each of the four pillars of

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

that strategy in 2016: reshape the portfolio, deliver outstanding launches, sustain innovation in R&D, and simplify the organization.

**Reshape the portfolio**

To reshape the portfolio, we segmented our businesses focusing on three targets: to sustain leadership, build competitive positions, and explore strategic options.

**Sustain leadership**

**Diabetes and Cardiovascular Diseases.** We remain committed to fighting the global epidemic of diabetes and to treating cardiovascular disease, the leading cause of death globally. Our three priorities over the next few years are to develop the insulin franchise with Lantus<sup>®</sup>, Toujeo<sup>®</sup>, and Soliqua 100/33 / Suliqua ; strengthen our pipeline; and lead the market shift to managing diabetes outcomes. In 2016, notable product achievements included continued global momentum behind Toujeo<sup>®</sup>, approval of Soliqua 100/33 in the US (launched in January 2017); and ongoing early stage development of dual agonist drug candidates.

Also in 2016, we took a substantial step forward in leading the market shift to managing diabetes outcomes by establishing Onduo, our diabetes solutions joint venture with world-class partner Verily (formerly Google Life Sciences).

In cardiovascular, we have the opportunity to transform the management of hypercholesterolemia through Praluent<sup>®</sup>, developed jointly with Regeneron. In a challenging payer environment, we continue to work on securing access for patients to this important medication. We look forward to the results of the ODYSSEY cardiovascular outcomes study of 18,000 patients, which continues as planned after its second interim analysis in November 2016.

**Vaccines.** Our growth will be driven by leading products in flu, pediatric combinations, and the launch of Dengvaxia<sup>®</sup>. Demand typically exceeds supply, so a key priority for us is to produce more. We are investing to secure and expand flu and pediatric capacity. To pursue their own distinct growth strategies, Sanofi Pasteur and MSD mutually agreed to end their joint vaccines operations in Europe. The change in operations took effect at the end of December 2016. To secure growth for the longer term, we are working on novel vaccines such as Meningitis combination, Fluzone<sup>®</sup> QIV HD and Clostridium difficile.

**Rare Diseases.** We continue to sustain our market share leadership in rare genetic diseases through the patient-centered approach unique to Sanofi Genzyme, product differentiation, and market access. We continue to grow the market through screening and manufacturing expansion. We also expect to advance our strong pipeline, where four of our assets have received breakthrough or fast-track designation from the FDA.

**Emerging Markets.** We are the pharmaceutical industry leader in emerging markets and a major multinational player in the BRIC-M countries (Brazil, Russia, India, China and Mexico).

**Build competitive positions**

**Multiple Sclerosis.** We already have a competitive position in multiple sclerosis: since entering the market in 2012, we have built a franchise with sales of 1.7 billion in 2016. We will continue to maximize our support to these products through life cycle management in a competitive market and we intend to strengthen our portfolio.

**Oncology.** We are rebuilding our oncology portfolio. We intend to maximize our clinical assets, particularly isatuximab, an anti-CD38 monoclonal antibody now in late stage development for multiple myeloma and SAR439684, a PD-1 inhibitor derived from our alliance with Regeneron, in development in the treatment of cutaneous squamous cell carcinoma.

**Immunology.** We have the cornerstones of an important new franchise in immunology through sarilumab (Kevzara) for rheumatoid arthritis and Dupixent in several indications including atopic dermatitis, asthma and nasal polyposis. Both drugs have been developed in collaboration with Regeneron and both are currently under regulatory review by the FDA. We aim to lead in atopic dermatitis with Dupixent, which should be the first in class biologic to reach the market.

**Consumer Healthcare.** On January 1, 2017, Sanofi and Boehringer Ingelheim successfully closed in most markets a transaction to swap Sanofi's animal health and BI's CHC businesses. With this transaction, we acquired BI's CHC business in all countries except China and enhanced our position in four of our strategic categories - Vitamins, Minerals and Supplements, Cough & Cold Care, Digestive Health, and Pain Care.

#### Explore strategic options

**Animal Health.** We have exited the animal health business through the swap with BI.

**Generics in Europe.** As announced in our 2020 strategic roadmap, we carefully reviewed all options for our European Generics business in 2016. In October 2016, we announced that we would initiate a carve-out process in order to divest this business. We will be looking for a potential acquirer that will leverage the mid and long-term sustainable growth opportunities for this business. We have also confirmed our commitment to our Generics business in other parts of the world, and will further focus on emerging markets in order to develop this business in those countries.

---

## **Table of Contents**

### **ITEM 4. INFORMATION ON THE COMPANY**

#### **Deliver outstanding launches**

Our second strategic priority is to deliver outstanding launches of new medicines and vaccines. We have focused the organization on six major product launches: Toujeo<sup>®</sup>, Praluent<sup>®</sup>, Dengvaxia<sup>®</sup>, Soliqua 100/33, sarilumab, and Dupixent

Performance of these products has been mixed, as described in greater detail in Item 5. Operating and Financial Review and Prospects Results of Operations. In 2016, we continued the global launch and ramp-up of Toujeo<sup>®</sup> in diabetes and Praluent<sup>®</sup> for hypercholesterolemia; we also launched Dengvaxia<sup>®</sup>, the first vaccine for dengue fever, and Soliqua 100/33 (in January 2017), a combination of lixisenatide and insulin glargine treatment for diabetes. We received priority review from the FDA for Dupixent in moderate to severe atopic dermatitis.

Sanofi and Regeneron received a Complete Response Letter (CRL) from the FDA regarding the Biologics License Application (BLA) for sarilumab (Kevzara), an investigational interleukin-6 receptor (IL-6R) antibody for the treatment of adult patients with moderately to severely active rheumatoid arthritis. For further information, see B.5. Global Research & Development Pharmaceuticals below.

#### **Sustain innovation in R&D**

Our strategy depends on continued innovation in R&D. We continue to strengthen our R&D pipeline, increasing the number of high-quality projects in the early stage pipeline and replenishing the late development pipeline as products launch. Having delivered real improvements in development productivity, we are now particularly focused on improving research productivity. In 2016, we aligned the R&D organization with the new Global Business Unit structure; reorganized Research into thematic clusters; continued to build capability in translational science; and recruited important new talent.

We have a number of anchor collaborations in R&D, most notably with Regeneron for monoclonal antibodies (increasingly focused on immuno-oncology) and with Alnylam for RNAi therapeutics in rare genetic diseases. Fostering these collaborations is an important part of our R&D strategy.

Our R&D investments will follow our business priorities, focusing on those businesses where we aim to sustain leadership and build competitive positions. We expect to increase our R&D investments to \$6 billion annually by 2020.

#### **Simplify the organization**

Our final strategic priority is to drive focus and simplification within our organization. In 2016, we implemented a new organizational structure, to enable us to be more closely

aligned with our strategy and more effective in our execution across R&D and commercial, from global to country level. Specifically, we have created:

- Global Business Units (GBUs) integrating global franchises and country-level commercial and medical organizations for each of our major businesses: Sanofi Genzyme (specialty care); Diabetes and Cardiovascular; General Medicines and Emerging Markets (established products, generics, and all pharmaceutical sales including Sanofi Genzyme and Diabetes and Cardiovascular in emerging markets); Sanofi Pasteur (vaccines and infectious disease); and Consumer Healthcare.

## Edgar Filing: Sanofi - Form 20-F

- Centralized global functions (Finance, Human Resources, Information Technology and Solutions, etc.).
- An R&D organization organized by therapy area to align with the GBUs for late stage products.
- A global Industrial Affairs platform aligned with the GBUs.
- A strengthened Medical Affairs function, with our new Chief Medical Officer, Dr. Ameet Nathwani, now a member of the Executive Committee.

Reshaping the plant network is a second element in our program of simplification. We have continued to reshape the network to better match our evolving business by implementing a more focused approach in emerging markets, improving competitiveness and simplifying product lines. At the same time, we have continued to invest in biologics capacity to support our product launches and growth.

One of the outcomes of simplification will be a reduction in costs. To balance the need for increased resources and to partly offset lower diabetes sales expectations, we are committed to deliver at least 1.5 billion in cost savings. The savings, which we are on track to deliver, will largely be reinvested in the business.

The third element of the simplification program is to unite the different parts of the Company behind a single vision, a common set of values, and a shared culture.

### **B.2. Main Pharmaceutical Products**

The sections below provide additional information on our main products. Our intellectual property rights over our pharmaceutical products are material to our operations and are described at B.7. Patents, Intellectual Property and Other Rights below. As disclosed in Item 8. Financial Information A. Consolidated Financial Statements and Other Financial Information Patents of this annual report, we are involved in significant litigation concerning the patent protection of a number of these products.

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

The table below shows the net sales of our main pharmaceutical products for the year ended December 31, 2016 (for more information on sales performance, see Item 5. Operating and Financial Review and Prospects - Results of Operations ).

Franchises / Product Name	2016 Net Sales ( million)	Drug Category / Main Areas of Use
<b>Rare Diseases</b>		
Cerezyme® (imiglucerase for injection)	748	Enzyme replacement therapy
Myozyme®/Lumizyme® (alglucosidase alpha)	725	· Gaucher disease Enzyme replacement therapy
Fabrazyme® (agalsidase beta)	674	· Pompe disease Enzyme replacement therapy
Aldurazyme® (laronidase)	201	· Fabry disease Enzyme replacement therapy
Cerdelga® (eliglustat)	106	· Mucopolysaccharidosis Type 1 Enzyme replacement therapy
<b>Multiple Sclerosis</b>		
Aubagio® (teriflunomide)	1,295	· Gaucher disease Type 1 Immunomodulating agent
Lemtrada® (alemtuzumab)	425	· Multiple Sclerosis (MS) Humanized monoclonal antibody
<b>Oncology</b>		
Jevtana® (cabazitaxel)	358	· Multiple Sclerosis (MS) Cytotoxic agent
Thymoglobulin® (anti-thymocyte globulin)	281	· Prostate cancer Polyclonal anti-human thymocyte antibody preparation
		· Acute rejection in organ transplantation
		· Aplastic anemia

Edgar Filing: Sanofi - Form 20-F

Taxotere® (docetaxel)	179	<ul style="list-style-type: none"> <li>· Graft-versus-Host Disease</li> <li>Cytotoxic agent</li> <li>· Breast cancer</li> <li>· Non small cell lung cancer</li> <li>· Prostate cancer</li> <li>· Gastric cancer</li> </ul>
Eloxatin® (oxaliplatin)	170	<ul style="list-style-type: none"> <li>· Head and neck cancer</li> <li>Cytotoxic agent</li> </ul>
Mozobil® (plerixafor)	152	<ul style="list-style-type: none"> <li>· Colorectal cancer</li> <li>Hematopoietic stem cell mobilizer</li> </ul>
Zaltrap® (afibercept)	65	<ul style="list-style-type: none"> <li>· Hematologic malignancies</li> <li>Recombinant fusion protein</li> <li>· Oxaliplatin resistant metastatic colorectal cancer</li> </ul>
<b>Diabetes</b>		
Lantus® (insulin glargine)	5,714	Long-acting analog of human insulin
Toujeo® (insulin glargine 300U/mL)	649	<ul style="list-style-type: none"> <li>· Type 1 and 2 diabetes</li> <li>Long-acting analog of human insulin</li> <li>· Type 1 and 2 diabetes</li> </ul>

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

Franchises / Product Name	2016 Net Sales ( million)	Drug Category / Main Areas of Use
Apidra® (insulin glulisine)	367	Rapid-acting analog of human insulin
Insuman® (insulin)	129	Type 1 and 2 diabetes Human insulin (rapid and intermediate acting)
Lyxumia® (lixisenatide)	33	Type 1 and 2 diabetes GLP-1 receptor agonist
Soliqua 100/33 / Suliqin (insulin glargine and lixisenatide)	N/A	Type 2 diabetes Type 2 diabetes
<b>Cardiovascular Diseases</b>		
Praluent® (alirocumab)	105	Cholesterol-lowering drug that inhibits PCSK9  Heterozygous familial hypercholesterolemia  Clinical atherosclerotic cardiovascular disease
Multaq® (dronedarone)	353	Anti-arrhythmic drug  Atrial Fibrillation (AF)
<b>Established Prescription Products</b>		
Lovenox® (enoxaparin sodium)	1,636	Low molecular weight heparin  Treatment and prevention of deep vein thrombosis
Plavix® (clopidogrel bisulfate)	1,544	Treatment of acute coronary syndromes Platelet adenosine diphosphate receptor antagonist  Atherothrombosis
Renagel® (sevelamer hydrochloride) / Renvela® (sevelamer carbonate)	922	Acute coronary syndrome with and without ST segment elevation Oral phosphate binders  High phosphorus levels in patients with chronic kidney disease (CKD) on dialysis

## Edgar Filing: Sanofi - Form 20-F

Aprovel® (irbesartan) / CoAprovel® (irbesartan & hydrochlorothiazide)	681	Angiotensin II receptor antagonist
Depakine (sodium valproate)	416	Hypertension
Synvisc® / Synvisc-One® (hylan G-F 20)	408	Anti-epileptic
		Viscosupplements
		Pain associated with osteoarthritis of the knee
Stilnox® / Ambien® / Myslee® (zolpidem tartrate)	304	Hypnotic
		Sleep disorders
Allegra® (fexofenadine hydrochloride)	186 <sup>(a)</sup>	Anti-histamine
		Allergic rhinitis
		Urticaria
<b>Consumer Healthcare</b>		
Allegra® (range of fexofenadine HCl-based products)	417	Anti-histamine
		Allergy symptoms including sneezing
Doliprane® (range of paracetamol / acetaminophen-based products)	309	Analgesic
		Pain and fever
Enterogermina®	159	Probiotic
		Maintenance and restoration of intestinal flora
Essentiale®	145	Natural soybean remedy
		To improve liver health
<b>Generics</b>		
Total	1,854	

(a) Excluding sales of self-care versions of Allegra®.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

**a) Rare Diseases**

Our Rare Diseases business is focused on products for the treatment of rare genetic diseases and other rare chronic debilitating diseases, including lysosomal storage disorders (LSDs), a group of metabolic disorders caused by enzyme deficiencies.

**Cerezyme®**

Cerezyme® (imiglucerase for injection) is an enzyme replacement therapy used to treat Gaucher disease, an inherited, potentially life-threatening LSD. It is estimated that Gaucher disease occurs in approximately one in 120,000 newborns in the general population and one in 850 in the Ashkenazi Jewish population worldwide, but the incidence and patient severity vary among regions.

Cerezyme® is the only therapy with a 25-year history of reducing, relieving and reversing many of the symptoms and risks of Type 1 and Type 3 (in certain markets) Gaucher disease. Cerezyme® is administered by intravenous infusion over one or two hours.

The principal markets for Cerezyme® are the US, Europe and Latin America.

**Cerdelga®**

Cerdelga® (eliglustat) is the first and only first-line oral therapy for Gaucher disease Type 1. A potent, highly specific ceramide analogue inhibitor of GL-1 synthesis with broad tissue distribution, Cerdelga® has demonstrated efficacy in the treatment of naive Gaucher disease patients and in patients who switch from enzyme replacement therapy (ERT).

Cerdelga® was approved by the FDA in August 2014 and by the European Commission in January 2015; the product is now available in several European countries. It was approved in Japan in March 2015 and launched in the same year. Regulatory submissions are ongoing in other countries. The principal market for Cerdelga® is currently the US.

**Myozyme® and Lumizyme®**

Myozyme® and Lumizyme® (alglucosidase alfa) are enzyme replacement therapies used to treat Pompe disease, an inherited, progressive and often fatal LSD. Pompe disease occurs in approximately one in 40,000 newborns worldwide, but the incidence and patient severity vary among regions.

Myozyme® has been marketed since 2006 in the US and the EU and is approved in 76 countries. Outside the US, Myozyme® is marketed for patients with both infantile- and late-onset disease. Lumizyme® has been marketed in the US since June 2010. Initially designed specifically to treat patients with late-onset Pompe disease and patients over eight years of age without evidence of cardiac hypertrophy, on August 1, 2014 it was approved for infantile-onset Pompe disease.

Myozyme® and Lumizyme® are administered by intravenous infusion once every two weeks. Both products are recombinant forms of the same human enzyme.

**Fabrazyme®**

Fabrazyme® (agalsidase beta) is an enzyme replacement therapy used to treat Fabry disease, an inherited, progressive and potentially life threatening LSD. Fabry disease occurs in approximately one in 35,000 newborns worldwide, but the incidence and patient severity vary among regions.

Fabrazyme® has been marketed in the EU since 2001 and in the US since 2003, and is approved in 75 countries. Fabrazyme® is administered by intravenous infusion once every two weeks.

**Aldurazyme®**

Aldurazyme® (laronidase) is the first and only approved treatment for mucopolysaccharidosis type 1 (MPS 1). A human recombinant enzyme therapy with over 13 years of clinical post-marketing experience, Aldurazyme® has been shown to be safe and effective in symptomatic MPS 1 patients of all phenotypes. MPS 1 occurs in approximately one per 100,000 live births worldwide, but the incidence and patient severity vary among regions. Aldurazyme® is administered once weekly as an intravenous infusion.

**b) Multiple Sclerosis**

Multiple sclerosis (MS) is an autoimmune disease in which a person's immune system attacks the central nervous system, damaging myelin, the protective sheath that covers nerve fibers. This causes a break in communication between the brain and the rest of the body, ultimately destroying the nerves themselves, and causing irreversible damage. More than 2.5 million people suffer from MS worldwide.

Our MS franchise consists of Aubagio® (teriflunomide), a once-daily, oral immunomodulator, and Lemtrada® (alemtuzumab), a monoclonal antibody. Both products have been developed to treat patients with relapsing forms of MS.

**Aubagio®**

Aubagio® (teriflunomide), a small molecule immunomodulatory agent with anti-inflammatory properties, reversibly inhibits dihydroorotate dehydrogenase, a mitochondrial enzyme involved in the de novo pyrimidine synthesis required for activated lymphocytes to multiply. The exact mechanism by which teriflunomide exerts its therapeutic effect in MS is unknown but may involve a reduction in the number of activated lymphocytes in the central nervous system. Aubagio® is a once-daily oral therapy. Aubagio® has shown significant efficacy across key measures of MS disease activity, including slowing the progression of physical disability, reducing relapses, and

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

reducing the number of brain lesions as detected by magnetic resonance imaging (MRI). Aubagio® is the first and only oral MS therapy to significantly slow the progression of disability in two Phase III trials (TEMSO and TOWER). Consistent with its effect on slowing disability progression, Aubagio® is the only oral therapy shown to prevent or delay a second clinical attack in patients who have experienced initial neurological symptoms suggestive of MS (TOPIC trial).

Ongoing development efforts include the TeriKIDS study to assess the safety and efficacy of teriflunomide in children (10-17 years old) and global post-marketing registries for pregnancy.

Aubagio® was granted marketing authorization by the FDA in September 2012 for the treatment of patients with relapsing forms of MS, and by the European Commission in August 2013 for the treatment of adult patients with relapsing remitting MS. Aubagio® is now approved in more than 70 countries around the world. To date, more than 65,000 people have been treated with Aubagio®.

We have filed lawsuits against Watson Laboratories, Inc., Aurobindo Pharma Ltd. and Alvogen Group, Inc. alleging infringement of two patents for Aubagio®. For further information, see Item 8. Information on Legal or Arbitration Proceedings – Aubagio® Patent Litigation .

The principal markets for Aubagio® in terms of sales are the US, Germany, France, Canada, the UK, Italy, and Spain.

**Lemtrada®**

Lemtrada® (alemtuzumab) is a humanized monoclonal antibody targeting the CD52 antigen. The exact mechanism by which alemtuzumab exerts its therapeutic effect in MS is unknown. Research suggests immunomodulatory effects through the selective depletion and repopulation of T and B lymphocytes, resulting in a resetting of the immune system. Lemtrada® is administered as two short courses 12 months apart; for the majority of patients no further treatment is necessary, making Lemtrada® the only disease-modifying therapy (DMT) that can provide long term durable efficacy in the absence of continuous dosing.

Lemtrada® was able to show statistically significant improvement across many key measurements of MS disease activity including improvement in physical disability, reducing relapses, and reducing the number of brain lesions as detected by MRI. Lemtrada® is the first and only approved DMT to show an improvement in six-month confirmed disability improvement (CDI) against an active comparator (CARE MS II study). Lemtrada® was also able to reduce brain volume loss over six years to levels seen in healthy controls, despite the majority of Lemtrada® patients receiving no treatment after the initial two treatment courses (extension of CARE MS I and II studies).

In September 2013, Lemtrada® was granted marketing authorization by the European Commission for treatment of adult patients with relapsing forms of MS with active disease defined by clinical or imaging features. In November 2014, the FDA approved Lemtrada® for the treatment of patients with relapsing forms of multiple sclerosis. Because of its safety profile, the FDA approval limited use of Lemtrada® to patients who have had an inadequate response to two or more drugs indicated for the treatment of MS and included a black-box warning on potential side effects. Lemtrada® is only available in the US through a restricted program called the Lemtrada® Risk Evaluation and Mitigation Strategy (REMS) Program. Lemtrada® is currently approved in more than 60 countries with additional marketing applications under review by regulatory authorities globally. To date, more than 11,800 people have been treated with Lemtrada®.

The principal markets for Lemtrada® in terms of sales are the US, the UK, Germany, Australia, Canada and Spain.

Bayer Healthcare receives contingent payments based on alemtuzumab global sales revenue. For additional information, see Note D.18. to the consolidated financial statements included at Item 18 of this annual report.

**c) Oncology**

**Jevtana®**

Jevtana® (cabazitaxel), a cytotoxic agent, is a semi-synthetic taxane promoting tubulin assembly and stabilizing microtubules, approved in combination with prednisone for the treatment of patients with hormone-refractory metastatic prostate cancer previously treated with a docetaxel-containing treatment regimen.

Jevtana® was granted marketing authorization by the FDA in June 2010, by the European Commission in March 2011, and in Japan in July 2014. The product is now approved in over 85 countries.

The main countries contributing to sales of Jevtana® in 2016 were the US, France, Germany, Japan, Italy and Spain.

**Taxotere®**

Taxotere® (docetaxel), a taxoid class derivative, inhibits cancer cell division by essentially freezing the cell's internal skeleton, which is comprised of microtubules. Microtubules assemble and disassemble during a cell-division cycle. Taxotere® promotes their assembly and blocks their disassembly, thereby preventing many cancer cells from dividing, which ultimately results in destroying many cancer cells.

Taxotere® is available in more than 90 countries as an injectable solution. It has been approved for use in 11 indications in five different tumor types (breast, prostate, gastric, lung, and head and neck).

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Generics of docetaxel have been launched in Europe, the US and Japan.

Sanofi is involved in Taxotere<sup>®</sup> product litigation in the US. See Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report.

**Eloxatin<sup>®</sup>**

Eloxatin<sup>®</sup> (oxaliplatin) is a platinum-based cytotoxic agent. Eloxatin<sup>®</sup>, in combination with infusional administration of two other chemotherapy drugs, 5-fluorouracil/leucovorin (the FOLFOX regimen), is approved by the FDA for adjuvant treatment of people with stage III colon cancer who have had their primary tumors surgically removed. This approval was based on evidence of an improvement in disease-free survival after four years.

Eloxatin<sup>®</sup> is in-licensed from Debiopharm and is marketed in more than 70 countries worldwide.

Generics of oxaliplatin have been launched in Europe, the US, Canada and Japan.

**Thymoglobulin<sup>®</sup>**

Thymoglobulin<sup>®</sup> (anti-thymocyte Globulin) is a polyclonal anti-human thymocyte antibody preparation that acts as a broad immunosuppressive and immunomodulating agent. The product's primary mechanism of action is T-cell depletion, which is complemented by a host of other immunomodulating effects. Thymoglobulin<sup>®</sup> is currently marketed in over 65 countries. Depending on the country, Thymoglobulin<sup>®</sup> is indicated for the treatment and/or prevention of acute rejection in organ transplantation; immunosuppressive therapy in aplastic anemia; and the treatment and/or prevention of Graft-versus-Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation.

The main countries contributing to Thymoglobulin<sup>®</sup> sales in 2016 were the US, China, France, Japan and South Korea.

**Mozobil<sup>®</sup>**

Mozobil<sup>®</sup> (plerixafor injection) is a hematopoietic stem cell mobilizer indicated in combination with granulocyte-colony stimulating factor (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) and multiple myeloma (MM).

**Zaltrap<sup>®</sup>**

Zaltrap<sup>®</sup> (aflibercept/ziv-aflibercept) is a recombinant fusion protein which acts as a soluble decoy receptor that binds to Vascular Endothelial Growth Factor-A (VEGF-A), Vascular Endothelial Growth Factor-B (VEGF-B) and placental growth factor (PIGF), preventing the bound VEGF from binding to their native receptors. VEGF-A is one of the mediators

contributing to angiogenesis. VEGF-B and PIGF, related growth factors in the VEGF family, may contribute to tumor angiogenesis as well.

The FDA approved Zaltrap<sup>®</sup> in August 2012 for use in combination with FOLFIRI (chemotherapy regimen made of 5-fluorouracil/leucovorin/irinotecan), in patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. To avoid confusion with Eylea<sup>®</sup>, the FDA assigned a new name, ziv-aflibercept, to the active ingredient. The European Commission approved Zaltrap<sup>®</sup> (aflibercept) in February 2013 to treat mCRC that is resistant to or has progressed after an

oxaliplatin-containing regimen.

Zaltrap® is now approved in 71 countries worldwide. Zaltrap® is commercialized in collaboration with Regeneron Pharmaceuticals, Inc. For additional information, see Item 5 Financial Presentation of Alliances Alliance Arrangements with Regeneron .

**d) Diabetes**

The prevalence of diabetes is expected to increase significantly by 2030, reflecting multiple socio-economic factors including sedentary lifestyles, excess weight and obesity, unhealthy diet and an aging population.

Our main diabetes products are Lantus® and Toujeo®, long acting analogs of human insulin; Apidra®, a rapid acting analog of human insulin; Insuman®, a range of human insulin; Lyxumia® (lixisenatide), a once-daily injectable prandial GLP-1 receptor agonist; and Soliqua 100/33 / Suliqua , an injectable once-daily insulin glargine and lixisenatide combination.

**Lantus®**

Lantus® (insulin glargine) is a long-acting analog of human insulin, indicated for once-daily subcutaneous administration in the treatment of adult patients with type 2 diabetes who require basal insulin for the control of hyperglycemia, and for adult and pediatric patients (label extension for pediatric use was granted in the EU in 2012) aged two years and over with type 1 diabetes.

Lantus® is the most-studied basal insulin, with 16 years of clinical evidence in diabetes treatment and a well-established safety profile.

Lantus® can be administered subcutaneously using syringes or specific pens including:

- Lantus® SoloSTAR®, a pre-filled disposable pen available in over 120 countries worldwide, that combines a low injection force of up to 80 units per injection with ease of use;

---

**Table of Contents**
**ITEM 4. INFORMATION ON THE COMPANY**

AllSTAR<sup>®</sup>, a reusable insulin pen developed specially for people with diabetes in emerging markets, indicated for use with Sanofi's insulin portfolio. AllSTAR<sup>®</sup> is currently available in a dozen countries, mostly in emerging markets. Lantus<sup>®</sup> remains the world's no. 1 selling insulin brand in terms of both sales and units and is available in over 130 countries worldwide. The leading countries for sales of Lantus<sup>®</sup> in 2016 were the US, China, France and Germany.

A biosimilar of Lantus<sup>®</sup> from Eli Lilly and Company (Lilly) was launched in several European markets in the third quarter of 2015 (including Germany, the UK, Spain and eight other countries), and has also been launched in Japan. Lilly's insulin glargine drug, Basaglar<sup>®</sup> (as it is known in the US), was launched in the US in December 2016; it has now been launched in several countries worldwide and approved in several additional countries. On September 16, 2016, we announced that we had filed a patent infringement suit against Merck Sharp & Dohme Corp. (Merck) in the US to defend our patent rights on Lantus<sup>®</sup> and Lantus<sup>®</sup> SoloSTAR<sup>®</sup> following Merck's filing of a New Drug Application with the FDA for their insulin glargine drug product. For further information, see Item 8 Information on Legal or Arbitration Proceedings Lantus<sup>®</sup> SoloSTAR<sup>®</sup> Patent Litigation.

**Toujeo<sup>®</sup>**

Toujeo<sup>®</sup> (insulin glargine 300 units/mL) has been granted marketing authorization by the FDA (February 2015), the European Commission (April 2015), and by the Ministry of Health, Labor and Welfare (J-MHLW) in Japan where its approved brand name is Lantus<sup>®</sup> XR (June 2015).

Toujeo<sup>®</sup> is available in Toujeo<sup>®</sup> SoloSTAR<sup>®</sup>, a disposable prefilled pen which contains 450 units of insulin glargine and requires one third of the injection volume to deliver the same number of insulin units as compared to Lantus<sup>®</sup> SoloSTAR<sup>®</sup>. The maximum single injection dose of 80 IU meets the needs of the vast majority of patients on basal insulin in the US, who require 80 IU or less per day.

Toujeo<sup>®</sup> has now been launched in more than 40 countries, including the US, Germany, Spain, France, the UK and Japan. Toujeo<sup>®</sup> is currently pending marketing authorization with other health authorities around the world and it is expected that additional countries including Italy, Mexico and Russia will launch Toujeo<sup>®</sup> in 2017, making this next-generation insulin glargine treatment for type 1 and type 2 diabetes widely available.

**Apidra<sup>®</sup>**

Apidra<sup>®</sup> (insulin glulisine) is a rapid-acting analog of human insulin. Apidra<sup>®</sup> is indicated for the treatment of adults with type 1 or type 2 diabetes for supplementary glycemic control. Apidra<sup>®</sup> has a more rapid onset and shorter duration of

action than fast-acting human insulin and can be used in combination with long-acting insulins such as Lantus<sup>®</sup> for supplementary glycemic control at mealtimes. Apidra<sup>®</sup> can be administered subcutaneously using syringes or specific pens including the Apidra<sup>®</sup> SoloSTAR<sup>®</sup> disposable pen.

Apidra<sup>®</sup> is available in over 100 countries worldwide.

**Insuman<sup>®</sup>**

Insuman<sup>®</sup> (human insulin) is a range of insulin solutions and suspensions for injection and is indicated for diabetes patients when treatment with insulin is required. Human insulin is produced by recombinant DNA technology in Escherichia coli strains. Insuman<sup>®</sup> is supplied in vials, cartridges, and pre-filled disposable pens (SoloSTAR<sup>®</sup>). The Insuman<sup>®</sup> range is comprised of rapid-acting insulin solutions (Insuman<sup>®</sup> Rapid and Insuman<sup>®</sup> Infusat) that contain soluble insulin, an intermediate-acting insulin suspension (Insuman<sup>®</sup> Basal) that contains isophane insulin,

and combinations of fast-acting and intermediate-acting insulins in various proportions (Insuman<sup>®</sup> Comb).

Insuman<sup>®</sup> is principally sold in emerging markets.

### **Lyxumia<sup>®</sup> / Adlyxin**

Lyxumia<sup>®</sup> (lixisenatide) is a once-daily prandial GLP-1 receptor agonist and is indicated for the treatment of adults with type 2 diabetes to achieve glycemic control in combination with oral glucose-lowering medicinal products and/or basal insulin when these, together with diet and exercise, do not provide adequate glycemic control.

In February 2013, the European Commission granted marketing authorization in Europe for Lyxumia<sup>®</sup>. On completion of pricing and reimbursement discussions, Sanofi initiated a phased launch of Lyxumia<sup>®</sup> in most EU countries. Lixisenatide was approved by the FDA in July 2016 under the brand name of Adlyxin after the results of the ELIXA trial demonstrated cardiovascular safety in type 2 diabetes patients with high cardiovascular risk. Adlyxin availability in the US is anticipated early 2017. Lixisenatide is approved under the proprietary name Lyxumia<sup>®</sup> in more than 60 countries and marketed in over 40. Commercial launches include most EU countries, Japan, Brazil, Mexico and India. Lixisenatide was in-licensed from Zealand Pharma A/S.

### **Soliqua 100/33 / Suliqua**

Soliqua 100/33 or Suliqua is a once-daily fixed-ratio combination of insulin glargine 100 Units/mL, a long-acting analog of human insulin, and lixisenatide, a GLP-1 receptor agonist. It has been studied in a Phase III program of more than 1,900 patients.

The FDA approved Soliqua 100/33 in November 2016 for the treatment of adults with type 2 diabetes inadequately controlled on basal insulin (less than 60 units daily) or lixisenatide. Soliqua 100/33 is now available in the US

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

(since January 5, 2017) in a single pre-filled pen for once-daily dosing covering 15 to 60 units of insulin glargine 100 units/mL and 5 to 20 mcg of lixisenatide using SoloSTAR<sup>®</sup> technology, the most frequently used disposable insulin injection pen platform in the world.

In January 2017, the European Commission granted marketing authorization in Europe for Suliqua (the product's brand name in Europe) for use in combination with metformin for the treatment of adults with type 2 diabetes to improve glycemic control when this has not been provided by metformin alone or metformin combined with another oral glucose-lowering medicinal product or with basal insulin.

Applications for regulatory approval have also been submitted in several other countries and are being reviewed.

**Afrezza<sup>®</sup>**

Afrezza<sup>®</sup> is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes. The product was launched in the US at the beginning of February 2015. Sanofi exercised its option to terminate the license and collaboration agreement with MannKind Corporation, the developer of Afrezza<sup>®</sup>, in January 2016 and transferred the rights for Afrezza<sup>®</sup> back to MannKind on April 4, 2016.

**Integrated Care Solutions**

This approach integrates therapeutic innovations, connected devices and technology, personalized services and support solutions, such as the My Dose Coach App which was submitted to the FDA in November 2016. In line with our partnership strategy, we have partnered with AgaMatrix to co-develop MyStar Dose Coach<sup>®</sup>, a dose helper for insulin glargine with an integrated blood glucose meter, which has obtained the CE mark.

Sanofi and Verily Life Sciences LLC (formerly Google Life Sciences), an Alphabet company, announced in September 2016 the launch of Onduo, a joint venture created through Sanofi and Verily's diabetes-focused collaboration. The joint venture is based in Cambridge, Massachusetts (United States). Onduo's mission is to help people with diabetes live full, healthy lives by developing comprehensive solutions that combine devices, software, medicine, and professional care to enable simple and intelligent disease management.

**e) Cardiovascular Diseases**

**Praluent<sup>®</sup>**

Praluent<sup>®</sup> (alirocumab) is a human monoclonal antibody (mAb) that blocks the interaction of proprotein convertase subtilisin/kexin type 9 (PCSK9) with low-density lipoprotein (LDL) receptors, increasing the recycling of LDL receptors and reducing LDL cholesterol levels.

Praluent<sup>®</sup> has been extensively studied through the ODYSSEY Phase III program with 16 global trials including more than 23,500 patients in more than 40 countries to evaluate the product's efficacy and safety across various high cardiovascular risk patients (due to but not limited to diabetes, family hypercholesterolemia or previous cardiovascular events) including patients with heterozygous familial hypercholesterolemia (HeFH), patients with primary hypercholesterolemia uncontrolled on statins and/or other lipid-modifying therapies, post acute coronary syndrome (ACS) patients and as a monotherapy for patients who are unable to tolerate an effective dose of statins.

The effect of Praluent<sup>®</sup> on cardiovascular morbidity and mortality within the post ACS patient population is being investigated in the ongoing ODYSSEY OUTCOMES trial.

## Edgar Filing: Sanofi - Form 20-F

Praluent® has been granted marketing authorization by the FDA (July 2015), the European Commission (September 2015) and the Japanese Ministry of Health, Labor and Welfare (J-MHLW) (July 2016). Praluent® is indicated as an adjunct to diet and maximally tolerated statin therapy in certain adult patients with uncontrolled LDL cholesterol. Praluent® is available in 75 mg and 150 mg dose injections for self-administration every two weeks.

As of December 2016, Praluent® had been approved in 44 countries and launched in 16 countries including the US, Canada, Japan, Germany, the UK, Spain, Austria, the Nordic countries, Mexico and the UAE.

Praluent® is developed and commercialized in collaboration with Regeneron Pharmaceuticals, Inc. For additional information on the commercialization of this product, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Regeneron .

There are ongoing patent infringement proceedings in several countries initiated against us and Regeneron Pharmaceuticals, Inc. by Amgen relating to Praluent® in which Amgen has requested injunctive reliefs. See Note D.22.b) to the consolidated financial statements included at Item 18 of this annual report and Item 8. Financial Information B. Significant changes of this annual report for more information .

### **Multaq®**

Multaq® (dronedarone) is an oral multichannel blocker with anti-arrhythmic properties for prevention of atrial fibrillation recurrences. Multaq® is among the most extensively studied anti-arrhythmic drugs in atrial fibrillation: it demonstrated a unique cardiovascular outcome benefit in the ATHENA study and effective rhythm control in the EURIDIS and ADONIS studies which was confirmed in real world investigations.

In August 2016, the District Court of Delaware ruled in favor of Sanofi in the Multaq® patent litigation holding that the defendants infringe both of the patents at suit; the

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

800 Formulation patent and the 167 Method of Use patent, expiring in 2018 and 2029, respectively. Both defendants appealed that ruling in September 2016. For further information, see Item 8 Information on Legal or Arbitration Proceedings Multi-Patent Litigation .

**f) Established Prescription Products**

**Plavix® / Iscover®**

Plavix® or Iscover® (clopidogrel bisulfate), a platelet adenosine diphosphate (ADP) receptor antagonist with a rapid onset of action that selectively inhibits platelet aggregation induced by ADP, is indicated for the prevention of atherothrombotic events in patients with a history of recent myocardial infarction (MI), recent ischemic stroke or established peripheral arterial disease (PAD).

Plavix® is indicated for patients with acute coronary syndrome (ACS):

For patients with non-ST-segment elevation ACS, including unstable angina/nonQ-wave myocardial infarction, Plavix® has been shown to decrease the rate of a combined endpoint of cardiovascular death, MI or stroke, as well as the rate of a combined endpoint of cardiovascular death, MI, stroke, or refractory ischemia. This applies equally to patients who are to be managed medically, and those who are to be managed with percutaneous coronary intervention (with or without stent) or coronary artery bypass grafting.

For patients with ST-segment elevation acute myocardial infarction, Plavix® has been shown to reduce the rate of death from any cause and the rate of a combined endpoint of death, re-infarction or stroke.

Plavix® is also indicated in combination with acetylsalicylic acid (ASA) for the prevention of atherothrombotic and thromboembolic events in atrial fibrillation, including stroke.

CoPlavix® / DuoPlavin®, a fixed-dose combination of clopidogrel bisulfate and ASA, is indicated for the prevention of atherothrombotic events in adult patients with acute coronary syndrome who are already taking both clopidogrel and ASA.

Plavix® or Iscover® are marketed in more than 80 countries. For additional information on the commercialization of these products, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Bristol-Myers Squibb .

A number of generics have been launched in Europe, the US and other markets. In Japan, generics were launched in June 2015 for the stroke indication, in October 2015 for MI and in December 2016 for the PAD indication, the last protected indication.

Plavix® is the leading anti-platelet in the Chinese market. The main countries contributing to sales of Plavix® / Iscover® in 2016 were China and Japan.

Sanofi is involved in Plavix® product litigation in the US. See Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report.

**Lovenox® / Clexane®**

## Edgar Filing: Sanofi - Form 20-F

Lovenox<sup>®</sup> or Clexane<sup>®</sup> (enoxaparin sodium) is registered for a wider range of clinical indications than any other low molecular weight heparin (LMWH). Its comprehensive clinical dossier has demonstrated a favorable risk-benefit ratio, notably in the prophylaxis and treatment of venous thromboembolism and in the treatment of acute coronary syndrome. In the prevention of venous thromboembolism, the use of Lovenox<sup>®</sup> continues to grow, particularly in prophylaxis of deep vein thrombosis (DVT) in patients hospitalized for an acute medical condition.

In the US, three enoxaparin generics have been approved in addition to our own authorized generic. In the EU, the European Commission granted marketing authorizations to two enoxaparin biosimilars in September 2016; one national marketing authorization has been granted in Poland where this biosimilar is available and other enoxaparin biosimilar dossiers are under assessment, but as of January 31, 2017 no enoxaparin biosimilars have been launched in Europe except in Poland.

Lovenox<sup>®</sup> or Clexane<sup>®</sup> is marketed in more than 100 countries. In 2016, Lovenox<sup>®</sup> was the leading injectable anti-thrombotic in all European countries.

### **Aprovel<sup>®</sup> / Avapro<sup>®</sup> / Karvea<sup>®</sup>**

Aprovel<sup>®</sup> or Avapro<sup>®</sup> or Karvea<sup>®</sup> (irbesartan) is an anti-hypertensive belonging to the class of angiotensin II receptor antagonists. These highly effective and well tolerated antagonists act by blocking the effect of angiotensin II, the hormone responsible for blood vessel contraction, thereby enabling blood pressure to return to normal. In addition to Aprovel<sup>®</sup> / Avapro<sup>®</sup> / Karvea<sup>®</sup>, we also market CoAprovel<sup>®</sup> /Avalide<sup>®</sup> / Karvezide<sup>®</sup>, a fixed-dose combination of irbesartan and hydrochlorothiazide (HCTZ), a diuretic that increases the excretion of water and sodium by the kidneys and provides an additional blood pressure lowering effect.

Aprovel<sup>®</sup> and CoAprovel<sup>®</sup> tablets are available in a wide range of dosages to fit the needs of patients with different levels of hypertension severity.

Aprovel<sup>®</sup> is indicated as a first-line treatment for hypertension and for the treatment of nephropathy in hypertensive patients with type 2 diabetes. CoAprovel<sup>®</sup> is indicated for patients whose blood pressure is not adequately controlled with a monotherapy, but also as initial therapy in patients at high risk or with markedly high baseline blood pressure or who are likely to need multiple drugs to achieve their blood pressure goals.

A fixed-dose combination with amlodipine (Aprovasc<sup>®</sup>) has been launched in several emerging market countries.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Aprovel® and CoAprovel® are marketed in more than 80 countries. For additional information on the commercialization of this product, see Item 5. Financial Presentation of Alliances Alliance Arrangements with Bristol-Myers Squibb . In Japan, the product is licensed to Shionogi Co. Ltd and BMS KK. BMS KK has sublicensed the agreement to Dainippon Pharma Co. Ltd.

A number of generics have been launched in Europe, the US and other markets.

The main countries contributing to sales of Aprovel® / Avapro® / Karvea® in 2016 were China and Japan.

**Renagel® and Renvela®**

Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate) are oral phosphate binders used by chronic kidney disease (CKD) patients on dialysis as well as late stage CKD patients in Europe to treat a condition called hyperphosphatemia, or elevated phosphorus levels, which is associated with heart and bone disease. Renvela® is a second-generation buffered phosphate binder.

In the US, there are an estimated 395,000 dialysis patients, approximately 90% of whom receive a phosphate binder. There are an estimated 350,000 dialysis patients in the EU and 65,000 in Brazil. In the EU, Renvela® is also approved to treat CKD patients not on dialysis.

Renagel® and Renvela® are marketed in more than 85 countries. In Japan and several Pacific Rim countries, Renagel® is marketed by Chugai Pharmaceutical Co., Ltd and its sublicensee, Kyowa Hakko Kirin Co., Ltd.

As of January 31, 2017, there have been no approvals of generics in the US. However, we expect potential generics approvals in the US in 2017. Generics of sevelamer carbonate are currently marketed in some European countries.

The main countries contributing to sales of Renagel® and Renvela® in 2016 were the US, France, Canada, Spain and Italy.

**Allegra® / Telfast®**

Allegra® or Telfast® (fexofenadine hydrochloride) is a long-lasting (12- and 24-hour) non-sedating prescription anti-histamine for the treatment of seasonal allergic rhinitis (hay fever) and uncomplicated hives. It offers patients significant relief from allergy symptoms without causing drowsiness.

We also market Allegra-D® 12 Hour and Allegra-D® 24 Hour, anti-histamine/decongestant combination products with an extended-release decongestant for effective non-drowsy relief of seasonal allergy symptoms, including nasal congestion. This combination is marketed in Japan under the Dellegra® brand name.

Generics of most forms of Allegra® / Telfast® have been approved in our major markets.

In the US, the Allegra® family moved to over-the-counter (OTC) use in adults and children aged two and over in 2011. Allegra® was also launched on the OTC market in Japan in November 2012, though it also remains available on prescription. See g) Consumer Healthcare below.

Allegra® / Telfast® is marketed in approximately 80 countries. The largest market for prescriptions of Allegra® is Japan, where competing generics entered the market in early 2013.

**Stilnox® / Ambien® / Myslee®**

Stilnox® (zolpidem tartrate) is indicated for the short-term treatment of insomnia. Stilnox® rapidly induces sleep that is qualitatively close to natural sleep and devoid of certain side effects that are characteristic of the benzodiazepine class as a whole. Its action lasts for a minimum of six hours and it is generally well tolerated, allowing the patient to awaken without notably impaired attention, alertness or memory throughout the day.

Stilnox® is marketed in over 100 countries. It is available under the brand name Ambien® / Ambien®CR in the US and Myslee® in Japan, where it is co-promoted jointly with Astellas.

Stilnox® and Ambien CR® are subject to generic competition in most markets, including the US, Europe and Japan.

In 2016, the main countries contributing to Stilnox® / Ambien® / Myslee® sales were Japan and the US.

**Synvisc® / Synvisc-One®**

Synvisc® and Synvisc-One® (hylan G-F 20) are viscosupplements used to treat pain associated with osteoarthritis. Synvisc® is indicated for the treatment of pain associated with osteoarthritis of the knee, hip, ankle, and shoulder joint in countries that have adopted CE marking, and for pain due to knee osteoarthritis in the US. Synvisc-One® is approved for use in patients with osteoarthritis of the knee in the US and countries that require CE marking. Currently the main viscosupplementation market is for the treatment of pain associated with osteoarthritis of the knee.

Synvisc® is a triple-injection product and Synvisc-One® a single-injection product. Both are administered directly into the intra-articular space of the joint to temporarily restore synovial fluid.

In 2016, the main countries contributing to Synvisc® and Synvisc-One® sales were the US, Mexico, France, Brazil and Canada.

**Depakine®**

Depakine® (sodium valproate) is a broad-spectrum anti-epileptic that has been prescribed for more than 40 years and remains a reference treatment for epilepsy worldwide.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Depakine® is also a mood stabilizer, registered in the treatment of manic episodes associated with bipolar disorder and, in numerous countries, in the prevention of mood episodes.

Depakine® is marketed in over 100 countries. We no longer hold any rights to Depakine® in the US, and sodium valproate generics are available in most markets.

Sanofi is involved in product litigation related to Depakine® in France. See Note D.22.a) to the consolidated financial statements included at Item 18 of this annual report.

**g) Consumer Healthcare**

Consumer Healthcare (CHC) became a growth platform of Sanofi in 2009. At the end of 2013, a Global CHC Division was created following the acquisition of Chattem (in 2010) and the US launch of self-care versions of Allegra® products (in 2011) that had previously been available only by prescription.

The sustained growth of our CHC business is based on three complementary development priorities:

• **Maximize the potential of existing brands** by accelerating our consumer-driven innovation processes and by geographical expansion of our portfolio. Highlights of our product launches throughout the world in 2016 include the following extensions: Aspercreme® Lidocaine Patch (US), Depura High Strength (Brazil), Ibuprofen (France), Enterogermina® 4 Billion (Italy), Bio-Organics Glycemix (Australia) and the roll-out of Doliprane® line extensions including for example, Doliprane Orodoz 500 mg or Doliprane® Vitamine C.

• **Shape new categories** by enhancing our strategy of launching self-care versions of products previously available only by prescription. A license agreement signed in 2014 with Lilly granted us exclusive rights to apply for approval of Cialis® as an OTC product in the US, Europe, Canada and Australia, and to sell it in those markets on receipt of all necessary regulatory approvals and once certain patents protecting the product have expired. On February 1, 2017, we announced the FDA approval of Xyzal® Allergy 24HR as an over-the-counter (OTC) treatment for the relief of symptoms associated with seasonal and year-round allergies.

• **Pursue external growth opportunities** to reach critical scale in key countries and optimize the portfolio in priority categories. Our aim was to achieve leadership in consumer healthcare, and we have done so by completing a business swap with Boehringer Ingelheim (BI). The transaction closed in most markets on January 1, 2017. With this transaction, Sanofi acquired BI's CHC business in all countries except China. The deal enhanced our position in four of our strategic categories – Nutritional, Cough & Cold, Digestive Health, and Pain Care – by bringing in iconic BI brands (Buscopan®, Pharmaton®, Bisolvon®, Mucosolvan®, Dulcolax®, Lysopaine®/Mucoangin®), and enabled us to achieve critical scale in key geographies.

To drive performance and ensure the successful integration of the Sanofi and BI businesses, we have created a separate CHC Global Business Unit.

Our CHC sales are supported by a range of products including:

- Allegra® is a range of fexofenadine HCl based products. Fexofenadine is an antihistamine for relief from allergy symptoms including sneezing, runny nose, itchy nose or throat, and itchy, watery eyes. Allegra® OTC is mainly sold in the US, and is also sold in more than 80 countries across the world.
- Nasacort® Allergy 24H is an intranasal steroid indicated for allergic rhinitis in adults and children aged 2 and older. Nasacort Allergy® 24H is sold mainly in the US.
- Doliprane® offers a range of paracetamol / acetaminophen-based products for pain and fever with a wide range of dosage options and pharmaceutical forms, and is sold mainly in France and various African countries.
- No-Spa® (drotaverine hydrochloride) is an abdominal anti-spasmodic, indicated for intestinal spasms, menstrual pain and bladder spasm. No-Spa® is sold mainly in Russia and Eastern Europe.
- Enterogermina® is a probiotic in the form of a drinkable suspension in 5 ml bottles or capsules containing two billion Bacillus clausii spores and also powder sachets (six billion). Enterogermina® is indicated for the maintenance and restoration of intestinal flora in the treatment of acute or chronic intestinal disorders (in babies and adults). Enterogermina® is sold primarily in Europe and also in Latin America and parts of Asia.
- Essentiale® is a natural soybean remedy to improve liver health. It is composed of essential phospholipids extracted from highly purified soya and contains a high percentage of phosphatidylcholine, a major component of the cell membrane. Essentiale® is used in fatty liver disease. Essentiale® is sold mainly in Russia, Eastern Europe, various countries in Southeast Asia and China.
- Maalox® contains two antacids, aluminum hydroxide and magnesium hydroxide, available in various forms, for the relief of heartburn and acid indigestion (symptoms of gastroesophageal reflux). Maalox® is available in 55 countries in Europe, Latin America and Asia.
- Magne B6® is a food supplement offering a wide range of magnesium and vitamin B6 based products. The therapeutic indication is primarily relief of symptoms associated with magnesium deficiency, such as irritability, anxiety, sleep disorders and women's health issues (premenstrual syndrome and menopausal problems). Magne B6® is available primarily in Europe and Russia.

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****h) Generics**

As announced in our 2020 strategic roadmap, we carefully reviewed all options for our European Generics business in 2016. In October 2016, we announced that we would initiate a carve-out process in order to divest this European Generics business. We have also confirmed our commitment to our Generics business in other parts of the world, and will further focus on emerging markets in order to develop this business in those countries.

**B.3. VACCINE PRODUCTS**

Sanofi Pasteur, the vaccines division of Sanofi, offers a broad range of vaccines. In 2016, Sanofi Pasteur provided more than one billion doses of vaccines immunizing more than 500 million people across the globe against 20 serious diseases, and generated net sales of \$4,577 million. Sales were favorably impacted by record sales of influenza vaccines, a strong performance from the Pediatric Combinations and Meningitis franchises, and the launch of Dengvaxia®.

Sanofi Pasteur is a world leader in the vaccine industry in terms of sales. In the US, Sanofi Pasteur is the leading producer of influenza and meningitis vaccines.

In Europe, Sanofi Pasteur's vaccine products have historically been developed and marketed by Sanofi Pasteur MSD (SPMSD), a joint venture that served 19 countries. Created in 1994 and held equally by Sanofi Pasteur and Merck & Co., Inc. (Merck), SPMSD also distributed Merck vaccines such as Gardasil® and Zostavax®. In 2016, SPMSD net sales amounted to \$940 million. The vaccines market has undergone significant changes since the creation of SPMSD, leading Sanofi Pasteur and Merck to adjust their strategic priorities. Over time, the decreasing complementarity between the two companies' vaccine portfolios made the joint venture model less relevant for both parties. Consequently, Sanofi Pasteur and Merck terminated the SPMSD joint venture at the end of December 2016, reintegrating their European vaccine activities into their own operations. Sanofi Pasteur is now directly managing its portfolio, which includes the following products: primary and booster pediatric vaccines for diphtheria, tetanus, pertussis, polio and Hib such as Pediacel®, Pentavac®, Repeva®, Revaxis®, Tetravac®, and Imovax® Polio; two 6-in-1 combination pediatric vaccines marketed as Hexyon® and Vaxelis®; the influenza vaccines Vaxigrip® / Mutagrip®; travel vaccines for hepatitis A, typhoid and yellow fever marketed as Avaxim®, Typhim VI®, Stamaril® and Viatim®; and the rabies vaccines Verorab® and Imovax® Rabies.

Outside of Europe, Sanofi Pasteur continues to expand in Asia, Latin America, Africa and the Middle East. In addition, Sanofi Pasteur is a key supplier to publicly funded international markets such as UNICEF, the Pan American Health Organization (PAHO) and the Global Alliance for Vaccines and Immunization (GAVI).

See B.5.3. Vaccines Research and Development below for a presentation of the Sanofi Pasteur R&D portfolio.

The table below lists net sales of vaccines by product range.

	2016 Net Sales
( million)	
Polio/Pertussis/Hib Vaccines	1,495
Influenza Vaccines	1,521
Meningitis/Pneumonia Vaccines	633
Adult Booster Vaccines	417
Travel and Other Endemic Vaccines	368

Dengue Vaccine	55
Other Vaccines	88
<b>Total Vaccines<sup>(a)</sup></b>	<b>4,577</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in Other revenues from 2016 onwards. The presentation of prior period Net sales and Other revenues has been amended accordingly; refer to Note A.5. to our consolidated financial statements. VaxServe, a Sanofi Pasteur company, acts as US distributor for a broad portfolio of products from Sanofi Pasteur and other manufacturers, giving access to channels not otherwise served by Sanofi Pasteur.

#### a) Pediatric, Combination and Poliomyelitis (Polio) Vaccines

Sanofi Pasteur is one of the key players in pediatric vaccines in both developed and emerging markets, with a broad portfolio of standalone and combination vaccines protecting against up to six diseases in a single injection. Due to the diversity of immunization schedules throughout the world, vaccines vary in composition according to regional specificities.

Pentaxim<sup>®</sup>, a pediatric combination vaccine protecting against diphtheria, tetanus, pertussis, polio and *Haemophilus influenzae* type b (Hib), was first marketed in 1997. To date, more than 260 million doses of Pentaxim<sup>®</sup> have been distributed in over 100 countries, and the vaccine has been included in the national immunization programs of more than 25 countries.

Hexaxim<sup>®</sup> is the only fully liquid, ready-to-use 6-in-1 (hexavalent) pediatric vaccine that provides protection against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. In 2013, the EMA approved this hexavalent pediatric vaccine in the EU, where it is sold under the brand name Hexyon<sup>®</sup> in Western Europe and under the brand name Hexacima in Eastern Europe. The rollout of this new hexavalent vaccine began in July 2013 in Germany and has since ramped up significantly, with 27 countries having launched Hexaxim<sup>®</sup> in their public or private immunization programs. In December 2014, the WHO granted prequalification status to Hexaxim<sup>®</sup> in a one-dose vial presentation. Hexaxim<sup>®</sup> is the only combination vaccine including acellular pertussis (acP) and inactivated polio vaccines (IPV) currently prequalified by the WHO. In

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

February 2016, SPMSD obtained a European license for its PR5i hexavalent combination vaccine, which will be marketed by a partnership between Sanofi Pasteur and Merck under the trademark Vaxelis<sup>®</sup>. PR5i antigens are manufactured by Sanofi Pasteur (Diphtheria, Tetanus, Pertussis (5acP) and Polio (IPV)), and by Merck (Hib and HepB).

Pentacel<sup>®</sup>, a pediatric combination vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hib), was launched in the US in 2008. There has been a tight supply of Pentacel<sup>®</sup> since 2013, which has required careful supply management to meet strong market demand. Supply constraints were in place throughout 2016. However, Pentacel<sup>®</sup> supply is improving in the US.

Pediacel<sup>®</sup> is a fully liquid pentavalent vaccine protecting against diphtheria, tetanus, pertussis, polio and Hib.

Act-HIB<sup>®</sup>, for the prevention of Haemophilus influenzae type b (Hib), is also an important growth driver within the pediatric product line.

Quadracel is a combination vaccine against diphtheria, tetanus, pertussis and polio. It is used as a booster to be administered as the fifth dose in the primary series of vaccines, allowing children to complete the entire childhood schedule with as few injections as possible. Quadracel was already licensed in Canada (1997) and Australia (2002), before being licensed in the US in April 2015. On January 31, 2017, Sanofi Pasteur announced that Quadracel had become available in the US.

Shan5, developed by Shantha, is a fully-liquid 5-in-1 vaccine protecting against five diseases (diphtheria, tetanus, pertussis, polio and Hepatitis B). Following improvements made to key manufacturing steps in the production of the antigen components of the vaccine, Shan5 regained its prequalification from the WHO in May 2014 and was launched in the Indian market in the last quarter of 2014. Over 46 million doses have been delivered to customers (including UNICEF) since the relaunch of Shan5 in 2014. Shan5 has also been retained for the GAVI/UNICEF tender for the 2017-2019 period.

In Japan, a key milestone was achieved in July 2014 with the licensing of Squarekids<sup>®</sup>, a quadrivalent pediatric combination vaccine offering protection against diphtheria, tetanus, pertussis and polio. Squarekids<sup>®</sup> was co-developed with our partner Kitasato Daiichi Sankyo Vaccine. The commercial launch took place in December 2015.

Sanofi Pasteur is the world's leading developer and manufacturer of polio vaccines, with both oral polio vaccines (OPVs) and injectable inactivated polio vaccines (IPVs) in its portfolio. Sanofi Pasteur's polio production capacity and historic commitment have enabled us to serve as an important industrial partner in helping to achieve the goal of worldwide polio eradication. The combined use of OPVs and IPVs is expected to improve the level of protection in

countries threatened by the possible resurgence of polio. In November 2013, GAVI announced its support for the introduction of IPV in the national immunization programs of the world's 71 poorest countries. The WHO expert group on immunization recommended that all countries introduce at least one dose of IPV in their routine immunization schedule by the first half of 2016. In September 2014, Nepal became the first GAVI supported country to introduce IPV. By the end of 2015, all 71 eligible countries had been approved for IPV support and 38 had completed their introductions, with the remaining countries to complete their introductions in the next several years. Sanofi Pasteur continues to partner with public health authorities, supplying much-needed vaccines and making substantial efforts to register Imovax<sup>®</sup> Polio, Shan IPV Polio and bivalent OPV in an impressive number of countries in record time. Sanofi Pasteur delivered 45 million doses of standalone IPVs to UNICEF for GAVI countries in 2016. As of today, polio remains endemic in three countries: Afghanistan, Pakistan and Nigeria.

**b) Influenza Vaccines**

## Edgar Filing: Sanofi - Form 20-F

Sanofi Pasteur is a world leader in the production and marketing of influenza vaccines, with about 200 million doses delivered in 2016. In terms of sales, 2016 was a record year for our influenza campaign. In recent years, demand for influenza vaccine has experienced strong growth in many countries, particularly in the US, Brazil and Mexico. Sanofi Pasteur expects the global demand for influenza vaccines to continue to grow within the next decade due to increased disease awareness, growth in emerging markets, and expanded recommendations by governmental and advisory bodies to be vaccinated against seasonal influenza.

Sanofi Pasteur has two distinct influenza vaccines that are sold globally, Fluzone<sup>®</sup> and Vaxigrip<sup>®</sup>, and is also focused on meeting the increasing demand for seasonal influenza vaccines through the launch of innovative vaccines. This differentiated product strategy, which is strengthening Sanofi Pasteur's leadership in the influenza market, has delivered the following products:

- Fluzone<sup>®</sup> High-Dose vaccine, launched in the US in 2010, was specifically designed to generate a more robust immune response against influenza in people aged 65 and older and provide greater protection against influenza. In November 2014, the FDA changed the prescribing information for Fluzone<sup>®</sup> High-Dose to document its superior clinical benefit compared to the standard Fluzone<sup>®</sup> dose (the high-dose vaccine was 24% more effective than standard Fluzone<sup>®</sup> in a large-scale efficacy study). In 2016, Fluzone<sup>®</sup> High-Dose continued to generate strong sales growth.
- Fluzone<sup>®</sup> Quadrivalent is a quadrivalent inactivated influenza vaccine containing two type A antigens and two type B antigens. Compared to the trivalent influenza vaccine, the addition of a second B strain to the vaccine

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

provides increased protection against the most prevalent circulating strains. In June 2013, Sanofi Pasteur obtained FDA authorization for Fluzone® Quadrivalent to be commercialized in the US for children aged over six months, adolescents and adults. Fluzone® Quadrivalent/FluQuadri® has since expanded its reach and is now available in 24 countries.

Intradermal (ID) trivalent influenza vaccines (Intanza®/IDflu®, launched in 2010 in Australia, Canada, the EU and several other countries, and Fluzone® ID launched in the US in 2011) also contribute to Sanofi Pasteur's influenza differentiation strategy. These innovative ID vaccines offer efficiency and simplicity of administration. In 2015, Fluzone® ID Quadrivalent was launched in the US.

Vaxigrip® is a trivalent vaccine licensed in over 150 countries globally for people aged six months and over. A quadrivalent formulation of Vaxigrip® (QIV) for people aged 3 years and over was licensed in 2016, with the launch scheduled for 2017. An EU license application for Vaxigrip® QIV in the 6 to 35 months age group is expected to be submitted in 2017.

**c) Adult and Adolescent Boosters**

Many countries now recommend pertussis immunization for adolescents and adults. These recommendations, combined with immunization awareness initiatives, have led to increased pertussis vaccination rates in these populations in recent years.

Adacel®, the first trivalent adolescent and adult booster offering protection against diphtheria, tetanus and pertussis, was launched in Canada in 2000, Germany in 2002 and the US in 2005. Adacel® has expanded globally, and is now licensed in over 65 countries with over 175 million doses distributed since launch. This vaccine plays an important role in efforts to better control pertussis, by preventing the disease in adolescents and adults and reducing exposure to infants who are not immunized or only partially immunized.

Repevax® (also marketed under the trademark Adacel-Polio®) is a combination vaccine that provides the same benefits as Adacel® but also offers protection against polio. Repevax® is useful in markets that recommend adolescent and/or adult immunizations to protect against both pertussis and polio. This vaccine is licensed in more than 30 countries worldwide.

**d) Meningitis and Pneumonia Vaccines**

Sanofi Pasteur is at the forefront of the development of vaccines to prevent bacterial meningitis and in 2014 celebrated 40 years of providing meningitis vaccines. In 2005, Sanofi Pasteur introduced Menactra®, the first quadrivalent conjugate vaccine against meningococcal meningitis, which is considered the deadliest form of meningitis in the world. In 2011, the FDA granted Sanofi Pasteur a license to expand the indication of Menactra® to

children as young as nine months of age. Menactra® is now indicated for people aged nine months through 55 years in the US, Canada, several Middle Eastern countries such as Saudi Arabia, and numerous other countries in all regions of the world. In most markets, a conjugated quadrivalent vaccine like Menactra® offers the best value proposition by protecting against four of the most common serogroups: A, C, Y, and W-135.

Menactra® is registered in 67 countries worldwide, with 11 years of clinical experience and over 89 million doses shipped since launch. The most recent launches in key countries include Russia, South Korea and Japan. The product once again performed strongly in 2016.

**e) Travel and Endemic Vaccines**

Sanofi Pasteur provides a wide range of travel and endemic vaccines including hepatitis A, typhoid, cholera, yellow fever, and Japanese encephalitis, as well as rabies vaccines and immunoglobulins. These vaccines and immunoglobulins are used in endemic settings in the developing world and are the foundation for important partnerships with governments and organizations such as UNICEF. They are also used by travelers and military personnel in industrialized countries and in endemic areas. Sanofi Pasteur is the leader in most of the world's travel and endemic vaccine markets and benefits from long-term expertise in this domain.

In 2009, Shantha launched Shanchol<sup>®</sup>, the first oral cholera vaccine produced in India for use in children and adults. Shanchol<sup>®</sup> received WHO prequalification in 2011. In 2013, the first oral cholera vaccine stockpile (which Shanchol<sup>®</sup> is part of) was created by the WHO, to respond to outbreaks and vaccine needs in areas of heightened risk.

IMOJEV<sup>®</sup>, a Japanese encephalitis vaccine, is the most recent addition to our travel and endemic vaccines portfolio and was successfully launched in Australia and Thailand in 2012. In 2014, IMOJEV<sup>®</sup> obtained an extension of indication for use in children aged nine months and over, and obtained WHO prequalification which provides access to the product in low-income countries. IMOJEV<sup>®</sup> is being progressively rolled out in endemic countries throughout Asia.

For yellow fever, we shipped a significant part of the outbreak prevention stockpile in record time in 2016 to support our WHO/UNICEF/GAVI partners in their fight against expansion of the ongoing outbreak confirming our key role in combatting this important public health threat.

**f) Dengue**

Dengue fever constitutes a major public health and economic burden in the endemic areas of the Asia-Pacific region and in Latin America. More than 100 countries, representing nearly half of the world's population, are at risk. Over the last 50 years, the incidence of the disease has increased 30-fold, an alarming rate given there was no

---

## **Table of Contents**

### **ITEM 4. INFORMATION ON THE COMPANY**

specific treatment available. In response to this global threat, which can impact children, adolescents and adults, the WHO has set ambitious objectives to reduce the burden of the disease on society. One of these objectives is to reduce morbidity by 25% and mortality by 50% by 2020. Following 20 years of innovative research and collaboration with local at-risk communities and dengue scientists around the world, Sanofi Pasteur has developed a dengue vaccine candidate and embarked on a global, multinational clinical development program.

In 2014, the results of two large-scale Phase III efficacy studies conducted in 10 countries in Asia and Latin America were published in *The Lancet* and *The New England Journal of Medicine*, respectively. These studies involved 31,000 participants aged two to 16 years living in highly endemic countries. The results showed an overall efficacy against symptomatic dengue of 56.5% in Asia and 60.8% in Latin America, with a favorable safety profile during the 25-month active surveillance period. Overall, the combined results of these studies showed efficacy against all four dengue serotypes. Importantly, these studies consistently showed highly significant reductions in severe dengue and hospitalization due to dengue during the 25-month active surveillance periods (80% reduction in severe disease and 67.2% reduction in hospital cases in Asia, and 95% protection against severe dengue and 80.3% reduction in risk of hospitalization in Latin America).

Based on those results, we have continued to work closely with local health authorities in various endemic countries to bring this important vaccine to people. Dengvaxia<sup>®</sup> has been approved in 14 countries to date: Mexico, the Philippines and Brazil in December 2015; El Salvador in February 2016; Costa Rica in June 2016; Guatemala, Paraguay and Indonesia in August 2016; Peru and Thailand in September 2016; Singapore, Bolivia and Cambodia in October 2016; and Venezuela in January 2017.

Dengvaxia<sup>®</sup> has also garnered support from medical societies. A recent WHO vaccine position paper provides global vaccine and immunization recommendations for infectious diseases. The WHO vaccine position paper for dengue endorses the recommendation of the WHO Strategic Advisory Group of Experts (SAGE) on dengue, advising that countries with high dengue transmission consider introduction of the dengue vaccine as part of an integrated disease prevention strategy including vector control to effectively lower their dengue disease burden. Dengvaxia<sup>®</sup> has also received recommendations from medical societies, including the Latin American Society of Pediatric Infectious Disease and five other medical societies (three in Brazil, one in the Philippines and one in Indonesia).

Dengvaxia<sup>®</sup> has been launched in a public vaccination campaign in Parana State (Brazil), as well as in a public program targeting students in public schools in the Philippines.

#### **B.4. ANIMAL HEALTH**

On January 1, 2017, we exited the animal health business through the Boehringer Ingelheim transaction. See Item 5. Operating and Financial Review and Prospects A. Operating results .

#### **B.5. GLOBAL RESEARCH & DEVELOPMENT**

The mission of Sanofi's R&D organization is to discover and develop therapies that prevent, treat or cure diseases. Our day-to-day commitment is to respond to patients' needs and to provide them with adapted therapeutic solutions in order to improve their well-being and extend their lives.

Sanofi R&D is a global organization integrating all R&D activities across two major segments: Pharmaceuticals and Vaccines.

To carry out our mission and maximize its impact, we strive to bring innovation to patients and to build a pipeline of high value projects. Its approach is neutral to the source of innovation, whether it comes from internal research or external innovation.

## Edgar Filing: Sanofi - Form 20-F

Medical value, scientific quality and operational effectiveness are the three drivers that underpin the strategy. The focus is on projects that have the potential to provide the best added medical value to patients and payers and to reduce healthcare costs for society.

By using a translational medicine approach, ensuring that research hypotheses are validated in humans as early as possible, R&D can translate basic research findings into medical practice more quickly and efficiently and improve the scientific quality of our projects.

### **B.5.1. Pharmaceuticals**

#### **B.5.1.1. Organization**

Our Global R&D organization is committed to responding to the real needs of patients by providing them with safe, cost-effective and appropriate therapeutic solutions, improving their access to treatment and delivering better health outcomes. In offering new solutions to patients, it is vital to understand the complexity of human diseases, to sustain innovation and to foster scientific excellence without losing sight of the need for operational efficiency.

To meet these challenges, Sanofi R&D has evolved towards an integrated organization encompassing a wide range of therapeutic areas aligned with the Global Business Units (GBUs), which are dedicated to supporting our commercial operations and reflect our strengths and expertise as well as the most pressing health issues.

Seven therapeutic areas (TAs) have been rolled out:

- Diabetes
- Oncology

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

- Cardiovascular and Metabolism
- Immunology & Inflammation
- Multiple Sclerosis, Neurology & Ophthalmology
- Infectious Diseases
- Rare Diseases

These TAs drive a portfolio of R&D projects, ensuring a strategically coherent approach and flawless implementation.

Each TA has its own experts who are responsible for analyzing medical needs, defining project strategy and development plans, and leading the Global Project Teams.

Our R&D Operations department handles all operational activities and delivers effective development through integrated, collaborative project teams. Those teams harness high caliber functional expertise and the most appropriate technologies across chemical, biological and pharmaceuticals operations, translational medicine and early development and clinical sciences.

In Research, a dedicated, integrated platform has been introduced that works across multiple disease areas and methods. This platform drives collaboration with internal and external partners to translate human biology research and state-of-the art technologies and processes into novel drug targets and world-class safe and effective drugs.

Sanofi's R&D operations are concentrated in three major hubs: North America, Germany and France. These hubs help build our scientific intelligence network and facilitate connections and knowledge-sharing between internal scientists, and with external partners and scientific communities, in order to accelerate our research activities.

**B.5.1.2. Governance**

Global Project Teams (GPTs) are responsible for developing project strategy and driving the execution of projects through functional sub-teams. GPTs are led by a Global Project Head (GPH) who works in collaboration with a Project Manager (PM), and are built around core functional team members representing each department collaborating in the development project.

Various committees assess product and project development across the R&D value chain, carry out in-depth scientific review, make go and no-go decisions and determine portfolio priorities.

Projects are assessed using two key criteria which allow management to rapidly understand how the portfolio is performing in terms of innovation, unmet medical needs, risk and value:

## Edgar Filing: Sanofi - Form 20-F

relative medical value, which encompasses the extent of the unmet need, the market dynamics and the likelihood of getting satisfactory market conditions; and

science translation, which includes the level of innovation and translatability of the science including likelihood of development success. The clinical portfolio is the result of decisions taken during these reviews, plus compounds entering the portfolio from the discovery phase or from third parties via acquisition, collaboration or alliances.

As described at Item 3. Key Information D. Risk Factors Risks Relating to Our Business research and development efforts may not succeed in adequately renewing the product portfolio and Risks Relating to the Group Structure and Strategy We may fail to successfully identify external business opportunities or realize the anticipated benefits from our strategic investments , our product development efforts are subject to the risks and uncertainties inherent in any new product development program.

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****B.5.1.3. Products**

The clinical portfolio for new products can be summarized as follows as of February 8, 2017:

	<b>Phase I</b>	<b>Phase II</b>	<b>Phase III /registration</b>
<b>Diabetes</b>	SAR341402	efpeglenatide /SAR493977	SAR342434 /insulin lispro
<b>Oncology</b>	SAR438335 SAR408701  SAR428926	SAR425899 SAR439684	sotagliflozin /SAR439954 isatuximab /SAR650984
<b>Cardiovascular &amp;</b>	SAR566658 SAR247799	SAR100842	
<b>Metabolism Immunology &amp;</b>	SAR407899 SAR439794	SAR439152 SAR156597	sarilumab /SAR153191
<b>Inflammation Multiple Sclerosis</b>	SAR440340 GZ402668	GZ389988 SAR422459	dupilumab /SAR231893
<b>Neurology</b>	SAR228810		
<b>Ophthalmology Infectious diseases</b>	UshStat® /SAR421869	ferroquine (combo OZ439) /SSR97193	
<b>Rare diseases</b>	fitusiran/SAR439774	olipudase alfa /GZ402665  GZ402671	patisiran (SAR438027)  GZ402666

Phase I studies are the first studies performed in humans, who are mainly healthy volunteers. Their main objective is to assess the tolerability, the pharmacokinetic profile (the way the product is distributed and metabolized in the body and the manner by which it is eliminated) and where possible the pharmacodynamic profiles of the new drug (i.e. how the product may react on some receptors).

Phase II studies are early controlled studies in a limited number of patients under closely monitored conditions to show efficacy and short-term safety and to determine the dose and regimen for Phase III studies.

Phase III studies have the primary objective of demonstrating or confirming the therapeutic benefit and the safety of the new drug in the intended indication and population. They are designed to provide an adequate basis for registration.

**a) Diabetes**

**Main compounds currently in Phase III and in the registration phase**

**SAR342434 (insulin lispro):** The program entered Phase III in November 2014. The Phase III clinical program compares SAR342434 rapid-acting solution to Humalog® (insulin lispro, Lilly) in patients with type 1 diabetes (SORELLA 1) and patients with type 2 diabetes (SORELLA 2), also using Lantus®. The entry into Phase III followed successful

completion of the Phase I study, in which SAR342434 rapid-acting solution demonstrated similar pharmacodynamic activity and pharmacokinetic exposure as compared to Humalog®. The dossier was submitted in 2016.

**Sotagliflozin (SAR439954):** new investigational oral dual inhibitor of SGLT1/2, which could be a potential treatment option for people with diabetes. The product was in-licensed from Lexicon in November 2015 and is in Phase III in the treatment of type 1 diabetes. The Phase III program in the treatment of type 2 diabetes was initiated in December 2016.

**Main products in early stage**

**Efpeglenatide (SAR439977),** a long-acting GLP1 receptor agonist derived from our license agreement with Hanmi, currently in Phase II.

**Dual GLP-1/glucagon receptor (SAR425899),** which entered Phase IIb in December 2016 for the treatment of patients with type 2 diabetes.

**Dual GLP-1/GIP receptor agonist (SAR438335),** in Phase I for the treatment of patients with type 2 diabetes.

**Rapid Acting Insulin (SAR341402),** in Phase I in the treatment of type 1 and type 2 diabetes

**Product discontinued in 2016**

**Stable glucagon analog (SAR438544),** assessed for the treatment of diabetes patients with severe hypoglycemia, was discontinued in Phase I.

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****Collaborations**

Sanofi Diabetes maintains a significant network of R&D collaborations with world leading academic institutions and startup companies, including collaborations with Joslin Diabetes Center (Cambridge, USA), and Gubra (a Danish biotech company specialized in gut hormone R&D). Sanofi and the Juvenile Diabetes Research Foundation (JDRF) continue to jointly fund selected innovation projects in the field of type 1 diabetes research and specifically Glucose Sensing Insulins.

Sanofi remains strongly committed to bringing integrated care to people with diabetes, and will continue to establish partnerships with a view to creating new solutions to improve patient outcomes.

Sanofi is continuing its collaboration with Evotec in an effort to develop beta cell-modulating diabetes treatments, which may reduce or even eliminate the need for insulin injections and may be a step towards a cure for type 1 diabetes.

Sanofi and Verily (formerly Google Life Sciences) have started a collaboration to improve care and outcomes for people with type 1 and type 2 diabetes. The collaboration pairs Sanofi's leadership in diabetes treatments and devices with Google's expertise in analytics, miniaturized electronics and low power chip design. This includes health indicators such as blood glucose and hemoglobin A1c levels, patient-reported information, medication regimens and sensor devices.

**b) Oncology****Main compounds currently in Phase III**

**Isatuximab (SAR650984)** is a naked chimeric immunoglobulin G1 (IgG1) monoclonal antibody (mAb) that is being developed under a license and collaboration agreement with Immunogen Inc. Isatuximab selectively binds to CD38, a cell surface antigen expressed in multiple myeloma cancer cells, and other hematological malignancies. Isatuximab kills tumor cells via multiple biological mechanisms including (i) antibody-dependent cellular-mediated cytotoxicity (ADCC); (ii) complement-dependent cytotoxicity (CDC); (iii) antibody-dependent cellular phagocytosis (ADCP); and (iv) direct induction of apoptosis (pro-apoptosis) without cross-linking. Isatuximab also inhibits CD38 ectoenzymatic activity and the expansion of immune-suppressive regulatory T cells and myeloid derived suppressor cells. The program is currently in Phase III clinical development. There are eight ongoing studies in multiple myeloma, two as a single agent and five trials investigating isatuximab in combinations with (i) lenalidomide/dexamethasone, (ii) carfilzomib, (iii) pomalidomide/ dexamethasone, and (iv) cyclophosphamide/bortezomib/dexamethasone. The ICARIA-MM Phase III trial compares isatuximab in

combination with pomalidomide and dexamethasone against pomalidomide and dexamethasone in patients with relapsed and refractory multiple myeloma.

**Main products in early stage**

**SAR439684**, a PD-1 inhibitor derived from our alliance with Regeneron, is currently in Phase IIb to support registration in the treatment of cutaneous squamous cell carcinoma.

**SAR408701** is an antibody drug conjugate (ADC) that binds to CEACAM-5, a membrane glycoprotein originally identified as a surface marker on adenocarcinomas of the human gastrointestinal tract. The compound is in Phase I.

**SAR566658** is an antibody drug conjugate (ADC) loaded with a maytansinoid derivative DM4 (huDS6-SPDB-DM4) targeting CA6. CA6 is a tumor specific epitope highly expressed on some solid tumors. The Phase I program has been completed, and Phase II in the treatment of breast cancer is scheduled to start in the first quarter of 2017.

**SAR428926** is an Antibody Drug Conjugate (ADC) that binds to Lysosomal Associated Membrane Protein 1 (LAMP1), a protein localized in the lumen of the lysosomes in normal tissue and which is found aberrantly expressed at the cell surface in a number of tumor tissues. SAR428926 is expected to selectively deliver its cytotoxic to LAMP1-expressing tumor cells. The compound is in Phase I.

### Collaborations

Sanofi Oncology has a large number of collaborations and alliances to support its R&D portfolio.

In 2015, we entered into a strategic collaboration and license agreement with Regeneron focusing on cancer immunotherapy. The objective of the collaboration is to generate high value development candidates in the emerging field of immuno-oncology, providing us with an opportunity to expand and accelerate our development pipeline and build a strong position in one of the most attractive segments of the oncology market. To date SAR439684, a PD-1 inhibitor monoclonal antibody derived from this collaboration, has entered Phase II clinical development.

Also in 2015, we entered into an exclusive strategic collaboration with the German biotech company BioNTech (Mainz) in the field of active immunization. The goal of the alliance is to discover and develop messenger RNA (mRNA) therapeutics for cancer immunotherapy by leveraging the scientific expertise of the two organizations. The first clinical candidate is expected in 2017.

These two ambitious alliances have the potential to address some of the unmet medical needs that remain in cancer treatment.

Sanofi Oncology has also established various alliances with leading academic cancer centers such as Institut Gustave

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Roussy, Institut Curie and the Dana Farber Cancer Institute, and with biotechnology companies like Immunogen and Evotec.

In 2016, we entered into a collaboration with Innate Pharma to develop innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells, and a collaboration with Warp Drive Bio to develop drugs targeting human oncogenes including RAS. Both these collaborations are in line with our ongoing commitment to the discovery and development of new cancer drugs and therapeutic strategies that will make a difference in the lives of cancer patients.

**c) Cardiovascular & Metabolism**

**Main products in early stage**

**SAR439152**, a myosin inhibitor derived from our partnership with MyoKardia, entered Phase IIa in October 2016 in the treatment of obstructive hypertrophic cardiomyopathy.

**SAR100842**, an LPA1 receptor antagonist, has completed the Phase I program in the treatment of diffuse cutaneous systemic sclerosis (dcSSc). The Phase IIa study is due to start in 2017.

**SAR407899**, a Rho-kinase inhibitor, has completed the Phase I program in the treatment of microvascular angina. The Phase IIa study is due to start in 2017.

**SAR247799**, an S1P1 agonist, entered Phase I in August 2016 in the treatment of cardiovascular diseases.

**d) Immunology & Inflammation**

**Main products in Phase III and the registration phase**

**Sarilumab (SAR153191)**, a monoclonal antibody against the Interleukin-6 Receptor derived from our alliance with Regeneron, is under development for moderate to severe rheumatoid arthritis (RA). The US Biological License Application (BLA) was submitted on October 30, 2015. On October 28, 2016, the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the Biologics License Applications (BLA) for sarilumab for the treatment of adult patients with moderately to severely active rheumatoid arthritis. The CRL refers to certain deficiencies identified during a routine good manufacturing practice inspection of the Sanofi Le Trait facility where sarilumab is filled and finished, one of the last steps in the manufacturing process. Satisfactory resolution of these deficiencies is required before the BLA can be approved. Based on review of Sanofi's responses to the FDA 483 letters as well as proposed corrective actions, the FDA has classified the Le Trait fill and finish facility as acceptable. Sanofi plans to re-submit the sarilumab BLA in the first quarter of 2017 subject to successful FDA preapproval inspection of Le Trait for dupilumab.

A European Marketing Authorization Application (MAA) was submitted on June 24, 2016 and the Japan NDA filing occurred on October 7, 2016.

In January 2017, Kevzara (sarilumab) was approved in Canada for the treatment of moderate to severe rheumatoid arthritis in adults.

## Edgar Filing: Sanofi - Form 20-F

The Global Phase III RA program (SARIL-RA) includes seven core trials enrolling more than 2,600 patients. Two pivotal RA trials (SARIL-RA-MOBILITY in methotrexate inadequate responders, assessing signs and symptoms and inhibition of structural damage; SARIL-RA-TARGET in inadequate responders to anti-TNF treatment, assessing signs and symptoms and effect on physical function) met all primary endpoints. Sarilumab was also administered as monotherapy in two studies, SARIL-RA-MONARCH and SARIL-RA-ONE.

Additional studies are:

- The SARIL-RA-EXTEND study aims to evaluate the long term safety and efficacy of sarilumab in combination with DMARDs in patients with active RA. This is an uncontrolled extension study that enrolled patients from earlier studies: MOBILITY, TARGET, ONE and ASCERTAIN (to benchmark safety against tocilizumab).

- SARIL-RA-EASY, a usability study comparing two devices: the auto-injector and the pre-filled syringe.

In addition to these international studies in adult RA:

- A Japanese program has been conducted with two Phase III studies in Japanese patients with RA (SARIL-RA-KAKEHASI and SARIL-RA-HARUKA).

- Two Phase II pediatric studies have been initiated, aimed at defining a suitable dose regimen in patients with polyarticular-course juvenile idiopathic arthritis (pJIA) and systemic juvenile arthritis (sJIA).

**Dupilumab (SAR231893)**, a monoclonal antibody against the Interleukin-4 alpha receptor, is derived from our alliance with Regeneron. Dupilumab modulates signaling of both the IL-4 and IL-13 pathways. It is currently being developed in several indications: atopic dermatitis in review, asthma in Phase III, nasal polyposis in Phase III, and eosinophilic esophagitis in Phase II.

- In **atopic dermatitis**, a submission has been filed with the FDA and accepted for priority review. The target action date is March 29, 2017. The product has also been accepted for review by the European Medicines Agency (EMA). The EMA and FDA have conditionally accepted Dupixent as the trade name for dupilumab.

- In **asthma**, the Phase III program consists of:

- a randomized, double-blind, placebo-controlled, dose-ranging study to evaluate dupilumab in patients with moderate to severe uncontrolled asthma, completed in May 2015;

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

- a 52-week Phase III randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy and safety of dupilumab in patients with moderate to severe uncontrolled asthma; and
- an open-label extension study of dupilumab in patients with asthma who have previously participated in dupilumab asthma clinical studies.
- In **nasal polyposis**, the Phase III program consists of:
  - 24-week and 52-week controlled clinical studies of dupilumab in patients with nasal polyposis to evaluate the efficacy of dupilumab compared to placebo on a background of mometasone furoate nasal spray (MFNS) in reducing nasal congestion/obstruction (NC) severity and endoscopic nasal polyp score (NPS) in patients with bilateral nasal polyposis. In addition the studies will evaluate as key secondary endpoints the reduction in computed tomography (CT) scan opacification of the sinuses, improvement in loss of smell and patient reported quality of life, and reduction in need for steroids or surgery.
- In **eosinophilic esophagitis**: Phase II study of dupilumab in adult patients with active eosinophilic esophagitis. A randomized, double-blind, parallel, placebo-controlled study to assess the efficacy, safety and tolerability of dupilumab in this population is ongoing.

**Main products in early stage**

**SAR156597** (humanized bi-specific monoclonal antibody targeting the cytokines IL-4 and IL-13) is currently in Phase IIB for the treatment of idiopathic pulmonary fibrosis and in Phase IIA for the treatment of diffuse systemic sclerosis.

**GZ389988** (TrKA) is a small molecule which inhibits binding of nerve growth factor (NGF) to its primary TrkA receptor, and is being developed as a treatment for pain resulting from osteoarthritis. The molecule entered Phase IIa in August 2016.

**SAR439794**, a TLR4 agonist, entered Phase I in September 2016 for the treatment of peanut allergy.

**SAR440340**, a human anti-IL33 monoclonal antibody derived from our alliance with Regeneron, entered Phase I

**Product discontinued in 2016**

**SAR113244**, an anti-CXCR5 humanized monoclonal antibody, was discontinued in Phase I in the treatment of systemic lupus erythematosus (SLE).

**e) Multiple Sclerosis, Neurology & Ophthalmology**  
**Multiple sclerosis**

## Edgar Filing: Sanofi - Form 20-F

**GZ402668 (GLD52)**, an IgG1 monoclonal antibody binding to CD52 (a cell surface antigen present at high levels on T and B lymphocytes) for the treatment of relapsing forms of multiple sclerosis (MS), is in Phase Ib in patients suffering from progressive MS.

### Neurology

**SAR228810**, an anti-protofibrillar Abeta monoclonal antibody, has completed the Phase I program in mild cognitive impairment due to Alzheimer's Disease (AD) and in mild AD. The Phase IIa study is due to start in 2017.

### Ophthalmology

**SAR422459**, a gene therapy product which uses a lentivector gene delivery technology to introduce a functional ABCR gene into photoreceptors in patients with autosomal recessive Stargardt's disease, an orphan inherited condition that leads to progressive vision loss from childhood. The product is currently in Phase IIa.

**UshStat® (SAR421869)**, a gene therapy product which uses a lentivector gene delivery technology to introduce a functional MYO7A gene into the photoreceptors and retinal pigment epithelium (RPE) cells in patients with Usher 1B syndrome, an orphan inherited condition that leads to progressive visual field constriction and vision loss from childhood. A Phase I/IIa clinical study is ongoing.

**Sarilumab**, the anti-IL6 receptor monoclonal antibody (also developed for rheumatoid arthritis, see above) is in Phase IIa in the treatment of non-infectious uveitis.

### Product discontinued in 2016

**SAR366234**, an EP2 receptor agonist of the prostaglandin E<sub>2</sub> (activation of which induces an increased outflow of aqueous humor outflow and a reduction of intra ocular pressure), was discontinued in Phase I.

### f) Infectious Diseases

**Ferroquine (OZ439)** is a first in class combination for malaria, developed in collaboration with the Medicines for Malaria Venture (MMV). Ferroquine is a new 4 amino quinoline being developed for the treatment of acute uncomplicated malaria, and is active against chloroquine sensitive and chloroquine resistant Plasmodium strains. Due to its long half-life it has the potential to be part of single dose cure regimens for the treatment of both *P. vivax* and *P. falciparum* malaria. OZ439 is a synthetic peroxide antimalarial drug candidate from MMV designed to provide a single dose oral cure in humans. A Phase IIB clinical study of the combination of the two products, conducted in adults and children with *P. falciparum* malaria, started in July 2015 in Africa and is expected to start in the second half of 2017 in Asia.

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****g) Rare Diseases****Main products in Phase III**

**Alnylam collaboration:** In October 2012, Genzyme entered into an exclusive license agreement with Alnylam, covering the ALN-TTR programs in the Asia-Pacific-Japan region. ALN-TTR01 and ALN-TTR02 Phase I results were published in the New England Journal of Medicine in August 2013. Results showed that RNAi therapeutics targeting transthyretin (TTR) achieved rapid, dose-dependent, durable, and specific knockdown of TTR, the disease-causing protein in TTR-mediated amyloidosis (ATTR). Genzyme's exclusive territory rights for the ALN-TTR programs were extended to the rest of the world excluding North America and Western Europe on January 14, 2014. The January 2014 agreement also included exclusive rights for Sanofi to opt into future Alnylam rare disease pipeline programs including fitusiran (see early stage products) for which we exercised a regional option in September 2015 and then stepped up to a co-development, co-commercialization option on November 14, 2016.

**Patisiran (SAR438027)** (mRNA inhibition Alnylam ALN-TTR02). The Phase III clinical trial is ongoing in the treatment of familial amyloid polyneuropathy, with results expected in the second half of 2017.

**GZ402666 (Neo GAA)** is a second generation enzyme replacement therapy targeting the treatment of Pompe disease. The Phase III program was launched in November 2016, with the COMET study targeting late onset Pompe disease patients.

**Main products in early stage**

**GZ402665 (rhASM) olipudase alfa** is an enzyme replacement therapy targeting the treatment of non-neurological manifestations of acid sphingomyelinase

deficiency (ASMD), also known as Niemann-Pick B disease. A Phase I/II study in the pediatric population has dosed nine out of twelve patients to date. These nine patients are in the adolescent cohort (12 years old to less than 18 years old) and child cohort (six years old to less than 12 years old). The infant cohort (birth to less than 6 years old) began enrollment in January 2017. The Phase II/III trial to support registration in the adult population started enrolling patients in 2016. To date, a total of 16 clinical trial sites have been initiated globally.

**GZ402671 (GCS inhibitor)** is in development in several indications. A Phase II trial for the treatment of Fabry disease has entered its extension phase. A Phase II trial in Parkinson's disease patients carrying a glucocerebrosidase gene (GBA) mutation (GBA-PD) started in December 2016. This is the first clinical trial in a genetic form of Parkinson's disease. The Phase II trial in Gaucher disease type 3 started in January 2017.

**Fitusiran (SAR439774)** Alnylam (ALN-AT3): Alnylam is developing a siRNA therapeutic to treat hemophilia (A and B) using a novel approach targeting antithrombin (AT) with AT knockdown leading to increase in thrombin generation. On November 14, 2016 Sanofi Genzyme, which already had regional rights to this program under the overall alliance agreement, exercised its option to increase its rights to co-commercialization and co-development. The Phase III program is expected to start in 2017.

**Product discontinued in 2016**

**Revusiran (SAR438714)** (mRNA inhibition, Alnylam: ALN-TTRsc). This product was discontinued in Phase III in the treatment of familial amyloidotic cardiomyopathy.



**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****B.5.2. Vaccines**

Our Human Vaccines R&D is focused on developing new prophylactic vaccines and improving existing ones.

The Sanofi Pasteur R&D portfolio includes 15 vaccines currently in advanced development as shown in the table below. The portfolio is well balanced, with seven vaccine products for novel targets and eight vaccines which are enhancements of existing vaccine products.

<b>PHASE I</b> <b>Respiratory Syncytial Virus*</b>	<b>PHASE II</b> <b>Rabies VRVg</b>	<b>PHASE III</b> <b>VaxiGrip® QIV IM</b>	<b>REGISTRATION</b> <b>VaxiGrip® QIV IM</b>
RSV infant vaccine	Purified vero rabies vaccine	Quadrivalent inactivated influenza vaccine (6-35 months)	Quadrivalent inactivated influenza vaccine (3 years+)
<b>Herpes Simplex virus Type 2*</b>	<b>Fluzone® QIV HD</b>	<b>Clostridium difficile*</b>	<b>Dengvaxia®*</b>
HSV-2 vaccine	Quadrivalent inactivated influenza vaccine High dose	Toxoid vaccine against <i>Clostridium difficile</i>	Mild-to-severe dengue fever vaccine (ongoing international registrations)
<b>Zika Virus*</b>	<b>Tuberculosis*</b>	<b>Japan Penta</b>	<b>PR5i</b>
Inactivated Zika vaccine	Recombinant subunit vaccine	DTP-Polio-Hib <sup>(a)</sup>	DTP-HepB-Polio-Hib <sup>(a)</sup>
		Pediatric pentavalent vaccine	Pediatric hexavalent vaccine (US)
	<b>HIV*</b>	<b>MenQuadTT</b>	
	Prevention of HIV infections in at-risk adults	Second generation meningococcal ACYW conjugate vaccine	
	<b>Adacel®+</b>		
	Tdap booster		
	<b>Shan6</b>		

## Edgar Filing: Sanofi - Form 20-F

DTP-HepB-Polio-Hib<sup>(a)</sup> Pediatric  
hexavalent vaccine, Shantha

(a) D=Diphtheria, T=Tetanus, P=Pertussis, Hib=Haemophilus influenzae b, HepB=Hepatitis B.

\* New targets

### **Influenza Vaccine**

To sustain our global leadership in the development of influenza vaccines, our R&D efforts are focused on innovative approaches. Following up on the development of quadrivalent flu vaccines (see B.3. Vaccine Products ), Sanofi Pasteur will continue to assess new formulations and alternative delivery systems, as well as approaches that broaden protective efficacy versus standard of care in order to address specific patient needs and offer innovative solutions for the future.

### **Meningitis Vaccine**

*Neisseria meningitidis* bacteria are a leading cause of meningococcal disease in the US, Europe, the African meningitis belt and other endemic regions such as Brazil and Australia.

Sanofi Pasteur is developing a second-generation quadrivalent conjugated meningococcal vaccine. This

vaccine uses an alternative technology to diphtheria conjugation as currently used in the commercialized vaccine. Phase II clinical trial results have demonstrated its safety and immunogenicity. Sanofi Pasteur is continuing the development of this vaccine to suit a wider range of age groups and a flexible range of vaccination schedules. The project has advanced to Phase III.

### **Rabies Vaccine**

A new generation serum-free Vero cell human rabies vaccine (VRVg, also known as VerorabVax<sup>®</sup>) is under development to allow both of our currently available human rabies vaccines, Verorab<sup>®</sup> and Imovax<sup>®</sup> Rabies, to be replaced globally by a single vaccine offering. The results of a Phase II clinical trial demonstrated the non-inferiority of VRVg versus Verorab<sup>®</sup> in pre-exposure prophylaxis. VRVg was approved in France as a line extension of Verorab<sup>®</sup> in 2011. More recent Phase II studies, conducted to license

---

## **Table of Contents**

### **ITEM 4. INFORMATION ON THE COMPANY**

VerorabVax<sup>®</sup> in countries where Verorab<sup>®</sup> was not previously licensed, have provided data indicating a requirement to adjust the formulation.

#### **Pediatric Vaccine**

Sanofi Pasteur, in partnership with Kitasato (KDSV) and Daiichi Sankyo (DS), is developing a pediatric pentavalent vaccine for the Japanese market. The vaccine includes diphtheria, tetanus, acP (DTaP) from KDSV, and inactivated polio IPV & Hib from Sanofi Pasteur. It is anticipated that this product, to be distributed by DS, will be the first pentavalent pediatric combination vaccine in the Japanese market. It would serve as a primary series and booster vaccine for Japanese children up to two years old. The project is currently in Phase III.

#### **PR5i (hexavalent vaccine)**

Sanofi Pasteur is co-developing with Merck & Co., Inc. (Merck) a hexavalent combination vaccine (PR5i 6-in-1 vaccine) to protect against diphtheria, tetanus, pertussis, polio, Hib and hepatitis B. A license application for this vaccine was submitted to the European Medicines Agency (EMA) by Sanofi Pasteur MSD (SPMSD) in January 2015. On December 17, 2015 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending marketing authorization for the product, to be commercialized as Vaxelis<sup>®</sup> in the European Union. On February 19, 2016, SPMSD was granted marketing authorization for Vaxelis<sup>®</sup>, which will be commercialized through a partnership of Merck and Sanofi Pasteur. A Biologics License Application was submitted to the US FDA in August 2014, and on November 2, 2015 the FDA issued a Complete Response Letter (CRL) for PR5i, which is to be commercialized through a partnership of Merck and Sanofi Pasteur. Sanofi Pasteur and Merck are currently reviewing the CRL and plan to further communicate with the FDA. PR5i is expected to be the first hexavalent vaccine in the US market.

#### **Shan6:**

A cost-effective, all-in-one liquid hexavalent combination vaccine (Shan6) is in development. This product, which is being developed for the Indian market and WHO pre-qualification, comprises a detoxified whole-cell pertussis component as well as diphtheria toxoid, tetanus toxoid, Haemophilus influenzae type b PRP-T, inactivated poliovirus types 1, 2, and 3 and hepatitis B virus components. A Phase I/II trial was initiated in India in October 2016, and Phase III preparations are underway.

#### **Adacel+ (Pertussis Vaccine)**

To sustain our global leadership in the development of pertussis vaccines, our R&D efforts are focused on developing an improved Tdap (tetanus toxoid, diphtheria toxoid, and 5-component Acellular pertussis containing

formulation), for use in individuals aged 10 and over in the US market.

#### **New Vaccine Targets**

**C.diff Toxoid** *Clostridium difficile* (C.diff) is a major public health concern in North America and Europe. In hospitals, it is the leading cause of infectious diarrhea in adults, particularly the elderly. The epidemiology of C.diff associated disease has been increasing at a worrying rate since 2003, driven primarily by the emergence of a treatment-resistant, highly virulent strain: CD027. There is currently no vaccine available and our toxoid based C.diff vaccine is the only candidate in Phase III. Sanofi Pasteur received a positive response from the FDA Center for Biologics Evaluation & Research (CBER) on the Fast Track Development Program submission in 2010. A multinational, large scale Phase III study, named Cdiffense, began in August 2013. This trial is focused on evaluating the vaccine's efficacy in preventing the first episode of C.diff infection in at-risk individuals, including adults with imminent hospitalization or current or impending residence in a long-term care or

rehabilitation facility. We voluntarily paused enrollment in the trial in July, 2016 while the data were thoroughly examined and assessed by the Independent Data Monitoring committee (IDMC). In December 2016 the IDMC recommended that the trial continue. We are currently in the process of seeking regulatory approval from the many countries where the trial is in progress to reinitiate enrolling more volunteers. Importantly, the trial did not stop and the existing volunteers continued to maintain protocol-specified visits. Phase II results were communicated in May 2014 showing the C.diff vaccine candidate to be generally well tolerated and immunogenic in the target population.

**Tuberculosis** Statens Serum Institute (SSI) of Denmark has granted Sanofi Pasteur a license to its technology for the use of certain fusion proteins in the development of a tuberculosis vaccine. The candidate vaccine is made up of recombinant protein units. Results from a 2008 Phase I trial found that the candidate vaccine was safe when administered to healthy adults living in a region of high endemic tuberculosis. A Phase I/II study in infants was initiated in South Africa in July 2013. A Phase II proof of concept study was initiated in young adolescents in South Africa in March 2014. Results are expected in 2018.

**Herpes Simplex Virus** Herpes simplex virus type 2 is a member of the herpes virus family and as such establishes life-long infections, with latent virus established in neural ganglia. Although antivirals currently exist to treat infections, no vaccine exists, greatly limiting options in disease management. The vaccine candidate is a live attenuated virus and is being assessed as a therapeutic and possibly prophylactic vaccine to reduce recurrence and transmission. A Phase I trial, sponsored by the US National Institutes of

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

Health (NIH), was initiated in October 2013 to evaluate the vaccine. In October 2014, Sanofi Pasteur signed a contract with Immune Design Corp. to collaborate on the development of a therapeutic herpes simplex virus vaccine.

**HIV:** Existing treatments for HIV are able to extend the life-span of an infected individual but unable to cure the disease. Prevention is considered a key approach to abating the HIV pandemic by reducing new infection. Prevention through the use of a prophylactic vaccine still remains an important unmet medical need. Due to the enormity of the disease burden in developing countries and the potential for initial licensing of an efficacious vaccine in the developing world, Sanofi Pasteur is working in a pox-protein public-private partnership (P5) to document efficacy of a pox-protein based HIV prophylactic vaccine in the Republic of South Africa. Specifically, following the modest success of RV144 (the first trial to show supporting evidence that vaccines could lower the risk of contracting HIV), the P5 partnership adopted a pox-protein based vaccine candidate as potentially providing greater protection for South Africa and conducted a Phase I/II study (HVTN 100). This study met all pre-specified safety and immunogenicity criteria and supported moving the vaccine regimen to a pivotal efficacy study (HVTN702), which started on October 26, 2016 in South Africa and will continue until 2021. HVTN702 will not only assess the vaccine's safety and efficacy, it will also help in discovering immune correlates of protection.

**RSVi:** Respiratory Syncytial Virus (RSV) is the most common cause of bronchiolitis in young children. Globally, RSV accounts for 22%-40% of lower tract respiratory illnesses, 50%-90% of bronchiolitis cases and 19%-40% of pneumonia cases, and causes up to 199,000 deaths each year. It is estimated that in the US alone, about 172,000 RSV hospitalizations occur each year in children under 5 years of age, resulting in significant health care costs. Sanofi Pasteur has signed a Cooperative Research and Development Agreement (CRADA) with the US NIH to develop a live attenuated RSV vaccine for routine immunization in infants aged 4 months and older. The lead candidate(s) are currently under Phase 1a evaluation and scheduled to enter Phase 1b evaluation by end of 2017.

**Zika:** Sanofi Pasteur entered into a Cooperative Research and Development Agreement (CRADA) with the Walter Reed Army Institute of Research (WRAIR) on a Zika vaccine project in 2016, under which WRAIR is transferring its Zika purified inactivated virus (ZPIV) vaccine technology to Sanofi Pasteur. The Biomedical Advanced Research and Development Authority (BARDA) of the US Department of Health and Human Services has agreed to provide \$43.2 million in funding for the manufacture of the inactivated Zika

vaccine and the Phase I-II clinical trials. WRAIR and NIAID are conducting a series of Phase I ZPIV trials while the technology is transferred to Sanofi Pasteur.

Sanofi Pasteur committed to researching and developing a vaccine to prevent Zika shortly after the World Health Organization declared an emergency last year, and believes that coordination among researchers, developers, manufacturers, regulatory agencies, the WHO, national health authorities, governments and non-governmental agencies is essential to combat public health emergencies. The inactivated Zika virus candidate entered Phase I in October 2016, and we are scheduled to enter Phase II with Sanofi Pasteur produced material by early 2018.

**B.5.3. R&D expenditures for late stage development**

Expenditures on research and development amounted to \$5,172 million in 2016, comprising \$4,618 million in the Pharmaceuticals segment and \$554 million in Human Vaccines. Research and development expenditures were the equivalent of about 15.3% of net sales in 2016, compared to about 14.9% in 2015 and in 2014. The stability in R&D expenditure as a percentage of sales over the past three years is attributable to active management of the portfolio and close cost control, and has been achieved despite a greater proportion of products being in late stage development. Preclinical research in the pharmaceutical segment amounted to \$1,094 million in 2016 compared to \$1,072 million in 2015 and \$986 million in 2014. Of the remaining \$3,523 million relating to clinical development in the Pharmaceuticals segment (\$3,458 million in 2015 and \$3,188 million in 2014), the largest portion was generated by Phase IIb post-marketing studies, reflecting the cost of monitoring large scale clinical trials.

## Edgar Filing: Sanofi - Form 20-F

For each of our current late stage (Phase III in 2016) compounds in the Pharmaceuticals segment, we set out below the date at which this compound entered into Phase III development, information concerning any compound patent in the principal markets for innovative pharmaceutical products (the US, the EU and Japan) as well as comments regarding significant future milestones that are reasonably determinable at this date. Because the timing of such milestones typically depends on a number of factors outside of our control (such as the time to validate study protocols and recruit subjects, the speed with which endpoints are realized, as well as the substantial time taken by regulatory review) it is frequently not possible to provide such estimates, and any such estimates as are given should be understood to be indicative only. See also Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

Phase III	Entry into Phase III <sup>(a)</sup> (month/year)	Compound Patent Term <sup>(b)</sup>			Comments
		US	EU	Japan	
SAR342434	November 2014	N/A	N/A	N/A	Phase III program in Type 1 & 2 diabetes completed
insulin lispro sotagliflozin	November 2015	2028	2027	2027	Dossier submitted Phase III program ongoing in Type 1 & 2 diabetes.
(SAR439954) sarilumab	August 2011	2028	2027	2027	First approval in Canada on January 12, 2017 in Rheumatoid Arthritis
(SAR153191)					Submitted in US in October 2015, and accepted for review in January 2016
dupilumab	October 2014	2027	2029	2029	Submission in EU in June 2016 and validated for review in July 2016 Atopic Dermatitis: Submitted in US and accepted for priority review, expected approval date is March 2017. Submitted in EU and accepted for review.
(SAR231893)					
patisiran	December 2013	2029	2029	2029	Phase III program in Asthma & Nasal polyposis ongoing. Phase III program ongoing in Familial Amyloid Polyneuropathy.
(SAR438027) GZ402666 isatuximab	November 2016	2029	2028	2028	Phase III program ongoing in Pompe Disease
(SAR650984)	December 2016	2028	2027	2027	Phase III program ongoing in multiple myeloma

(a) First entry into Phase III in any indication.

(b) Subject to any future supplementary protection certificates and patent term extensions.

With respect to the compound patent information set out above, investors should bear in mind the following additional factors:

The listed compound patent expiration dates do not reflect possible extensions of up to five years available in the US, the EU, and Japan for pharmaceutical products. See B.7. Patents, Intellectual Property and Other Rights – Patent Protection for a description of supplementary protection certificates and patent term extensions.

Depending on the circumstances surrounding any final regulatory approval of the compound, there may be other listed patents or patent applications pending that could have relevance to the product as finally approved; the relevance of any such application would depend upon the claims that ultimately may be granted and the nature of the final regulatory approval of the product.

Regulatory exclusivity tied to the protection of clinical data is complementary to patent protection, and in many cases may provide more efficacious or longer lasting marketing exclusivity than a compound's patent estate. See B.7. Patents, Intellectual Property and Other Rights Regulatory Exclusivity for additional information. In the United States the data protection generally runs five years from first marketing approval of a new chemical entity extended to seven years for an orphan drug indication and twelve years from first marketing approval of a biological product. In the EU and Japan the corresponding data protection periods are generally ten years and eight years, respectively.

## **B.6. MARKETS**

A breakdown of revenues by business segment and by geographical region for 2016, 2015, and 2014 can be found at Note D.35. to our consolidated financial statements included at Item 18 of this annual report.

The following market shares and ranking information are based on consolidated national pharmaceutical sales data (excluding vaccines), in constant euros, on a September 2016 MAT (Moving Annual Total) basis. The data are mainly from QuintilesIMS (MIDAS), supplemented by country-specific sources: Knobloch (Mexico), GERS (France hospital channel), and HMR (Portugal). Market share data for the Consumer Healthcare business are from Nicholas Hall, June 2016 MAT. For more information on market shares and rankings see Presentation of Financial and Other Information at the beginning of this Annual Report on Form 20-F.

### **B.6.1. Marketing and Distribution**

We have a commercial presence in approximately 100 countries, and our products are available in more than 170 countries. Our main markets in terms of net sales are respectively:

Emerging Markets (see definition in Information on the Company Introduction above): Sanofi is the leading healthcare company in emerging markets. Sanofi is the fifth largest pharmaceutical company in China.

The US: we rank eleventh with a market share of 3.9% (3.9% in 2015).

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Europe: we are the second largest pharmaceutical company in France where our market share is 7.5% (7.8% in 2015), and we rank third in Germany with a 4.6% market share.

Other countries: our market share in Japan is 2.0% (2.7% in 2015).

A breakdown of our aggregate net sales by geographical region is presented in Item 5. Operating and Financial Review and Prospects Results of Operations Year Ended December 31, 2016 Compared with Year Ended December 31, 2015.

Although specific distribution patterns vary by country, we sell prescription drugs primarily to wholesale drug distributors, independent and chain retail drug outlets, hospitals, clinics, managed-care organizations and government institutions. Rare disease products are also sold directly to physicians. With the exception of Consumer Healthcare products, our drugs are ordinarily dispensed to patients by pharmacies upon presentation of a doctor's prescription.

We use a range of channels from in-person to digital to disseminate information about and promote our products among healthcare professionals and patients, ensuring that the channels not only cover our latest therapeutic advances but also our established prescription products, which satisfy patient needs in some therapy areas. We regularly advertise in medical journals and exhibit at major medical congresses. In some countries, products are also marketed directly to patients by way of television, radio, newspapers and magazines, and digital channels (such as the internet). National education and prevention campaigns can be used to improve patients' knowledge of their conditions.

Our sales representatives, who work closely with healthcare professionals, use their expertise to promote and provide information on our drugs. They represent our values on a day-to-day basis and are required to adhere to a code of ethics and to internal policies in which they receive training. As of December 31, 2016, we had a global sales force of 30,815 people excluding the Animal Health business.

Although we market most of our products through our own sales forces, we have entered into and continue to form partnerships to co-promote/co-market certain products in specific geographical areas. Our major alliances are detailed at Item 5. Operating and Financial Review and Prospects Financial Presentation of Alliances. See also Item 3. Key Information D. Risk Factors We rely on third parties for the discovery, manufacture and marketing of some of our products.

Our vaccines are sold and distributed through multiple channels including physicians, pharmacies, hospitals, private companies and distributors in the private sector, and

governmental entities and non-governmental organizations in the public and international donor markets.

**B.6.2. Competition**

The pharmaceutical industry continues to experience significant changes in its competitive environment.

There are four types of competition in the prescription pharmaceutical market:

competition between pharmaceutical companies to research and develop new patented products or address unmet medical needs;

## Edgar Filing: Sanofi - Form 20-F

- competition between different patented pharmaceutical products marketed for the same therapeutic indication;
- competition between original and generic products or between original biological products and biosimilars, at the end of regulatory exclusivity or patent protection; and
- competition between generic or biosimilar products.

We compete with other pharmaceutical companies in all major markets to develop innovative new products. We may develop new technologies and new patented products wholly in-house, but we also enter into collaborative R&D agreements in order to access new technologies. See Note D.21. to our consolidated financial statements included in Item 18 of this annual report.

Sanofi is the sixth largest pharmaceutical company globally by sales. Our prescription drugs compete in all major markets against patented drugs from major pharmaceutical companies. Our competitors in key businesses include: Novo Nordisk, Boehringer Ingelheim and Merck in diabetes; Lilly in diabetes and oncology; Bristol-Myers Squibb in oncology; Novartis in diabetes, multiple sclerosis, and oncology; Shire in rare diseases; Pfizer in rare diseases and oncology; Biogen, Teva and Merck Serono in multiple sclerosis; Bayer in multiple sclerosis and oncology; Roche and Johnson & Johnson in oncology; AstraZeneca in diabetes, cardiovascular disease and oncology; and Amgen in cardiovascular disease.

Following our acquisition of Boehringer Ingelheim's consumer healthcare business, we will be one of the leaders in the consumer healthcare market, tied at 4.4% market share with GSK and Bayer. Other key competitors include Johnson & Johnson, Pfizer, and Reckitt Benckiser, as well as local players, especially in emerging markets.

Our generics business is the seventh largest globally by sales and competes with multinational corporations such as Teva, Sandoz (a division of Novartis), Mylan and Actavis and local players, especially in emerging markets.

In our Human Vaccines business we are one of the top four players, competing primarily with large multinational players including Merck, GlaxoSmithKline, and Pfizer.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

We also face competition from generic drugs that enter the market when our patent protection or regulatory exclusivity expires, or when we lose a patent infringement lawsuit (see B.7. Patents, Intellectual Property and Other Rights below). Similarly, when a competing patented drug from another pharmaceutical company faces generic competition, those generic products can also affect the competitive environment of our own patented product. See Item 3. Key Information D. Risk factors Risks relating to our business .

Competition from producers of generics has increased sharply in response to healthcare cost containment measures and to the increased number of products for which patents or regulatory exclusivity have expired.

Generics manufacturers who have received all necessary regulatory approvals for a product may decide to launch a generic version before the patent expiry date, even in cases where the owner of the original product has already commenced patent infringement litigation against the generics manufacturer. Such launches are said to be at risk for the promoter of the generic product because it may be required to pay damages to the owner of the original product in the context of patent infringement litigation; however, these launches may also significantly impair the profitability of the pharmaceutical company whose product is challenged.

Drug manufacturers also face competition through parallel trading, also known as reimportation. This takes place when drugs sold abroad under the same brand name as in a domestic market are imported into that domestic market by parallel traders, who may repackage or resize the original product or sell it through alternative channels such as mail order or the internet. This situation is of particular relevance to the EU, where these practices have been encouraged by the current regulatory framework. Parallel traders take advantage of the price differentials between markets arising from factors including sales costs, market conditions (such as intermediate trading stages), tax rates, or national regulation of prices.

Finally, pharmaceutical companies face illegal competition from counterfeit drugs. The WHO estimates that counterfeit products account for 10% of the market worldwide, rising to 30% in some countries. However, in markets where powerful regulatory controls are in place, counterfeit drugs are estimated to represent less than 1% of market value.

**B.6.3. Regulatory Framework**

**B.6.3.1. Overview**

The pharmaceutical and health-related biotechnology sectors are highly regulated. National and supranational health authorities administer a vast array of legal and regulatory requirements that dictate pre-approval testing and quality standards to maximize the safety and efficacy of a

new medical product. These authorities also regulate product labeling, manufacturing, importation/exportation and marketing, as well as mandatory post-approval commitments that may include pediatric development.

The submission of an application to a regulatory authority does not guarantee that a license to market will be granted. Furthermore, each regulatory authority may impose its own requirements during the course of the product development and application review. It may refuse to grant approval and require additional data before granting approval, even though the same product has already been approved in other countries. Regulatory authorities also have the authority to request product recalls, product withdrawals and penalties for violations of regulations based on data that are made available to them.

Product review and approval can vary from six months or less to several years from the date of application depending upon the country. Factors such as the quality of data, the degree of control exercised by the regulatory authority, the review procedures, the nature of the product and the condition to be treated, play a major role in the length of time a product is under review.

## Edgar Filing: Sanofi - Form 20-F

In 2016, the International Council for Harmonization (ICH) started implementing its reform mandate.

The aims are to reinforce the foundations of the ICH; expand harmonization globally beyond the traditional ICH Members, i.e. the three founding members (EU, Japan, US) plus Canada and Switzerland as observers; and facilitate the involvement of additional regulators and industry associations around the world. Eight countries, four Regional Harmonization Initiatives and five interested organizations have joined as observers since then.

International collaboration between regulatory authorities continues to develop with the implementation of confidentiality arrangements and memoranda of understanding between both ICH and non-ICH regulatory authorities. Examples include work-sharing on Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) inspections, as well as regular interactions between the US and the EU in the form of clusters (i.e. pediatrics, oncology, advanced therapy medicinal products, vaccines, pharmacogenomics, orphan drugs, biosimilars, and blood products).

In addition to the joint efforts listed above, Free Trade Agreements (FTAs) have proven to be one of the best ways to open up foreign markets to exporters and to allow for discussions on harmonization topics for regulatory authorities. Some agreements, such as the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), are international in nature, while others are between specific countries.

The Trans-Pacific Partnership, under discussion since 2008, was finalized on October 5, 2015. This free trade agreement,

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

which was negotiated between Australia, New Zealand, the US, Peru, Chile, Mexico, Canada, Singapore, Brunei, Malaysia, Vietnam and Japan, covers 40% of the global economy. Provisions affecting the BioPharma industry include a patent exclusivity term for biologics. Recent changes in the US political landscape, with the introduction of the new administration, have brought uncertainties to the future of the agreement.

The Transatlantic Trade and Investment Partnership (TTIP) is still being negotiated. This proposed free trade agreement between the EU and the US is intended to promote multilateral economic growth. Specifically with respect to the BioPharma industry, the agreement aims to enable regulators to work together more closely to ensure medicines are safe and effective.

The requirements of many countries (including Japan and several EU member states) to negotiate selling prices or reimbursement rates for pharmaceutical products with government regulators significantly extend the time to market entry beyond the initial marketing approval. While marketing approvals for new pharmaceutical products in the EU have been largely centralized within the European Medicines Agency (EMA), pricing and reimbursement remain a matter of national competence.

**In the EU**, there are three main procedures for applying for marketing authorization:

- The centralized procedure is mandatory for drugs derived from biotechnologies, new active substances designed for human use to treat HIV, viral diseases, cancer, neurodegenerative diseases, diabetes and auto-immune diseases, orphan drugs and innovative products for veterinary use. When an application is submitted to the EMA, the scientific evaluation of the application is carried out by the Committee for Medicinal Products for Human Use (CHMP) and a scientific opinion is prepared. This opinion is sent to the European Commission which adopts the final decision and grants an EU marketing authorization. Such a marketing authorization is valid throughout the EU and the drug may be marketed within all EU member states.
  - If a company is seeking a national marketing authorization in more than one member state, two procedures are available to facilitate the granting of harmonized national authorizations across member states: the mutual recognition procedure or the decentralized procedure. Both procedures are based on the recognition by national competent authorities of a first assessment performed by the regulatory authority of one member state.
  - National authorizations are still possible, but are only for products intended for commercialization in a single EU member state or for line extensions to existing national product licenses.
- Generic products are subject to the same marketing authorization procedures. A generic product must contain the same active medicinal substance as a reference product approved in the EU. Generic applications are abridged: generic manufacturers only need to submit quality data and demonstrate that the generic drug is bioequivalent to the originator product (i.e. performs in the same manner in the patient's body), but do not need to submit safety or efficacy data since regulatory authorities can refer to the reference product's dossier. Generic product applications can be filed and approved in the EU only after the originator product eight-year data exclusivity period has expired. Further, generic manufacturers can only market their generic products after a 10- or 11-year period has elapsed from the date of approval of the originator product. In case of orphan drugs, generic product applications may not be filed before the expiry of a 10 or 12 year period from the date of approval of the originator product.

Another relevant aspect in the EU regulatory framework is the sunset clause under which any marketing authorization ceases to be valid if it is not followed by marketing within three years or if marketing is interrupted for a period of three consecutive years.

## Edgar Filing: Sanofi - Form 20-F

In 2016, the EMA recommended 81 medicines for marketing authorization (versus 93 in 2015), including 27 new active substances.

Among the 81 medicines recommended, 17 (21%) had an orphan designation (versus 18 in 2015 and 17 in 2014), providing medicines for patients with rare diseases. Seven medicines were evaluated under accelerated assessment in 2016 (versus five in 2015 and seven in 2014); this mechanism is reserved for medicines that have the potential to address unmet medical needs. Eight medicines were recommended for a conditional marketing authorization; this is one of the EMA's early access routes to patients, and is intended for medicines that address an unmet medical need and that target seriously debilitating, life-threatening or rare diseases, or are intended for use in emergency situations in response to a public health threat.

Post-authorization safety monitoring of pharmaceutical products is carefully regulated in Europe. EU pharmaceutical legislation for medicinal products describes the respective obligations of the marketing authorization holder (MAH) and of the regulatory authorities to set up a system for pharmacovigilance in order to collect, collate and evaluate information about suspected adverse reactions.

It is possible for the regulatory authorities to withdraw products from the market for safety reasons. Responsibilities for pharmacovigilance rest with the regulatory authorities of all the EU member states in which the marketing authorizations are held. In accordance with applicable legislation, each EU member state has a pharmacovigilance system for the collection and evaluation of information

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

relevant to the risk-benefit balance of medicinal products. The regulatory authority regularly monitors the safety profile of the products available in its territory, takes appropriate action where necessary, and monitors the compliance of marketing authorization holders (MAHs) with their pharmacovigilance obligations. All relevant information is shared between the regulatory authorities and the MAH, in order to allow all parties involved in pharmacovigilance activities to fulfill their obligations and responsibilities.

The pharmacovigilance legislation was amended in 2012. The amendments aim to further strengthen the protection of patient health by promoting prompt and appropriate regulatory action on European medicines. In particular, the amendments included major changes to notification requirements: MAHs of human medicines now have to notify EU regulators of any action to withdraw a product from a market, together with the reason for this action. Changes also included the creation of a Pharmacovigilance Risk Assessment Committee (PRAC), a scientific advisory committee at EMA level, with a key role in the assessment of all aspects of the risk management relating to the use of medicinal products for human use approved in the European Economic Area (EEA). This includes measures relating to the detection, assessment, minimization and communication of the risk of adverse reactions, having due regard to the therapeutic effect of the medicinal product. This committee is also responsible for the design and evaluation of post-authorization safety studies (PASS) and pharmacovigilance audits.

In Europe, the PRAC has performed reviews of marketed products (by class or on ad hoc basis) through various procedures. For Sanofi 153 products underwent PRAC review through signal and referral procedures from July 2012 to December 2016, generating 99 labeling variations (26 new variations in 2016) and five additional risk minimization measures. In only two cases for Sanofi (Myolastan<sup>®</sup>, and methadone oral solutions containing povidone) did the review lead to the product being withdrawn from the EU market.

The EU pharmacovigilance legislation also strengthens the legal basis for regulators to require post-authorization safety and efficacy studies throughout the life cycle of a medicinal product, with regulatory supervision of protocols and results. Such studies are aimed at collecting data to enable the safety or efficacy of medicinal products to be assessed in everyday medical practice. The granting of marketing authorization is conditional on such studies being performed. Consequently, the pharmaceutical industry now has to build the need for PASS and post-authorization efficacy studies (PAES) into development and life cycle management plans. Sanofi has put in place robust processes to ensure that PASS and PAES can be properly implemented as required, either as part of a Risk Management Plan (RMP) or following a health authority request.

A further requirement introduced by the EU pharmacovigilance legislation is for pharmaceutical companies to prepare Periodic Safety Update Reports (PSURs). These are not limited to safety data, but instead present a critical analysis of the risk-benefit balance of a medicinal product, taking into account new or emerging information in the context of cumulative information on risks and benefits.

There is in addition a legal requirement for an enhanced adverse reaction collection and management system (EudraVigilance) that delivers better health protection through simplified reporting, higher quality data, and improved search, analysis and tracking functionalities. Associated with this is a legal requirement for MAHs to monitor EudraVigilance data, to the extent to which they have access to such data. Following an EudraVigilance functionalities audit for the first quarter of 2017, a move to EMA centralized reporting is planned for November 2017.

The database of medicinal products aims to deliver structured and quality assured information on medicinal products authorized in the EU supporting the terminologies of products, substances, and organizations that underpin pharmacovigilance and regulatory systems. Since January 1, 2015, MAHs have been required to notify the EMA of any new marketing authorizations within 15 calendar days from the date of authorization, and to notify the EMA of any change in the terms of a marketing authorization as soon as possible within 30 calendar days following the date on which the changes were authorized.

The EMA's medical literature monitoring (MLM) service was launched on September 1, 2015 to monitor selected medical literature for reports of suspected adverse drug reactions containing certain active substances, and to enter reports into EudraVigilance database.

## Edgar Filing: Sanofi - Form 20-F

There is a legal requirement for EMA to set up a repository for Periodic Safety Update Reports (PSURs) and their assessment reports on PSURs in order to facilitate centralized PSUR reporting and to enhance access to data and information, thereby supporting risk/benefit assessments of medicines. The PSUR Repository achieved full functionality in June 2015 and its use in the EU became mandatory on June 13, 2016.

**In the US**, applications for approval are submitted for review to the FDA, which has broad regulatory powers over all pharmaceutical and biological products that are intended for sale and marketing in the US. To commercialize a product in the US, a new drug application (NDA) under the Food, Drug and Cosmetic (FD&C) Act, or a Biological License Application (BLA) under the Public Health Service (PHS) Act, must be submitted to the FDA for filing and pre-market review. Specifically, the FDA must decide whether the product is safe and effective for its proposed use; if the benefits of the drug's use outweigh its risks; whether the

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

drug's labeling is adequate; and if the manufacturing of the drug and the controls used for maintaining quality are adequate to preserve the drug's identity, strength, quality and purity. Based upon this review, the FDA can require post-approval commitments and requirements. Approval for a new indication of a previously approved product requires submission of a supplemental NDA (sNDA) for a drug or a supplemental BLA (sBLA) for a biological product.

Sponsors wishing to market a generic drug can file an Abbreviated NDA (ANDA) under 505(j) of the FD&C Act. These applications are abbreviated because they are generally not required to include data to establish safety and effectiveness, but need only demonstrate that their product is bioequivalent (i.e., performs in humans in the same manner as the originator's product). Consequently, the length of time and cost required for development of generics can be considerably less than for the innovator's drug. The ANDA pathway in the US can only be used for generics of drugs approved under the FD&C Act.

The FD&C Act provides another abbreviated option for NDA approved products, which is a hybrid between an NDA and ANDA called the 505(b)(2) pathway. This 505(b)(2) pathway enables a sponsor to rely on the FDA's findings that the reference product is safe and effective, based on the innovator's preclinical and clinical data.

The FDA Center for Drug Evaluation and Research (CDER) approved 22 novel drugs in 2016 (versus 45 in 2015, 41 in 2014, 27 in 2013 and 39 in 2012). Designations and pathways to expedite drug development and review include Fast Track (8), Breakthrough Therapy (7), Accelerated Approval (6), and Priority Review (15). Of the 22 novel drugs approved in 2016, 16 (73%) were designated in one or more expedited categories.

CDER identified eight of the 22 novel drugs approved in 2016 (36%) as First-in-Class, one indicator of the innovative nature of a drug. Approximately 41% of the novel drugs approved in 2016 (9 of 22) were approved to treat rare or orphan diseases that affect 200,000 or fewer Americans.

Congress encouraged development of new human drugs and biological products for prevention and treatment of certain tropical diseases (FDAAA 2007) and rare pediatric diseases (FDASIA 2012) by offering additional incentives for obtaining FDA approval of such products. To date four tropical disease priority review vouchers (PRVs) and seven pediatric rare disease PRVs have been granted. In 2014, Regeneron purchased a pediatric rare disease PRV from BioMarin which was redeemed for the priority review of their PCSK9 product Praluent®, thus cutting short the review time by 4 months. Sanofi purchased a second pediatric rare disease PRV from Retrophin in the summer of 2015, which was redeemed in December 2015 for the priority review of its diabetes fixed combination product Soliqua 100 / 33, which was approved by FDA in November 2016. In

December 2016, Congress extended the rare pediatric disease priority review voucher program to 2020 for designation and 2022 for marketing approval authorization.

**In Japan**, the regulatory authorities can require local clinical studies, though they also accept multi-national studies. In some cases, bridging studies have been conducted to verify that foreign clinical data are applicable to Japanese patients and obtain data to determine the appropriateness of the dosages for Japanese patients. These additional procedures have created a significant delay in the registration of some innovative products in Japan compared to the EU and the US. In order to solve this drug-lag problem, the Japanese Ministry of Health, Labor and Welfare (J-MHLW) introduced a new National Health Insurance (NHI) pricing system on a trial basis in April 2010. Reductions in NHI prices of new drugs every two years are compensated by a Premium for a maximum of 15 years. A Premium is granted in exchange for the development of unapproved drugs or off-label indications with high medical needs. Once an official request for development of an unapproved drug or off-label indication has been made, the pharmaceutical companies must file literature-based reports within six months or submit a clinical trial notification for registration within one year after the official development request. For unapproved drugs with high medical needs, clinical trials in Japanese patients are generally required. Otherwise, a fine equivalent to 105% (with 5% representing interest) of sales based on

the premium would have to be paid back to the government.

To promote the development of innovative drugs and bring them into early practical use in Japan ahead of the world, *Sakigake* (a Japanese term meaning forerunner ) review designation program was introduced from April 2015 on a trial basis. The Pharmaceuticals and Medical Devices Agency (PMDA) will review designated products on a priority basis with the aim of reducing their review time from the normal 12 months to 6 months.

Based on the reform of the NHI price system finalized in 2013, the Premium classification will be restricted to new products from companies which conduct R&D on pharmaceuticals truly conducive to the improvement of healthcare quality, i.e. (i) pediatric/orphan drugs, and (ii) drugs to treat diseases that cannot be adequately controlled with existing drugs. The Premium policy will continue its trial stage.

The PMDA has set a target for 80% (as opposed to the current 50%) of all applications to be reviewed in 12 months for products with standard review status and in 9 months for products with priority review status by the end of 2018.

The PMDA also plans to eliminate the review lag between the filing and approval of drugs and medical devices relative to the FDA by the end of 2020.

The Pharmaceuticals and Medical Devices Act was implemented on November 25, 2014. There are three major

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

objectives. The first objective is to strengthen safety measures for drugs and medical devices. In particular, MAHs must prepare a package insert based on the latest knowledge and notify the J-MHLW before placing products on the market or when revisions are made. The second objective is to accelerate the development of medical devices. The third-party accreditation system will be expanded to specially controlled generic medical devices (i.e. Class III devices). Consequently, the PMDA can accelerate the review of innovative medical devices. The third objective is accelerated commercialization of regenerative medicinal products.

The term Regenerative Medicinal Products used in the law includes cellular and tissue-based products and gene therapies. This concept is similar to Advanced Therapy Medicinal Products (ATMPs) in the EU. The law allows for conditional regulatory approval based on confirmation of probable efficacy and safety in small-scale clinical trials, followed up by comprehensive studies to confirm safety and efficacy in a wider population that would then lead to a regular (full) approval.

For new drugs and biosimilar products with approval applications submitted on or after April 2013, Japan has implemented an RMP (Risk Management Plan), similar to the EU Pharmacovigilance system.

For generic products, the data necessary for filing are similar to EU and US requirements. Pharmaceutical companies only need to submit quality data, and data demonstrating bioequivalence to the originator product, unless the drug is administered intravenously. Clinical Trial Data (CTD) submission for generics will be mandatory from March 2017.

**B.6.3.2. Biosimilars**

Products can be referred to as biologics when they are derived from natural sources, including blood products or products manufactured within living cells (such as antibodies). Most biologics are complex molecules or mixtures of molecules which are difficult to characterize and require physico-chemical-biological testing, and an understanding of and control over the manufacturing process.

The concept of generics is not scientifically appropriate for biologics due to their high level of complexity. Consequently the concept of biosimilar products is more appropriate. A full comparison of the purity, safety and efficacy of the biosimilar product against the reference biological product should be undertaken, including assessment of physical-chemical-biological, non-clinical and clinical similarity.

**In the EU**, a regulatory framework for developing and evaluating biosimilar products has been in place since 2005. The CHMP has issued several product/disease specific guidelines for biosimilar products including guidance on preclinical and clinical development of biosimilars of Low

Molecular Weight Heparin (LMWH) and of insulins. Starting in 2011 and continuing through 2016, the CHMP has been engaged in revising most of the existing biosimilar guidelines (general overarching guidelines, quality, and non-clinical and clinical product-specific guidelines).

While the CHMP has adopted a balanced approach for all biosimilars, allowing evaluation on a case-by-case basis in accordance with relevant biosimilar guidelines, it has also indicated that in specific circumstances, a confirmatory clinical trial may not be necessary. This applies if similar efficacy and safety can clearly be deduced from the similarity of physicochemical characteristics, biological activity/potency, and pharmacokinetic and/or pharmacodynamic profiles of the biosimilar and the reference product. With respect to vaccines, the CHMP currently takes the view that it is at present unlikely that these products can be characterized at the molecular level, and that each vaccine product must be evaluated on a case-by-case basis.

**In the US**, the Patient Protection and Affordable Care Act (Affordable Care Act), signed into law by President Obama in March 2010, amended the Public Health Service Act to create an abbreviated licensure pathway (351k) for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-licensed biological product.

## Edgar Filing: Sanofi - Form 20-F

In 2016 the FDA published for consultation two biosimilar draft guidance documents on labeling and transition products. Sanofi submitted comments to the public docket on both guidance documents. Of particular interest to Sanofi was the draft guidance, Implementation of the Deemed to be a License Provision of the Biologics Price Competition and Innovation Act of 2009, which covers the transition of Legacy Protein Products from the drug approval system to the biologics system by March 23, 2020. Sanofi transition products include insulin products, Cerezyme® and Thyrogen®. The Biosimilar Guidance on interchangeability was published in January 2017.

To date four biosimilar products have been approved by the FDA.

US Federal and state officials, including the new administration, are continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

**In Japan**, guidelines defining the regulatory approval pathway for follow-on biologics were finalized in March 2009. These guidelines set out the requirements on preclinical clinical and Chemistry, Manufacturing and Control (CMC) data to be considered for the development of the new application category of biosimilars. Unlike the CHMP guidelines, the main scope of the Japanese guidelines includes recombinant proteins and polypeptides, but not polysaccharides such as LMWH.

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

Many regulatory authorities worldwide have in place, or are in the process of developing, a regulatory framework for biosimilar development and approval. It should be noted that although many emerging markets are basing their regulations and guidance on WHO or EMA documentation, some markets have approved biosimilars under an existing regulatory framework that is not specific to biosimilars.

**B.6.3.3. Generics**

**In the EU** 16 positive opinions were issued under the centralized procedure for generics in 2016 (versus 21 in 2015, 8 in 2014 and 16 in 2013). Most of the generics applications for chemical entities use the mutual recognition and decentralized procedures. Pricing systems for generics remain at national level in the EU.

**In the US**, to help the FDA ensure that participants in the US generic drug system comply with US quality standards and to increase the likelihood that American consumers get timely access to low cost, high quality generic drugs, the FDA and the industry have jointly agreed to a comprehensive program (Generic Drug User Fee Amendments) to supplement traditional appropriated funding, focused on safety, access, and transparency. For the period October 1, 2015 through September 30, 2016 the FDA planned to review and act on 75% of original ANDA submissions within 15 months from the date of submission. For this period, 651 ANDAs were approved, 184 received tentative approval and 1725 complete responses were issued. To date, the FDA has met or exceeded its goals.

**In Japan**, the 2014 reforms to the NHI price system included a new special price reduction rule for long-listed drugs. The new rule reduces the NHI prices of long-listed drugs whose generic replacement rates are less than 20% five years after their first generics join the NHI price list. Reductions are 2.0% in the first NHI price revision, 1.75% if the substitution rate is 20% or higher but less than 40%, and 1.5% if the rate is 40% or higher but less than 60%. The rule was introduced in April 2014.

Under the new price system, NHI prices of first generics (previously set at 60%) were set at 50% of the price of the originator product. A 40% rule is applied to oral first generics once more than ten products with the same ingredients have obtained listing.

In addition, a maximum *Sakigake premium* of 20% was introduced in April 2016 for Sakigake-designated products, which have new mechanisms of action and obtain approval in Japan ahead of the rest of the world.

**B.6.3.4. Medical Devices**

**In the EU**, there is no pre-market authorization by a regulatory authority. Instead there is a Conformity Assessment Procedure (for medium and high risk devices), possibly involving an independent third party Notified Body

(NB) depending on the classification of the device. Once certified, medical devices have to bear the CE-mark allowing them to circulate freely in the EU/EFTA (European Free Trade Association) countries and Turkey. Medical devices are currently regulated by three core Directives.

In September 2012, the European Commission adopted proposals to introduce two regulations to overhaul and tighten the current EU rules on medical devices (EU Medical Device Directive 93/42/EC, amended in 2007 as Directive 2007/47/EC).

In 2013, the European Parliament endorsed essential measures to strengthen patient safety. These measures are supported by the industry and include: improving the competence and control of NBs; introducing unannounced site visits by NBs; increasing the transparency and traceability of medical devices; introducing stricter post-market follow-up, and improved stakeholder engagement. In addition, a scrutiny procedure was introduced at least for high-risk Class III devices (novel technologies or specific public health threats).

## Edgar Filing: Sanofi - Form 20-F

The revised framework also formally introduced the concept of companion diagnostic, which is expected to deliver a more accurate definition of the patient population that will benefit from a given product. Sanofi has several companion diagnostics in development.

On June 15, 2016, the medical device (MD) and in vitro diagnostics (IVD) regulation texts were approved by the European Council. The texts are expected to be formally adopted in 2017. The regulations would then apply to the medical devices and in vitro diagnostics sectors with an expected transition period of five years.

**In the US**, the FDA Center for Devices and Radiological Health (CDRH) is responsible for regulating firms that manufacture, repackage, relabel and/or import medical devices sold in the US. The CDRH also regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions.

Medical devices are classified into Class I, II, and III. Regulatory control increases from Class I to Class III. The device classification regulation defines the regulatory requirements for a general device type. Most Class I devices are exempt from Premarket Notification 510(k); most Class II devices require Premarket Notification 510(k); and most Class III devices require Premarket Approval.

The basic regulatory requirements that manufacturers of medical devices distributed in the US must comply with are: Establishment Registration; Medical Device Listing; Premarket Notification 510(k) (unless exempt) or Premarket Approval; Investigational Device Exemption; Quality System Regulation; Labeling Requirements and Medical Device Reporting.

---

## **Table of Contents**

### **ITEM 4. INFORMATION ON THE COMPANY**

#### **B.6.3.5. OTC drugs**

**In the EU**, four European centralized prescription to OTC (Rx-to-OTC) switches have occurred since 2009. GlaxoSmithKline Consumer Healthcare's Alli (orlistat) weight-loss medicine was the first in January 2009, followed by Nycomed's 20mg pantoprazole tablets in June 2009, AstraZeneca's Nexium Control (esomeprazole) in 2013 and EllaOne, an emergency contraceptive, in January 2015. No new centralized OTC switch was granted in 2016. For nationally authorized products, switches follow national rules for OTC classification.

**In the US**, the FDA approved two prescription to OTC switches in 2016: Differin Gel (adapalene) and Flonase Sensimist Allergy Relief (fluticasone).

**In Japan**, the J-MHLW drug safety committee set new rules in 2013 on the details of safety evaluations for drugs newly switched from prescription to OTC, following the passage of a bill to revise the Pharmaceutical Affairs Law (PAL). The J-MHLW gives the green light for online sales of such OTC drugs if no safety concerns arise during an initial three-year safety evaluation period (the previous safety evaluation period was four years). During this three-year evaluation period, drugs that moved from prescription to OTC are categorized as products that require pharmacist consultations when purchased. Under the new rules, the J-MHLW requires marketing authorization holders to submit interim reports upon the completion of their post marketing surveillance (PMS).

The PMS needs to cover 3,000 patients for oral drugs and 1,000 patients for topical drugs. Based on these interim reports and other reports on adverse events, the J-MHLW performs the first evaluation on whether there are any safety concerns three years after the launch. If no safety concerns are identified during this three-year safety evaluation period, the classification of these Rx-to-OTC switches will be downgraded to Category 1 OTC drugs, i.e. drugs which do not require pharmacist consultation and can be sold online. The J-MHLW performs the second safety evaluation one year after the transfer to Category 1 OTC drugs. If no safety concerns are identified, the classification of the Category 1 OTC drugs will be downgraded to Category 2 OTC drugs, i.e. drugs that can be handled by pharmacists but also by registered salespersons.

Generic OTC drugs can be filed after completion of the three-year PMS period and will be approved in seven months.

The J-MHLW launched a new panel in April 2016 that would pick up Rx-to-OTC switch candidates. Under the new scheme, the MHLW accepts requests for Rx-to-OTC switch candidates from various stakeholders such as medical societies, consumers, and pharmaceutical companies, and then these requests will be publicly reviewed by the new panel in order to minimize pressures from medical societies. Based on its deliberations, the panel would refer the

shortlisted requests to the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) committee on nonprescription drugs, which effectively makes decisions on marketing approval for OTCs. The ministry is also planning to seek public comments.

#### **B.6.3.6. Transparency and public access to documents**

##### **Transparency regarding regulatory information and clinical trials**

Over recent years the pharmaceutical industry has been subject to growing pressure for greater transparency about clinical trials (conduct and results). Regulatory authorities are also being pushed for more openness and transparency, for example by making more comprehensive disclosures about the rationale and basis of regulatory decisions on medicinal products, so as to enhance the credibility of the regulatory process. This is a significant driver of the transparency initiatives undertaken in several countries.

## Edgar Filing: Sanofi - Form 20-F

Pharmaceutical manufacturers have committed to publishing protocols and results of clinical studies performed with their products in publicly accessible registries. In addition, both ICH and non-ICH countries often impose mandatory disclosure of clinical trials information.

From a regulatory perspective, ambitious initiatives have been undertaken by the major regulatory authorities. We have processes in place to address these initiatives.

**EU pharmaceutical legislation** for medicinal products requires national regulatory authorities and the EMA to actively publish information concerning authorization and supervision of medicinal products. The EMA has introduced a series of initiatives aimed at improving the transparency of its activities, such as improving the format of the European Public Assessment Report and web-published product approvals, withdrawals and rejections. In addition, there is an increased focus on comparative efficacy and effectiveness. The new EU pharmacovigilance legislation aims at giving greater transparency, especially with regard to communication of safety issues (e.g. public hearings, specific European web portals with information on medicinal products). Finally, patients and consumers are increasingly involved in the work of the EMA's scientific committees.

The EMA has committed to continuously extending its approach to transparency. A key goal in this process is the proactive publication of clinical trial data for medicines once the decision-making process on an application for a EU-wide marketing authorization is complete.

Early October 2014, the EMA adopted Policy 70 for publication of clinical trial reports. The policy came into force on January 1, 2015. It applies to clinical reports contained in any new marketing authorization applications for centralized marketing authorizations, and article 58 applications (medicines that are intended exclusively for markets outside the EU) submitted after that date.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

For post-authorization procedures for existing centrally authorized medicinal products, the effective date was July 1, 2015 for extension of indication and line extension applications submitted as of that date.

There is a two-step approach for the implementation of the policy:

- The first phase concerns the publication of clinical reports only, the data from which will be accessible on the EMA website.
  - In the second phase, the EMA will endeavor to find the most appropriate way to make Individual Patient Data (IPD) available, in compliance with privacy and data protection laws.
- In order to operationalize EMA Policy 70, Sanofi launched an internal project to define, develop, implement and control a sustainable process, supported by associated tools and documents, as well as resourcing, training and communication plans to manage clinical documents and data redaction in compliance with Policy 70. In 2016, the EMA Policy 70 process was fully transitioned to the business operational teams; and awareness communication is ongoing not only for current submissions, but also to streamline the process for ongoing and future studies.

**In the US**, the FDA launched a Transparency Initiative in June 2009. The objective of the initiative was to render the FDA much more transparent and open to the American public by providing the public with useful, user-friendly information about agency activities and decision making.

The FDA Transparency Initiative has three phases: Phase I – Improving the understanding of the FDA basics (completed with ongoing updates); Phase II – Improving the FDA’s disclosure of information to the public (ongoing); and Phase III – Improving the FDA’s transparency to regulated industry (ongoing). Proposals to improve transparency and access to information were released for consultation for both Phase II and Phase III. Some of the less controversial proposals have been implemented; others, such as proactive release of information that the Agency has in its possession, may require revisions to US federal regulations.

In September 2016, the US Department of Health and Human Services, National Institute of Health (NIH) published Final Rule under Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) on the Dissemination of Clinical Trial Information. The Final Rule requires registration and results submission for applicable clinical trials (ACTs); clarifies and expands registration data elements; expands scope of results reporting requirements to include trials of unapproved products; clarifies and expands results data elements; and revises Quality Control (QC) and posting process.

**In Japan**, the J-MHLW/PMDA actively publishes information concerning approvals of medicinal products (ethical drugs,

nonprescription drugs, and quasi-drugs) and medical devices. For ethical drugs discussed at the J-MHLW’s Pharmaceutical Affairs and Food Sanitation Council, the redacted clinical trials data modules 1&2 (except for commercial confidential information and personal data) have been made publicly available on the PMDA website.

**Transparency regarding Health Care Professionals**

**In the EU**, there is no harmonized approach regarding transparency for Health Care Professionals (HCPs). For transparency purposes, there is increased external scrutiny of interactions between pharmaceutical companies and HCPs at national level, with legal provisions or healthcare industry voluntary undertakings in some countries (such as the UK, Denmark, France, or Portugal).

## Edgar Filing: Sanofi - Form 20-F

The European Federation of Pharmaceutical Industries Association (EFPIA) released in mid-2013 a new Code on Disclosure of Transfers of Value from Pharmaceutical Companies to HCPs and Healthcare Organizations (HCOs), the EFPIA HCP/HCO Disclosure Code. EFPIA members were required to comply with this new code and transpose it into their national codes in full by December 2013.

This new Code includes stricter rules on hospitality and gifts, with the requirement for member associations to include a threshold on hospitality and the prohibition of gifts in their national codes.

**In the US**, the Physician Payments Sunshine Act, or Sunshine Act, was passed as part of the Affordable Care Act. The law is designed to bring transparency to financial relationships between physicians, teaching hospitals, and the pharmaceutical industry. Manufacturers and group purchasing organizations (GPOs) must report certain payments or transfers of value including payments for research, travel, honoraria and speaking fees, meals, educational items like textbooks and journal reprints whether made directly to a physician or teaching hospital or indirectly through a third party. The law also requires manufacturers and GPOs to report physicians who have an ownership interest in the company. Reports are made to the Centers for Medicare and Medicaid Services, a government agency.

**In Japan**, the Japan Pharmaceutical Manufacturers Association (JPMA) member companies started releasing information on their funding to healthcare professionals in 2013 and patient groups in 2014 under the trade group's voluntary guidelines to boost financial transparency. Under the JPMA's transparency guidelines for the relations between companies and medical institutions, its members currently report their payments in five categories: R&D, academic research support, manuscript/writing fees, provision of information, and other expenses.

---

## **Table of Contents**

### **ITEM 4. INFORMATION ON THE COMPANY**

#### **B.6.3.7. Other new legislation proposed or pending implementation**

**In the US**, former President Obama signed on December 13, 2016 the 21st Century Cures Act, intended to promote biomedical innovation and personalized medicines. The 21st Century Cures Act includes increased funding for the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) and provides for the implementation of, among other reforms, enhanced pathways for medical product approval and the modernization and harmonization of clinical trial procedures over a period of several years.

In the United States, user fees for manufacturers of medical products are reauthorized on a five-year cycle. The current fee programs, approved under FDASIA in 2012, will sunset September 30, 2017. The fees, known as PDUFA VI, MDUFA IV, BsUFA II and GDUFA II, will be delivered to Congress in 2017 as an omnibus bill. A fifth possible human health user fee, OMUFA, is currently being negotiated.

#### **Clinical trial regulation in the EU**

The new Clinical Trial Regulation ((EU) 536/2014) of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC, was published in the Official Journal of the EU on May 28, 2014.

Pharmaceutical companies and academic researchers will be required to post the results of all their European clinical trials in a publicly-accessible database.

The legislation will streamline the rules on clinical trials across Europe, facilitating cross-border cooperation to enable larger, more reliable trials, as well as trials on products for rare diseases. It simplifies reporting procedures, and gives the European Commission the authority to perform audits. Once a clinical trial sponsor has submitted an application dossier to a Member State, the Member State will have to respond to it within fixed deadlines.

One of the main objectives of the European Commission in introducing the clinical trial regulation was to simplify the clinical trial approval process. The new legislation was drafted as a more stringent form of regulation instead of a directive in order to reach better harmonization between countries, without interfering with Member States' competences in terms of ethical aspects.

The major points are:

- The timeline for approving a clinical trial proposal is set at 60 days without questions (and a maximum of 99 with questions and clock stops). This can be seen as a setback for the industry, as the Commission's proposal was based on 41 days without questions and a maximum of 74 days including all possible delays. In the case of advanced therapy medicinal products, the timeline can be extended by another 50 days, making 110 days in total.
- To make both the reference state and the relevant Member States comply with the timelines, the legislation includes the concept of tacit approval. The fact that this feature was accepted by all parties can be seen as a positive outcome for the industry.
- Selection of reference Member State by the sponsor was maintained.

As regards transparency requirements for clinical trial data submitted through a single EU submission portal and stored in a Union-level database, the new clinical trial regulation allows for protection of personal data of patients and commercially confidential information, which is in line with the industry data sharing laid out in Policy 70 (see previous section). A single EU submission portal and database fully operational is the prerequisite for regulation implementation: go-live is currently scheduled for September 2018, making the Regulation applicable in October 2018.

During the three-year transition period, both sets of rules will apply in parallel.

### **Falsified medicines**

The EU has reformed the rules for importing active substances for medicinal products for human use into the EU (Directive 2011/62/EU). Since January 2013, all imported active substances must have been manufactured in compliance with GMP standards or standards at least equivalent to GMP. The manufacturing standards in the EU for active substances are those specified in Q7 as issued by the International Council for Harmonization (ICH). With effect from July 2, 2013, such compliance must be confirmed in writing by the competent authority of the exporting country, except for countries with waivers. Written confirmation must also confirm that the plant where the active substance was manufactured is subject to control and enforcement of GMP at least equivalent to that in the EU.

Several implementing measures for the Falsified Medicines Directive were adopted: the establishment of a common EU logo for online pharmacies was adopted in June 2014, giving Member States until July 2015 to prepare for its application. The detailed rules for the safety features appearing on the outer packaging of medicinal products for human use have been adopted, meaning that all prescription drugs or reimbursed drugs commercialized on the European market will have to be serialized by February 2019.

### **Nagoya Protocol**

The Nagoya Protocol to the Convention on Biological Diversity on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization was adopted in Nagoya at the tenth Conference of the Parties of the Convention on Biological Diversity (CBD) on

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

October 29, 2010. The Nagoya Protocol came into force in October 2014 and at end December 2016 had 96 ratifications/accessions. The Nagoya Protocol is intended to create greater legal certainty and transparency for both providers and users of genetic resources by:

- establishing more predictable conditions for access to genetic resources; and
  - helping to ensure benefit-sharing when genetic resources leave the contracting party providing the genetic resources.
- On April 16, 2014, the European Parliament and the Council adopted the new regulation (EU 511/2014) on compliance measures for users, based on the Nagoya Protocol on Access to Genetic resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union. It came into force in October 2014.

In October 2015, the European Commission published the implementation Act (Regulation 2015/1866).

The pharmaceutical industry is due to implement compliance procedures for non-human biological materials used in the discovery, development, manufacturing and packaging of medicinal products to be submitted in the EU, starting after 2015. These will also include documentation from the originating country and acquisition date for materials that were acquired before the Regulation came into force.

Within Sanofi, a **Nagoya ready** project was launched mid-2015 to ensure compliance with international treaties on the sustainable use of biodiversity.

**In Japan**, the relevant ministries are currently considering local measures for the ratification of the Nagoya Protocol. The schedule for ratification has yet to be determined. The details of local measures for the implementation of the Nagoya Protocol cannot be disclosed due to ongoing discussion, but the relevant ministries are considering a framework where terms and conditions can be set for mutual agreement and a consent can be obtained in advance from providers in accordance with laws and regulations in a source country when genetic resources from the source country are used in Japan.

**NDA electronic clinical trial data submission**

**In the EU**, electronic submission for marketing authorization and variation applications has already been in place for many years. To allow secure submission over the Internet for all types of eCTD applications for human medicines, the EMA launched the eSubmission Gateway, which is now mandatory for all eCTD submissions through the centralized procedure, in order to improve efficiency and decrease costs for applicants.

As of July 1, 2015, companies are obliged to use electronic application forms provided by the EMA for all centralized marketing authorization applications for human and veterinary medicines. From January 2016, the use of

electronic application forms is also mandatory for all other EU marketing authorization procedures (i.e. MRP, DCP and national submissions).

**In Japan**, electronic submission of CDISC-based clinical data will become mandatory after the transition period that runs from October 2016 to March 2020, allowing the authority to efficiently store and analyze the data to improve its efficacy and safety predictions.

Such mandatory electronic submissions are expected to be limited to clinical trial data for new drugs newly filed for regulatory approval. The necessity for electronic submission for Phase I trial data will likely be decided on a case-by-case basis, while pharmaceutical companies will be required to file nonclinical toxicity study data in one of the Standard for the Exchange on Non clinical Data (SEND) formats in due course.

### **B.6.4. Pricing & Reimbursement**

Rising overall healthcare costs are leading to efforts to curb drug expenditures in most markets in which we operate. Increasingly, these efforts result in pricing and market-access controls for pharmaceuticals. The nature and impact of these controls vary from country to country, but some common themes are reference pricing, systematic price reductions, formularies, volume limitations, patient co-pay requirements, and generic substitution. In addition, governments and third-party payers are increasingly demanding comparative/relative effectiveness data to support their decision-making process. They are also increasing their use of emerging healthcare information technologies such as electronic prescribing and health records to enforce transparency and tight compliance with these regulations and controls. As a result, the environment in which pharmaceutical companies must operate in order to make their products available to patients and providers who need them continues to grow more complex each year.

While a drive to expand healthcare coverage has become a noticeable feature in many regions, providing opportunities for industry, it has also brought pressure on these new budgets, bringing with it a wave of price and volume control measures. Many countries and regions have increased pressure on pricing through joint procurement and negotiation. National production, whether through a policy of industrialization, through technology transfer agreements or through preferential conditions for local production, is equally a growing issue.

Significant trends:

In the United States there is increased scrutiny on the price of branded pharmaceutical products, and therefore heightened sensitivity to patient exposure to high out-of-pocket expense.

Private health insurance is offered widely as part of employee benefit packages, and is the main source of

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

access to subsidized healthcare provision. Some individuals purchase private health plans directly, while publicly-subsidized programs provide cover for retirees, the poor, the disabled, uninsured children, and serving or retired military personnel. Double-coverage is widespread. Public health insurances include:

- Medicare, which provides health insurance for retirees and for people with permanent disabilities. The basic Medicare scheme (Part A) provides hospital insurance only and the vast majority of retirees purchase additional cover through some or all of three other plans named Part B, Part C and Part D. Part D enables Medicare beneficiaries to obtain outpatient drug subsidies. Almost two-thirds of all Medicare beneficiaries have enrolled in a Part D plan.

- Medicaid, which provides health insurance for those on low incomes.

Managed care organizations (MCOs) combine the functions of health insurance, delivery of care, and administration. MCOs use specific provider networks and specific services and products. There are three types of managed care plans: Health Maintenance Organizations (HMOs), Preferred Provider Organizations (PPOs), and Point of Service (POS).

Pharmacy benefit managers (PBMs) serve as intermediaries between insurance companies, pharmacies and manufacturers to secure lower drug costs for commercial health plans, self-insured employer plans, Medicare Part D plans, and federal and state government employee plans.

The rollout of former President Obama's healthcare reform package pursuant to The Affordable Care Act is increasing the government's role with respect to price, reimbursement, and coverage levels for healthcare services and products within the large government healthcare sector. This law also imposed cost containment measures and rebates and fees on pharmaceutical companies. Some US states are also considering legislation that would influence the marketing and prices of, and access to, drugs. US Federal and state officials, including the new administration, are continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

Affordable access for patients is critical to our industry's success; however, the cost of access via third party intermediaries—Pharmaceutical Benefit Managers (PBMs), Health Plans and Government Markets—is calling into question the integrity of the healthcare system and the sustainability of our business.

As the US approached the so-called Patent Cliff major market insurers realized the traditional business revenue model was threatened and there was an immediate shift to a model that would increase enrollment and cut costs. In recent years mergers and acquisitions have been the largest

source of payer revenue growth, as acquired patients translate to increased demand. Industry consolidation now appears to have stabilized in the US, and there are currently three major PBMs and three major health insurers who will remain dominant.

With a decline in generic conversion and no further scope for consolidation, payers are seeking alternative methods to cut costs. As payers consolidate they can leverage their size and market share to demand higher rebates in return for increased access. If a manufacturer is reluctant to offer a higher rebate, the insurer will resort to interventions to enforce formulary controls.

As a soft measure to control access, payers use step therapy (to ensure use of low-cost therapies) and prior authorization (to require proof of medical necessity). For example, some US payers have placed significant restrictions on usage of Praluent<sup>®</sup>, which has resulted in significant out-of-pocket expenditures for Medicare patients.

A more extreme tactic, initially provoked by pharma coupons, is adding a product to an exclusion list; this means that (i) a patient has to pay out of pocket and (ii) manufacturer coupons are rejected at the pharmacy. For example, since 2014, we have increased the level of rebates granted for Lantus<sup>®</sup> in order to maintain favorable formulary positions with key payers in the US. Despite these efforts, in 2016 CVS and UnitedHealthcare (a PBM and MCO, respectively) decided that effective January 1, 2017 and April 1, 2017, respectively, Lantus<sup>®</sup> and Toujeo<sup>®</sup> will be excluded from the formulary across the commercial and MMC (Medicaid Managed Care) template formularies covering approximately 34.7 million people, thus reducing the potential patient populations to whom Lantus<sup>®</sup> may be prescribed.

US insurers have prioritized the need to control costs in specialty categories, and will maximize exclusions and protocols to achieve savings. There is a particular focus on all chronic disease states, which will limit the ability of new entrants to achieve coverage without demonstration of comparative effectiveness. Finally, US insurers are quick to adopt Follow-On-Biologic (copycat) versions of branded drugs as a good enough alternative to leverage higher rebates as compared with incumbent products.

In addition, distributors have increased their capacity to negotiate price and other terms as a consequence of the growing number of mergers of retail chains and distributors, resulting consolidation of the distribution channel.

The industry in China is going through a transformative period. The most significant changes as regards innovation in the industry are the highly-publicized price negotiations with the NHFPC (National Health and Family Planning Commission), and the subsequent order to list drugs on provincial formularies. The first update of the NRDL

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

(National Reimbursement Drug List) since 2009 is expected in 2017. The CFDA (China Food and Drugs Administration) has also made clear its intent to clear the backlog of regulatory reviews. The market itself is due to transform through a series of smaller measures. For example, a two-invoice policy will simplify the supply chain, and tax reform has reallocated funds to poorer provinces for healthcare. While these can be viewed as positive, there are many uncertainties. The CFDA finally abandoned a proposal to tie regulatory approval to price commitments based on international price referencing, while it has been announced that the NRDL will use the lowest provincial tender price as a reimbursement basis, which is strongly contested. Whatever the outcome, we can expect many other measures in the Chinese market following a call to step up the pace of reforms.

Recent trends in European policy have been towards joint procurement and joint negotiations, ignited by the controversy on funding Hepatitis C drugs. At the same time, political instability (such as the post-Brexit UK and new measures in Greece) is ever-present. However, some positive signs have begun to appear, such as a dedicated budget for innovative medicines in Italy, though these remain exceptions in a political environment that is increasingly hostile to the industry.

Japan has made high-profile price cuts this year outside of the biennial review, and seems set to move to a yearly price review with the overall objective of cutting costs; again, this reflects budget pressure induced by the funding of Hepatitis C drugs.

In South America, inflation has had a major effect on the sustainability of the industry in the region, most notably in Venezuela.

The Eurasian Economic Union has signed a final agreement on a single market for medicines (Armenia, Belarus, Kazakhstan, Kyrgyzstan and Russia), which should streamline processes but also increase the region's negotiating power. Similar developments have been taking place in South America: UNASUR (Union of South American Nations) has announced a centralized pricing database, while discussions are ongoing on joint procurement of expensive oncology medicines.

We believe that third-party payers will continue to act to curb the cost of pharmaceutical products. While the impact of those measures cannot be predicted with certainty, we are taking the necessary steps to defend the accessibility and price of our products in order to reflect the value of our innovative product offerings:

- In compliance with local law we actively engage with our key stakeholders to define criteria for assessing the value of our products to them. These stakeholders, including physicians, patient groups, pharmacists, government authorities and third-party payers, can have a significant impact on market access for our products.

- We continue to add flexibility and adaptability to our operations so as to better prepare, diagnose, and address issues in individual markets. Conscious of the importance of recognizing the value of our products and the high cost of research and development, we continue to analyze innovative pricing and access strategies that balance patient access with appropriate rewards for innovation. Specifically, we are involved in risk-sharing agreements with payers, whereby part of the financial risk related to a treatment's success is carried by the marketing company. Those agreements provide that clinical efficacy be monitored after launch, for a specified period of time and patient population. The price and reimbursement level of the drug is then either confirmed or revised based on the post-marketing results.

We are also actively testing and running tiered pricing models where this is possible, allowing wider access to therapies for populations that would otherwise be denied this.

## B.7. PATENTS, INTELLECTUAL PROPERTY AND OTHER RIGHTS

### Patent Protection

We own a broad portfolio of patents, patent applications and patent licenses worldwide. These patents are of various types and may cover:

- active ingredients;
- pharmaceutical formulations;
- product manufacturing processes;
- intermediate chemical compounds;
- therapeutic indications/methods of use;
- delivery systems; and
- enabling technologies, such as assays.

Patent protection for individual products typically extends for 20 years from the patent filing date in countries where we seek patent protection. A substantial part of the 20-year life span of a patent on a new molecule (small molecule or biologic) has generally already passed by the time the related product obtains marketing approval. As a result, the effective period of patent protection for an approved product's active ingredient is significantly shorter than 20 years. In some cases, the period of effective protection may be extended by procedures established to compensate

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

regulatory delay in Europe (a Supplementary Protection Certificate or SPC), the US (a Patent Term Extension or PTE) and Japan (also a PTE).

Additionally, the product may benefit from the protection of patents obtained during development or after the product's initial marketing approval. The protection a patent provides the related product depends upon the type of patent and its scope of coverage, and may also vary from country to country. In Europe for instance, applications for new patents may be submitted to the European Patent Office (EPO), an intergovernmental organization which centralizes filing and prosecution. As of December 2015, an EPO patent application may cover the 38 European Patent Convention member states, including all 28 member states of the EU. The European Patent establishes corresponding national patents with uniform patent claims among the member states. However, some older patents were not approved through this centralized process, resulting in patents having claim terms for the same invention that differ by country. Additionally, a number of patents prosecuted through the EPO may pre-date the European Patent Convention accession of some current European Patent Convention member states, resulting in different treatment in those countries.

In 2013, EU legislation was adopted to create a European patent (Unitary Patent) and a Unified Patent Court. However, it will only enter into force once the agreement on the Unified Patent Court is ratified by at least 13 Member States including France, Germany, and the United Kingdom. As of the date of this document, 12 countries including France have ratified the agreement.

The Unitary Patent will provide unitary protection within the participating states of the EU (when ratified by the member states with the exception of Spain). The Unified Patent Court will be a specialized patent court with exclusive jurisdiction for litigation relating to European patents and Unitary Patents. The Court will be composed of a central division (headquartered in Paris) and by several local and regional divisions in the contracting Member States to the agreement. The Court of Appeal will be located in Luxembourg.

We monitor our competitors and vigorously seek to challenge patent infringements when such infringements would negatively impact our business objectives. See Item 8 A. Consolidated Financial Statements and Other Financial Information A.3. Information on Legal or Arbitration Proceedings Patents of this annual report.

The expiration or loss of a patent covering a new molecule, typically referred to as a compound patent, may result in significant competition from generic products and can result in a dramatic reduction in sales of the original branded product (see Item 3. Key Information D. Risk Factors ). In

some cases, it is possible to continue to obtain commercial benefits from product manufacturing trade secrets or from other types of patents, such as patents on processes, intermediates, structure, formulations, methods of treatment, indications or delivery systems. Certain categories of products, such as traditional vaccines and insulin, have been historically relatively less reliant on patent protection and may in many cases have no patent coverage, although it is increasingly frequent for novel vaccines and insulins to be patent protected. Patent protection is of comparatively lesser importance to our Consumer Healthcare and generics businesses, which rely principally on trademark protection.

**Regulatory Exclusivity**

In some markets, including the EU and the US, many of our pharmaceutical products may also benefit from multi-year regulatory exclusivity periods, during which a generic competitor may not rely on our clinical trial and safety data in its drug application. Exclusivity is meant to encourage investment in research and development by providing innovators with exclusive use, for a limited time, of the innovation represented by a newly approved drug product. This exclusivity operates independently of patent protection and may protect the product from generic competition even if there is no patent covering the product.

In the US, the FDA will not grant final marketing approval to a generic competitor for a New Chemical Entity (NCE) until the expiration of the regulatory exclusivity period (five years) that commences upon the first marketing authorization of the reference product. The FDA will accept

## Edgar Filing: Sanofi - Form 20-F

the filing of an Abbreviated New Drug Application (ANDA) containing a patent challenge one year before the end of this regulatory exclusivity period (see the descriptions of ANDAs in [Product Overview](#) [Challenges to Patented Products](#) below). In addition to the regulatory exclusivity granted to NCEs, significant line extensions of existing NCEs may qualify for an additional three years of regulatory exclusivity. Also, under certain limited conditions, it is possible to extend unexpired US regulatory and patent-related exclusivities by a pediatric extension. See [Pediatric Extension](#) , below.

In the US, a different regulatory exclusivity period applies to biological drugs. The Biologics Price Competition and Innovation Act of 2009 ( BPCIA ), was enacted on March 23, 2010 as part of the much larger health care reform legislation known as the Affordable Care Act. The BPCIA introduced an approval pathway for biosimilar products. A biosimilar product is a biologic product that is highly similar to the reference (or innovator) product notwithstanding minor differences in clinically inactive components, and which has no clinically meaningful differences from the reference product in terms of the safety, purity, and potency of the product. The BPCIA provides that an application for a

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

biosimilar product that relies on a reference product may not be submitted to the FDA until four years after the date on which the reference product was first licensed, and that the FDA may not approve a biosimilar application until 12 years after the date on which the reference product was first licensed. US Federal and state officials, including the new Administration, are continuing to focus on the cost of health coverage and health care although the future policy, including the nature and timing of any changes to the Affordable Care Act, remains unclear.

In the EU, regulatory exclusivity is available in two forms: data exclusivity and marketing exclusivity. Generic drug applications will not be accepted for review until eight years after the first marketing authorization (data exclusivity). This eight-year period is followed by a two-year period during which generics cannot be marketed (marketing exclusivity). The marketing exclusivity period can be extended to three years if, during the first eight-year period, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which are deemed to provide a significant clinical benefit over existing therapies. This is known as the "8+2+1" rule.

In Japan, the regulatory exclusivity period varies from four years for medicinal products with new indications, formulations, dosages, or compositions with related prescriptions, to six years for new drugs containing a medicinal composition, or requiring a new route of administration, to eight years for drugs containing a new chemical entity, to ten years for orphan drugs or new drugs requiring pharmaco-epidemiological study.

**Emerging Markets**

One of the main limitations on our operations in emerging market countries is the lack of effective intellectual property protection or enforcement for our products. The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIP) required developing countries to amend their intellectual property laws to provide patent protection for pharmaceutical products since January 1, 2005, although it provided a limited number of developing countries an extension to 2016. Additionally, these same countries frequently do not provide non-patent exclusivity for innovative products. While the situation has gradually improved, the lack of protection for intellectual property rights or the lack of robust enforcement of intellectual property rights poses difficulties in certain countries. Additionally, in recent years a number of countries facing health crises have waived or threatened to waive intellectual property protection for specific products, for example through compulsory licensing of generics. See Item 3. Key Information D. Risk Factors Risks Relating to Sanofi's Structure and Strategy The globalization of our business exposes us to increased risks in specific areas .

**Pediatric Extension**

In the US and the EU, under certain conditions, it is possible to extend a product's regulatory exclusivity for an additional period of time by providing data regarding pediatric studies.

In the US, the FDA may ask a company for pediatric studies if it has determined that information related to the use of the drugs in the pediatric population may produce health benefits. The FDA has invited us by written request to provide additional pediatric data on several of our main products. Under the Hatch-Waxman Act, timely provision of data meeting the FDA's requirements (regardless of whether the data supports a pediatric indication) may result in the FDA extending regulatory exclusivity and patent life by six months, to the extent these protections have not already expired (the so-called "pediatric exclusivity").

In Europe, a regulation on pediatric medicines provides for pediatric research obligations with potential associated rewards including extension of patent protection (for patented medicinal products) and six month regulatory exclusivity for pediatric marketing authorization (for off-patent medicinal products).

In Japan, there is no pediatric research extension of patent protection (for patented medicinal products). However, regulatory exclusivity may be extended from eight to ten years.

### **Orphan Drug Exclusivity**

Orphan drug exclusivity may be granted in the US to drugs intended to treat rare diseases or conditions (affecting fewer than 200,000 patients in the US, or in some cases more than 200,000 with no expectation of recovering costs).

Obtaining orphan drug exclusivity is a two step process. An applicant must first seek and obtain orphan drug designation from the FDA for its drug. If the FDA approves the drug for the designated indication, the drug will generally receive orphan drug exclusivity.

Orphan drug exclusivity runs from the time of approval and bars approval of another application (ANDA, 505(b)(2), New Drug Application (NDA) or Biologic License Application (BLA)) from a different sponsor for the same drug in the same indication for a seven year period. Whether a subsequent application is for the same drug depends upon the chemical and clinical characteristics. The FDA may approve applications for the same drug for indications not protected by orphan exclusivity.

Orphan drug exclusivities also exist in the EU and Japan.

### **Product Overview**

We summarize below the intellectual property coverage in our major markets of the marketed products described

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

above at B.2. Main Pharmaceutical Products . In the discussion of patents below, we focus on active ingredient patents (compound patents) and for NCEs on any later filed patents listed, as applicable, in the FDA’s list of Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book ) or in their foreign equivalents. For Biologics the Orange Book listing does not apply. These patents or their foreign equivalents tend to be the most relevant in the event of an application by a competitor to produce a generic or a biosimilar version of one of our products (see Challenges to Patented Products below). In some cases, products may also benefit from pending patent applications or from patents not eligible for Orange Book listing (for NCEs) (e.g. patents claiming industrial processes). In each case below, we specify whether the active ingredient is claimed by an unexpired patent. Where patent terms have been extended to compensate for regulatory delay, the extended dates are presented below. US patent expirations presented below reflect US Patent and Trademark Office dates, and also reflect six month pediatric

extensions as applicable. Where patent terms have expired we indicate such information and mention if generics are on the market.

We do not provide later filed patent information relating to formulations already available as an unlicensed generic. References below to patent protection in Europe indicate the existence of relevant patents in most major markets in the EU. Specific situations may vary by country, most notably with respect to older patents and to countries that have only recently joined the EU.

We additionally set out any regulatory exclusivity from which these products continue to benefit in the US, EU or Japan. Regulatory exclusivities presented below incorporate any pediatric extensions obtained. While EU regulatory exclusivity is intended to be applied throughout the EU, in some cases Member States have taken positions prejudicial to our exclusivity rights.

*Aldurazyme® (laronidase)*

<p><b>US</b> Compound: November 2019</p> <p>Later filed patents: ranging through July 2020</p> <p><i>Allegra® (fexofenadine hydrochloride)</i></p>	<p><b>EU</b> Compound: November 2020 in some EU countries only</p>	<p><b>Japan</b> Compound: November 2020</p>
--	--	---

<p><b>US</b> Compound: expired Generics on the market Converted to Over-the-Counter</p> <p><i>Amaryl® (glimepiride)</i></p>	<p><b>EU</b> Compound: expired Generics on the market</p>	<p><b>Japan</b> Compound: expired Generics on the market Converted to over-the counter</p>
---	---	--

## Edgar Filing: Sanofi - Form 20-F

### US

Compound: expired  
*Apidra*<sup>®</sup> (*insulin glulisine*)

### EU

Compound: expired

### Japan

Compound: expired

### US

Compound: June 2018

Later filed patents: ranging

through September 2027

*Aprovel*<sup>®</sup> (*irbesartan*)

### EU

Compound: September 2019 with SPC in most of the EU countries

Later filed patent: March 2022

### Japan

Compound: May 2022 with PTE

Later filed patent: July 2022

Regulatory exclusivity: April 2017

### US

Compound: expired  
Generics on the market

### EU

Compound: expired  
Generics on the market

### Japan

Compound: expired

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****Aubagio® (teriflunomide)**

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: expired Later filed patents: coverage ranging through September 2034 Regulatory exclusivity: September 2017 <b>Cerdelga® (eliglustat)</b>	Compound: expired Later filed patent: coverage ranging through September 2030 Regulatory exclusivity: August 2023	Compound: expired Later filed patent: coverage ranging through March 2024

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: April 2022  (2026 with PTE when granted) Later filed patent: November 2030 (pending) Regulatory exclusivity: August 2019 Orphan Drug Exclusivity: August 2021 <b>Cerezyme® (imiglucerase)</b>	Compound: July 2022  (2027 with SPC when granted) Later filed patent: November 2030 Regulatory/Orphan exclusivity: January 2025	Compound: March 2025 with PTE  Later filed patent: November 2030 (pending) Regulatory exclusivity: March 2023

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: expired <b>Depakine® (sodium valproate)</b>	Compound: N/A	Compound: N/A

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: N/A <sup>(a)</sup>	Compound: N/A <sup>(a)</sup> Later filed patent: Depakine® Chronosphere formulation (October 2017)	Compound: N/A <sup>(a)</sup> Later filed patent: Depakine® Chronosphere formulation (October 2017)

(a) No rights to compounds in the US, EU and Japan.  
**Fabrazyme® (agalsidase beta)**

Edgar Filing: Sanofi - Form 20-F

<b>US</b> Compound: N/A Later filed patents: expired <i>Insuman® (human insulin)</i>	<b>EU</b> Compound: N/A	<b>Japan</b> Compound: N/A Later filed patents: expired
<b>US</b> Compound: N/A  <i>Jevtana® (cabazitaxel)</i>	<b>EU</b> Compound: N/A  Later filed patent: August 2018	<b>Japan</b>  Compound: N/A
<b>US</b> Compound: March 2021 with PTE Later filed patents: coverage ranging through October 2030	<b>EU</b> Compound: expired Later filed patents: coverage ranging through October 2030 (pending) Regulatory exclusivity: March 2021	<b>Japan</b> Compound: March 2021 with PTE Later filed patents: coverage ranging through October 2030 Regulatory exclusivity: July 2022

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****Lantus® (insulin glargine)**

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: expired Later filed patents <sup>(a)</sup> ranging through March 2028	Compound: Expired Later filed patents ranging through June 2023	Compound: expired Later filed patents ranging through June 2023

(a) On September 16, 2016, several Sanofi entities filed a patent infringement suit against Merck Sharp & Dohme Corp. ( Merck ) in the United States District Court for the District of Delaware. In its suit, Sanofi alleges infringement of ten patents. The suit was triggered by a notification received from Merck in early August, in which Merck stated that it had filed an NDA (505(b)(2) New Drug Application) with FDA for an insulin glargine drug product. Merck also stated that its NDA included a paragraph IV certification challenging all of the ten Sanofi patents then listed in the FDA Orange Book for Sanofi's Lantus® and Lantus® SoloStar® products. This suit resulted in a stay during which the FDA cannot approve Merck's NDA. The 30 month stay is expected to expire on the earlier of (1) February 8, 2019 or (2) a court decision in favor of Merck. The Court has scheduled a bench trial to begin on May 29, 2018, a claim construction hearing for August 21, 2017 and briefing on summary judgment motions on certain issues pertaining to some of the patents-in-suit to begin on October 2, 2017.

**Lemtrada® (alemtuzumab)**

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: expired Later filed patents: ranging through September 2027 (pending) <b>Lovenox® (enoxaparin sodium)</b>	Compound: expired  Later filed patent: September 2027	Compound: expired Later filed patent: September 2027 (pending)

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: N/A Generics on the market <b>Lumizyme® / Myozyme® (alglucosidase alpha)</b>	Compound: expired	Compound: expired

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: N/A Later filed patents: coverage ranging through February 2023 <sup>(a)</sup> Biologics Regulatory Exclusivity: April 2018	Compound: N/A Later filed patents: July 2021	Compound: N/A Later filed patents: July 2021  Orphan Regulatory Exclusivity: April 2017

(a) Genzyme filed a notice of appeal to the Federal Circuit to challenge successful inter partes review (IPR). For more information refer to Item 8 Consolidated Financial Statements and other Financial Information Information on Legal and Arbitration Proceedings Genzyme Myozyme® Lumizyme Patent Litigation (United States).

## Edgar Filing: Sanofi - Form 20-F

### *Lyxumia®/Adlyxin (lixisenatide)*

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: July 2020 <sup>(a)</sup> (July 2025 with PTE when granted)	Compound: July 2020 <sup>(a)</sup> (2025 with SPC in most EU countries)	Compound: July 2024 <sup>(a)</sup> with PTE
Later filed patents: coverage ranging through December 2033 (pending)	Later filed patents: coverage ranging through March 2034 (pending)	Later filed patents: coverage ranging through November 2030
Regulatory Exclusivity: July 2021	Regulatory Exclusivity: February 2023	Regulatory Exclusivity: June 2021

*(a) Lixisenatide compound patent licensed exclusively from Zealand Pharma*

### *Mozobil® (plerixafor)*

<b>US</b>	<b>EU</b>	<b>Japan</b>
Compound: N/A	Compound: N/A	Compound: N/A
Later filed patents: coverage ranging through July 2023	Later filed patent: July 2022 (2024 with SPC in some EU countries)	Later filed patent: July 2022
	Orphan Drug Exclusivity: August 2019	

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****Multaq<sup>®</sup> (dronedaron hydrochloride)**

<b>US</b> Compound: expired Later filed patents: coverage ranging through December 2031	<b>EU</b> Compound: expired Later filed patent: June 2018 (2023 with SPC in most EU countries) Regulatory exclusivity: December 2019	<b>Japan</b> Compound: expired Later filed patent: June 2018
---	---	--

**Soliqua 100/33 / Suliqua (lixisenatide + insulin glargine)**

<b>US</b> Compound: July 2020 <sup>(a)</sup>  (July 2025 with PTE when granted) Later filed patents: coverage ranging through November 2030 (pending) Regulatory Exclusivity: July 2021	<b>EU</b> Compound: July 2020 <sup>(a)</sup>  (2025 with SPC in most EU countries) Later filed patents: coverage ranging through November 2030 Regulatory Exclusivity: January 2027	<b>Japan</b> Compound: July 2024 <sup>(a)</sup> with PTE  Later filed patents: coverage ranging through November 2030 Regulatory Exclusivity: to be determined
--	--	--

(a) Lixisenatide compound patent licensed exclusively from Zealand Pharma  
**Plavix<sup>®</sup> (clopidogrel bisulfate)**

<b>US</b> Compound: expired Generics on the market <b>Praluent<sup>®</sup> (alirocumab)</b>	<b>EU</b> Compound: expired Generics on the market	<b>Japan</b> Compound: expired
--	--	-----------------------------------

<b>US</b> Compound: December 2029 Later filed patents: coverage ranging through September 2032 (pending)  Biologics Regulatory Exclusivity: July 2027	<b>EU</b> Compound: December 2029 Later filed patents: coverage ranging through September 2032  (pending) Regulatory exclusivity:  September 2025	<b>Japan</b> Compound: December 2029 Later filed patents: coverage ranging through September 2032 (pending)
---	--	---

**Renagel<sup>®</sup> (sevelamer hydrochloride)**

## Edgar Filing: Sanofi - Form 20-F

### US

Compound: N/A  
Later filed patent: October 2020

*Renvela*<sup>®</sup> (*sevelamer carbonate*)

### EU

Compound: N/A  
Later filed patent:

October 2020

Generics on the market

### Japan

Compound: N/A  
Later filed patent:

October 2020

### US

Compound: N/A  
Later filed patents: October 2025 (tablet) and  
December 2030 (sachet)

*Stilnox*<sup>®</sup> (*zolpidem tartrate*)

### EU

Compound: N/A  
Later filed patent: September 2026 (sachet)  
Generics on the market

### Japan

Compound: N/A  
Later filed patents: November 2025 (tablet)  
and September 2026 (sachet)

### US

Compound: expired  
Generics on the market

### EU

Compound : expired  
Generics on the market

### Japan

Compound : expired  
Later filed patent: Ambien<sup>®</sup>  
CR formulation (December 2019) not  
commercialized

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY***Synvisc® (hyaline G-F 20)*

**US**  
Compound: expired  
*Synvisc-One® (hyaline G-F 20)*

**EU**  
Compound: N/A

**Japan**  
Compound: expired

**US**  
Compound: expired

**EU**  
Compound: N/A

**Japan**  
Compound: expired

*Toujeo® (insulin glargine)*

Later filed patent: December 2025

Later filed patent: December 2025

**US**  
Compound: expired  
Later filed patents:  
coverage ranging through May 2031

**EU**  
Compound: expired  
Later filed patents:  
coverage ranging through May 2031

**Japan**  
Compound: expired  
Later filed patents:  
coverage ranging through July 2033 with  
PTE  
Regulatory exclusivity: July 2019

Regulatory exclusivity: February 2018  
*Zaltrap® (afibercept)*

**US**  
Compound: May 2020 (July 2022 with PTE  
when granted)\*  
Later filed patents: coverage ranging through  
April 2032 (applications pending)  
Biologics Regulatory Exclusivity:  
November 2023

**EU**  
Compound: May 2020 (May 2025 with SPC  
in some EU countries)\*  
Later filed patents: coverage ranging  
through April 2032 (pending)  
Regulatory Exclusivity: February 2023

**Japan**  
Compound: May 2020\* (PTE to be  
determined once product is approved)  
Later filed patents: coverage ranging  
through April 2032 (pending)

\* Patents under license of Regeneron Pharmaceuticals, Inc.

Patents held or licensed by Sanofi do not in all cases provide effective protection against a competitor's generic version of our products. For example, notwithstanding the presence of unexpired patents, competitors launched generic versions of Allegra® in the US (prior to the product being switched to over-the-counter status) and Plavix® in the EU.

We caution the reader that there can be no assurance that we will prevail when we assert a patent in litigation and that there may be instances in which Sanofi determines that it does not have a sufficient basis to assert one or more of the patents mentioned in this report, for example in cases where a competitor proposes a formulation not appearing to fall within the claims of our formulation patent, a salt or crystalline form not claimed by our composition of matter patent, or an indication not covered by our method of use patent. See Item 3. Key Information D. Risk

Factors Risks Relating to Legal and Regulatory Matters We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected .

As disclosed in Item 8 of this annual report, we are involved in significant litigation concerning the patent protection of a number of our products.

### Challenges to Patented Products

#### Abbreviated New Drug Applications (ANDAs)

In the US, companies have filed Abbreviated New Drug Applications (ANDAs), containing challenges to patents related to a number of our products. An ANDA is an application by a drug manufacturer to receive authority to market a generic version of another company's approved product, by demonstrating that the purportedly generic version has the same properties as the original approved product. ANDAs may not be filed with respect to drugs licensed as a biological. See B.6.3. Regulatory Framework B.6.3.2. Biosimilars below. An ANDA relies on the safety and other technical data of the original approved product, and does not generally require the generic manufacturer to conduct clinical trials (thus the name abbreviated new drug application), presenting a significant benefit in terms of time and cost. As a result of regulatory protection of our safety and other technical data, the ANDA may generally be filed only five years following the initial US marketing authorization of the original product. See Regulatory Exclusivity above. This period can be reduced to four years if the ANDA includes a challenge to a patent listed in the FDA's Orange Book. However, in such a case if the patent holder or licensee brings suit in response to the patent challenge within the statutory window, then the FDA

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY**

is barred from granting final approval to an ANDA during the 30 months following the patent challenge (this bar is referred to in our industry as a 30-month stay), unless, before the end of the 30 months, a court decision or settlement has determined either that the ANDA does not infringe the listed patent or that the listed patent is invalid and/or unenforceable.

FDA approval of an ANDA after this 30-month period does not resolve outstanding patent disputes, but it does remove the regulatory impediments to a product launch by a generic manufacturer willing to take the risk of later being ordered to pay damages to the patent holder.

The accelerated ANDA-type procedures are potentially applicable to many, but not all, of the products we manufacture. See B.6.3. Regulatory Framework 6.3.2. Biosimilars and Regulation below. We seek to defend our patent rights vigorously in these cases. Success or failure in the assertion of a given patent against a competing product is not necessarily predictive of the future success or failure in the assertion of the same patent or *a fortiori* the corresponding foreign patent against another competing product due to factors such as possible differences in the formulations of the competing products, intervening developments in law or jurisprudence, local variations in the patents and differences in national patent law and legal systems. See Item 3. Key Information D. Risk Factors Risks Relating to Legal and Regulatory Matters We rely on our patents and other proprietary rights to provide exclusive rights to market certain of our products, and if such patents and other rights were limited or circumvented, our financial results could be materially and adversely affected.

· Section 505(b)(2) New Drug Applications in the US

Our products and patents are also subject to challenge by competitors via another abbreviated approval pathway, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. This provision expressly permits an applicant to rely, at least in part, on the FDA's prior findings of safety and effectiveness of a drug that has obtained FDA approval. The FDA may still require applicants to provide additional preclinical or clinical data to ensure that differences from the reference drug do not compromise safety and effectiveness. This pathway allows for approval for a wide range of products, especially for those products that represent only a limited change from an existing approved drug. The 505(b)(2) pathway is distinct from the ANDA pathway, which allows for approval of a generic product based on a showing that it is equivalent to a previously approved product.

A 505(b)(2) applicant is required to identify the reference drug on which it relies, as well as to certify to the FDA concerning any patents listed for the referenced product in the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). Specifically, the applicant must certify in the application that,

for each patent that claims the drug or a use of the drug for which the applicant is seeking approval:

- there is no patent information listed for the reference drug (paragraph I certification);
- the listed patent has expired for the reference drug (paragraph II certification);
- the listed patent for the reference drug has not expired, but will expire on a particular date and approval is sought after patent expiration (paragraph III certification); or

## Edgar Filing: Sanofi - Form 20-F

the listed patent for the reference drug is invalid, unenforceable, or will not be infringed by the manufacture, use or sale of the product for which the 505(b)(2) NDA is submitted (paragraph IV certification).

A paragraph III certification may delay the approval of an application until the expiration of the patent. A paragraph IV certification generally requires notification of the patent owner and the holder of the NDA for the referenced product. If the patent owner or NDA holder brings patent litigation against the applicant within the statutory window, a 30-month stay is entered on the FDA's ability to grant final approval to the 505(b)(2) applicant unless, before the end of the stay, a court decision or settlement determines the listed patent is invalid, not enforceable, and/or not infringed. A 505(b)(2) application may also be subject to non-patent exclusivity, and the FDA may be prohibited from giving final approval to a 505(b)(2) application until the expiration of all applicable non-patent exclusivity periods.

In the EU, a generic drug manufacturer may only reference the data of the regulatory file for the original approved product after data exclusivity has expired. However, there is no patent listing system in Europe comparable to the Orange Book, which would allow the patent holder to prevent the competent authorities from granting marketing approval by bringing patent infringement litigation prior to approval. As a result, generic products may be approved for marketing following the expiration of marketing exclusivity without regard to the patent holder's rights. Nevertheless, in most of these jurisdictions once the competing product is launched, and in some jurisdictions even prior to launch (once launch is imminent), the patent holder may seek an injunction against such marketing if it believes its patents are infringed. See Item 8 of this annual report.

### **Trademarks**

Our products are sold around the world under trademarks that we consider to be of material importance in the aggregate. Our trademarks help to identify our products and to protect the sustainability of our growth. Trademarks are particularly important to the commercial success of CHC and generics.

It is our policy to protect and register our trademarks with a strategy adapted to each product or service depending on

---

## **Table of Contents**

### **ITEM 4. INFORMATION ON THE COMPANY**

the countries where they are commercialized: on a worldwide basis for worldwide products or services, or on a regional or local basis for regional or local products or services.

The process and degree of trademark protection vary country by country, as each country applies its own trademark laws and regulations. In most countries, trademark rights may only be obtained through formal trademark application and registration. In some countries, trademark protection can be based primarily on use. Registrations are granted for a fixed term (in most cases ten years) and are renewable indefinitely, except in some countries where maintenance of the trademarks is subject to their effective use.

When trademark protection is based on use, it covers the products and services for which the trademark is used. When trademark protection is based on registration, it covers only the products and services designated in the registration certificate. Additionally, in certain cases, we may enter into a coexistence agreement with a third party that owns potentially conflicting rights in order to avoid any risk of confusion and better protect and defend our trademarks.

Our trademarks are monitored and defended based on this policy and in order to prevent counterfeit, infringement and/or unfair competition.

#### **B.8. Production and Raw Materials**

For many years, we have chosen, as often as possible, to keep the manufacture of our products in-house in order to ensure better quality management. Our production process consists of three principal stages: the manufacture of pharmaceutical active ingredients, the transformation of those ingredients into drug products, and packaging those products.

Our general policy is to produce our main active ingredients and principal drug products at our own plants in order to reduce our dependence on external manufacturers and to maintain strict and precise control over the entire production cycle. In significant cases, however, we rely on third parties for the manufacture and supply of certain active ingredients, drug products and medical devices. Active ingredients are manufactured using raw materials sourced from suppliers who have been subject to rigorous selection and approval procedures, in accordance with international standards and our own internal directives. We have outsourced some of our production under supply contracts associated with acquisitions of products or businesses or with plant divestitures, or to establish a local presence to capitalize on growth in emerging markets. Our main pharmaceutical subcontractors are Famar, MSD, Unither, Delpharm and Saneca. Those subcontractors follow our general quality and logistics policies, as well as meeting other criteria. See Item 3. Key Information D. Risk Factors Risks Relating to Our Business .

We also obtain active ingredients from third parties under partnership agreements. This applies to the monoclonal antibodies developed with Regeneron.

Our pharmaceutical production sites are divided into three categories:

- global sites, which serve all markets: located mainly in Europe, these facilities are dedicated to the manufacture of our active ingredients, injectable drug products, and a number of our main solid-form drug products;
- regional sites, which serve markets at regional level, in Europe and particularly the BRIC-M countries (Brazil, Russia, India, China and Mexico), giving us a strong industrial presence in emerging markets; and
- local sites, which serve their domestic market only.

## Edgar Filing: Sanofi - Form 20-F

Sanofi Pasteur produces vaccines at sites located in the United States, Canada, France, Mexico, China, Thailand, Argentina and India. The pharmaceutical sites at Le Trait (France) and Anagni (Italy) also contribute to Sanofi Pasteur's industrial operations by making available their aseptic filling and freeze-drying facilities.

All of our production facilities – whether in Pharmaceuticals, Sanofi Genzyme or Vaccines – are good manufacturing practice (GMP) compliant, in line with international guidelines.

Many of our industrial sites are approved by the US Food and Drug Administration (FDA):

- our Pharmaceuticals facilities in France (Ambarès, Tours, Le Trait, Maisons Alfort, Compiègne and Lyon Gerland), the United Kingdom (Haverhill and Holmes Chapel), Ireland (Waterford), Germany (Frankfurt), Italy (Anagni) and the United States (Saint Louis and Chattanooga);
  - the Sanofi Genzyme facilities in the United States (Allston, Framingham, Ridgefield, Northpointe-Lynnwood and Northborough) and in Belgium (Geel); and
  - our Vaccines sites in France (Marcy l'Étoile, and Le Trait which handles filling and packaging of Fluzon® ID for the US market), the United States (Swiftwater, Canton and Rockville) and Canada (Toronto).
- Wherever possible, we seek to have multiple plants approved for the production of key active ingredients and our strategic finished products (this is the case with Lovenox®, for example).

In May 2010, Genzyme's Allston facility in the United States entered into a consent decree with the FDA following FDA inspections at the facility that resulted in observations and a warning letter raising Current Good Manufacturing Practices (CGMP) deficiencies. A consent decree is a court order entered into by agreement between a company and the government (in this case the FDA) that requires the company to take certain actions as set out in the decree.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Under the terms of the consent decree, Genzyme Allston was permitted to continue manufacturing during the remediation process subject to compliance with the terms of the consent decree.

The consent decree required Genzyme to implement a plan to bring operations at the Allston facility into compliance with applicable laws and regulations. The plan had to address all deficiencies reported to Genzyme or identified as part of an inspection completed by a third-party expert in February 2011. This workplan was submitted to the FDA in April 2011 and accepted by the FDA in January 2012. Modifications to the remediation workplan were accepted by the FDA in March 2012 and April 2015.

The workplan was successfully completed on March 31, 2016. The next step in the consent decree is a third-party certification process; this is ongoing, and is due to be finalized by the end of 2017.

Once the certification process is finalized, the Allston facility will remain under consent decree for an additional period of at least five years, with yearly inspections by the FDA.

In April 2014, the FDA withdrew the warning letter relating to the Sanofi Pasteur sites at Toronto (Canada) and Marcy 1 Étoile (France). Sanofi Pasteur is implementing an ongoing program to improve compliance at those sites by applying a Global Quality Plan. This has already resulted in important improvements, as acknowledged in the most recent CGMP inspection conducted by the FDA at the Marcy 1 Étoile site in September 2015.

More details about our manufacturing sites are given below at section D. Property, Plant and Equipment .

**B.9. Insurance and Risk Coverage**

We are protected by four key insurance programs, relying not only on the traditional corporate insurance and reinsurance market but also on our captive insurance company, Carraig Insurance DAC (Carraig).

These four key programs cover Property & Business Interruption, General & Product Liability, Stock and Transit, and Directors & Officers Liability.

Carraig participates in our coverage for various lines of insurance including Property & Business Interruption, Stock and Transit, and General & Product Liability. Carraig is run under the supervision of the Irish regulatory authorities, is wholly-owned by Sanofi, and has sufficient resources to meet those portions of our risks that it has agreed to cover.

It sets premiums for our entities at market rates. Claims are assessed using the traditional models applied by insurance and reinsurance companies, and the company's reserves are regularly verified and confirmed by independent actuaries.

Our Property & Business Interruption program covers all our entities worldwide, wherever it is possible to use a centralized program operated by our captive insurance company. This approach shares risk between our entities, enabling us to set deductibles and guarantees that are appropriate to the needs of local entities. It also incorporates a prevention program, including a comprehensive site visit program covering our production, storage, research and distribution facilities and standardized repair and maintenance procedures across all sites. Specialist site visits are conducted every year to address specific needs, such as testing of sprinkler systems or emergency plans to deal with flooding risks.

The Stock and Transit program protects all goods owned by Sanofi while they are in transit nationally or internationally whatever the means of transport, and all our inventories wherever they are located. Sharing risk between our entities means that we can set deductibles at appropriate

## Edgar Filing: Sanofi - Form 20-F

levels, for instance differentiating between goods that require temperature controlled distribution and those that do not. We have developed a prevention program with assistance from experts, implementing best practices in this area at our distribution sites. This program, which is led by our captive insurance company, has substantial capacity, largely to deal with the growth in sea freight which can lead to a concentration of value in a single ship.

Our General & Product Liability program has been renewed for all our subsidiaries worldwide wherever it was possible to do so, despite the increasing reluctance in the insurance and reinsurance market to cover product liability risks for large pharmaceutical groups. For several years, insurers have been reducing product liability cover because of the difficulty of insuring some products that have been subject to numerous claims. These products are excluded from the cover provided by insurers, and hence from the cover obtained by us on the insurance market. This applies to a few of our products, principally those described in Note D.22.a) to our consolidated financial statements included at Item 18 in this annual report. Because of these market conditions we have increased, year by year, the extent to which we self-insure.

The principal risk exposure for our pharmaceutical products is covered with low deductibles at country level, the greatest level of risk being retained by our captive insurance company. The level of risk self-insured by Sanofi including via our captive reinsurance company enables us to retain control over the management and prevention of risk. Our negotiations with third party insurers and reinsurers are tailored to our specific risks. In particular, they allow for differential treatment of products in the development phase, for the discrepancies in risk exposure between European countries and the United States, and for specific issues arising in certain jurisdictions such as generics coverage in the United States. Coverage is adjusted every year in order

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

to take into account the relative weight of new product liability risks, such as those relating to rare diseases with very low exposure or to healthcare products which do not require marketing approval.

Our cover for risks that are not specific to the pharmaceutical industry (general liability) is designed to address the potential impacts of our operations.

For all lines of business of Carraig, outstanding claims are covered by provisions for the estimated cost of settling all claims incurred but not paid at the balance sheet date, whether reported or not, together with all related claims handling expenses. Where there is sufficient data history from Sanofi or from the market for claims made and settled, management with assistance from independent actuaries prepares an actuarial estimate of the company's exposure to unreported claims for the risks covered. The actuaries perform an actuarial valuation of the company's IBNR (incurred but not reported) and ALAE (allocated loss adjustment expense) liabilities at year end. Two ultimate loss projections (based upon reported losses and paid losses respectively) are computed each year using the Bornhuetter-Ferguson method; these projections form the basis for the provisions set.

The Directors & Officers Liability program protects all legal entities under our control, and their directors and officers. Our captive insurance company is not involved in this program.

We also operate other insurance programs, but these are of much lesser importance than those described above.

All our insurance programs are backed by best in class insurers and reinsurers and are designed in such a way that we can integrate most newly acquired businesses on a continuous basis. Our cover has been designed to reflect our risk profile and the capacity available in the insurance market. By centralizing our major programs, we are able to provide world-class protection while reducing costs.

**B.10. Health, Safety and Environment**

Our manufacturing and research operations are subject to increasingly stringent health, safety and environmental (HSE) laws and regulations. These laws and regulations are complex and rapidly changing, and Sanofi invests the necessary sums in order to comply with them. This investment, which aims to respect health, safety and the environment, varies from year to year.

Applicable environmental laws and regulations may require us to eliminate or reduce the effects of chemical substance discharge at our various sites. The sites in question may belong to Sanofi, and may be currently operational, or may have been owned or operational in the past. In this regard, Sanofi may be held liable for the costs of removal or remediation of hazardous substances on, under or in the

sites concerned, or on sites where waste from activities has been stored, without regard to whether the owner or operator knew of or under certain circumstances caused the presence of the contaminants, or at the time site operations occurred the discharge of those substances was authorized.

As is the case for a number of companies in the pharmaceutical, chemical and intense agrochemical industries, soil and groundwater contamination has occurred at some of our sites in the past, and may still occur or be discovered at others. In Sanofi's case, such sites are mainly located in the United States, Germany, France, Hungary, the Czech Republic, Italy and the United Kingdom. As part of a program of environmental surveys conducted over the last few years, detailed assessments of the risk of soil and groundwater contamination have been carried out at current and former Sanofi sites. In cooperation with national and local authorities, Sanofi regularly assesses the rehabilitation work required and carries out such work when appropriate. Long-term rehabilitation work is in progress or planned in Mount Pleasant, East Palo Alto and Portland in the United States; Merial Barceloneta in Puerto Rico; Frankfurt in Germany; Brindisi in Italy; Dagenham in the United Kingdom; Ujpest in Hungary; Prague in the Czech Republic; Beaucaire, Valernes, Limay, Romainville, Neuville, Vitry and Merial Toulouse in France; and on a number of sites divested to third parties and covered by contractual environmental guarantees granted by Sanofi.

## Edgar Filing: Sanofi - Form 20-F

We may also have potential liability for investigation and cleanup at several other sites. We have established provisions for the sites already identified and to cover contractual guarantees for environmental liabilities for sites that have been divested. In France specifically, we have provided the financial guarantees for environmental protection required under French regulations.

Potential environmental contingencies arising from certain business divestitures are described in Note D.22.e to the consolidated financial statements. In 2016, Sanofi spent 81 million (including 0.3 million related to the held-for-exchange Animal Health business) on rehabilitating sites previously contaminated by soil or groundwater pollution.

Due to changes in environmental regulations governing site remediation, our provisions for remediation obligations may not be adequate due to the multiple factors involved, such as the complexity of operational or previously operational sites, the nature of claims received, the rehabilitation techniques involved, the planned timetable for rehabilitation, and the outcome of discussions with national regulatory authorities or other potentially responsible parties, as in the case of multiparty sites. Given the long industrial history of some of our sites and the legacy obligations arising from the past involvement of Aventis in the chemical and agrochemical industries, it is impossible to quantify the future impact of these laws and regulations with precision. See Item 3.D. Risk Factors Environmental Risks of Our Industrial Activities .

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

We have established, in accordance with our current knowledge and projections, provisions for cases already identified and to cover contractual guarantees for environmental liabilities relating to sites that have been divested. In accordance with Sanofi standards, a comprehensive review is carried out once a year on the legacy of environmental pollution. In light of data collected during this review, we adjusted our provisions to approximately 737 million as of December 31, 2016 (including 5 million related to the held-for-exchange Animal Health business) versus 720 million as of December 31, 2015. The terms of certain business divestitures, and the environmental obligations and retained environmental liabilities relating thereto are described in Note D.22. to our consolidated financial statements.

To our knowledge, Sanofi did not incur any liability in 2016 for non-compliance with current HSE laws and regulations that could be expected to significantly jeopardize its activities, financial situation or operating income. We also believe that we are in substantial compliance with current HSE laws and regulations and that all the environmental permits required to operate our facilities have been obtained.

Regular HSE audits (52 in 2016, including 3 at Merial sites) are carried out by Sanofi in order to assess compliance with our standards (which implies compliance with regulations) and to initiate corrective measures. Additionally, 10 specialized audits covering biosafety (including two for Merial) and 111 prevention visits (including seven for Merial) were carried out by our teams in 2016. Moreover, 91 specific visits were performed jointly with experts representing our insurers (including 18 at Merial sites).

Sanofi has implemented a worldwide master policy on health, safety and environment to promote the health and well-being of the employees and contractors working on its sites and respect for the environment. We consider this master policy to be an integral part of our commitment to social responsibility. In order to implement this master policy, 78 rules (policies) have been drawn up in the key fields of HSE management, Good HSE Practices, safety in the workplace, process safety, occupational hygiene, health in the workplace and protection of the environment.

**Health**

From the development of compounds to the commercial launch of new drugs, Sanofi research scientists continuously assess the effect of products on human health. This expertise is made available to employees through two committees responsible for chemical and biological risk assessment. Sanofi's COVALIS Committee is responsible for the hazard determination and classification of all active pharmaceutical ingredients and synthesis intermediates handled at Sanofi facilities. This covers all active ingredients handled in production at company sites or in processes sub-contracted for manufacture. Any important issues involving

raw materials or other substances that lack established occupational exposure limits may also be reviewed. The COVALIS Committee determines the occupational exposure limits required within Sanofi. Our TRIBIO Committee is responsible for classifying all biological agents according to their degree of pathogenicity, and applies rules for their containment and the preventive measures to be respected throughout Sanofi. See Item 3. Key Information D. Risk Factors Environmental Risks of Our Industrial Activities Risks from the handling of hazardous materials could adversely affect our results of operations .

Appropriate occupational hygiene practices and programs are defined and implemented in each site. These practices consist essentially of containment measures for collective and individual protection against exposure in all workplaces where chemical substances or biological agents are handled. All personnel are monitored with an appropriate medical surveillance program, based on the results of professional risk evaluations linked to their duties.

In addition, dedicated resources have been created to implement the EU Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). To fully comply with the new European Regulation on Classification, Labeling and Packaging of chemicals, Sanofi has registered the relevant hazardous chemical substances with the European Chemicals Agency (ECHA).

**Safety**

## Edgar Filing: Sanofi - Form 20-F

Sanofi has rigorous policies to identify and evaluate safety risks and to develop preventive safety measures, and methods for checking their efficacy. Additionally, Sanofi invests in training that is designed to instill in all employees a sense of concern for safety, regardless of their duties. These policies are implemented on a worldwide scale to ensure the safety of all employees and to protect their health. Each project, whether in research, development or manufacturing, is subject to evaluation procedures, incorporating the chemical substance and process data communicated by the COVALIS and TRIBIO Committees described above. The preventive measures are designed primarily to reduce the number and seriousness of work accidents and to minimize exposures involving permanent and temporary Sanofi employees as well as our sub-contractors.

The French chemical manufacturing sites in Aramon, Sisteron and Vertolaye, as well as the plants located in the Hoechst Industry Park in Frankfurt, Germany, and the chemical production site in Budapest, Hungary, are listed Seveso III (from the name of the European directive that deals with potentially dangerous sites through a list of activities and substances associated with classification thresholds). In accordance with French law on technological risk prevention, the French sites are also subject to heightened security inspections due to the toxic or flammable materials stored on the sites and used in the operating processes.

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Risk assessments of processes and installations are drawn up according to standards and internal guidelines incorporating the best state of the art benchmarks for the industry. These assessments are used to fulfill regulatory requirements and are regularly updated. Particular attention is paid to any risk-generating changes such as process or installation changes, as well as changes in production scale and transfers between industrial or research units.

We have specialized process safety-testing laboratories that are fully integrated into our chemical development activities, apply methods to obtain the physico-chemical parameters of manufactured chemical substances (intermediate chemical compounds and active ingredients) and apply models to measure the effect of potentially leachable substances in the event of a major accident. In these laboratories the parameters for qualifying hazardous reactions are also determined, in order to define scale-up process conditions while transferring from development stage to industrial scale. All these data ensure that our risk assessments are relevant.

We believe that the safety management systems implemented at each site, the hazard studies carried out and the risk management methods implemented, as well as our third-party property insurance policies covering any third-party physical damage, are consistent with legal requirements and the best practices in the industry.

**Environment**

The main objectives of our environmental policy are to implement clean manufacturing techniques, minimize the use of natural resources and reduce the environmental impact of our activities. In order to optimize and improve our environmental performance, we have a strategy of

continuous improvement practiced at all our sites through the annual implementation of HSE progress plans. We believe that this strategy clearly expresses the commitment of both management and individuals to health, safety and the environment. In 2016, five of our European sites were included in the scope of the European CO<sub>2</sub> Emissions Credit Trading Scheme aimed at helping to reach the targets set by the Kyoto protocol.

Our recent efforts in terms of environmental protection have mainly targeted reductions in energy consumption, greenhouse gas emissions control, improvements in the performance of water treatment installations, reduction of volatile organic compound emissions, raw material savings and recycling, and reductions in waste materials or increases in the percentage being recycled. Measured against the benchmark year for our targets (2010), direct and indirect emissions from our production and research facilities (scope 1 & 2 and excluding vehicle fleets) have fallen by 19.2% overall. We are targeting a 20% reduction in CO<sub>2</sub> emissions in 2020 vs. 2010 on a constant structure basis.

An internal committee of experts called ECOVAL assesses the environmental impact of the pharmaceutical agents found in products marketed by Sanofi. It has developed an environmental risk assessment methodology and runs programs to collect the necessary data for such assessments. Additional ecotoxicity assessments are being performed on certain substances which predate current regulations, in order to obtain information that was not gathered when they were launched (as regulatory requirements were different at that time) and evaluate environmental risks resulting from their use by patients.

**Table of Contents****ITEM 4. INFORMATION ON THE COMPANY****C. Organizational Structure****C.1. SIGNIFICANT SUBSIDIARIES**

Sanofi is the holding company of a consolidated group consisting of over 400 companies. The table below sets forth our significant subsidiaries as of December 31, 2016.

For a fuller list of the principal companies in our consolidated group, see Note F. to our consolidated financial statements, included in this annual report at Item 18.

Significant Subsidiary	Date of Incorporation	Country of Incorporation	Principal Activity	Financial
				and Voting Interest
Aventis Inc.	07/01/1968	United States	Pharmaceuticals	100%
Aventis Pharma SA	09/24/1974	France	Pharmaceuticals	100%
Genzyme Corporation	11/21/1991	United States	Pharmaceuticals	100%
Hoechst GmbH	07/08/1974	Germany	Pharmaceuticals	100%
Merial, Inc.	08/01/1997	United States	Animal Health	100%
Merial SAS	02/25/1941	France	Animal Health	100%
Sanofi-Aventis Amérique du Nord	09/20/1985	France	Pharmaceuticals	100%
Sanofi-Aventis Deutschland GmbH	06/30/1997	Germany	Pharmaceuticals	100%
Sanofi-Aventis Europe	07/15/1996	France	Pharmaceuticals	100%
Sanofi-Aventis US LLC	06/28/2000	United States	Pharmaceuticals	100%
Sanofi-Aventis Participations SAS	02/25/2002	France	Pharmaceuticals	100%
Sanofi Pasteur	02/08/1989	France	Vaccines	100%
Sanofi Pasteur Inc.	01/18/1977	United States	Vaccines	100%
Sanofi Winthrop Industrie	12/11/1972	France	Pharmaceuticals	100%
Chattem, Inc.	11/11/1909	United States	Pharmaceuticals	100%

Since 2009, we have transformed Sanofi through numerous acquisitions (see A. History and Development of the Company above), in particular those of Genzyme in April 2011 and Merial in September 2009. The financial effects of the Genzyme acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2013, included in our annual report on Form 20-F for that year. The financial effects of the Merial acquisition are presented in Note D.1.3. to our consolidated financial statements for the year ended December 31, 2010, included in our annual report on Form 20-F for that year. During 2016, Sanofi and Boehringer Ingelheim (BI) finalized the negotiations initiated in December 2015 with a view to swapping Sanofi's Animal Health business for BI's Consumer Healthcare business. The financial effects of this transaction, which closed on January 1, 2017, are presented in Note G. to our consolidated financial statements, included at Item 18 of this annual report on Form 20-F. At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their Sanofi Pasteur MSD joint venture. The financial effects of the resulting divestment/acquisition are presented in Note D.1.2. to our consolidated financial statements.

## Edgar Filing: Sanofi - Form 20-F

In certain countries, we carry on some of our business operations through joint ventures with local partners. In

addition, we have entered into worldwide collaboration agreements (i) with Regeneron, relating to Zaltrap<sup>®</sup>, human therapeutic antibodies such as Praluent<sup>®</sup> and antibodies in immuno-oncology; and (ii) with BMS, relating to Plavix<sup>®</sup>. For further information, refer to Note C. to our consolidated financial statements, Principal Alliances .

### **C.2. INTERNAL ORGANIZATION OF ACTIVITIES**

Sanofi and its subsidiaries collectively form a group organized around two activities: Pharmaceuticals and Human Vaccines (Vaccines).

The Animal Health business, which was divested on January 1, 2017 as part of the transaction with Boehringer Ingelheim, is no longer an operating segment within the meaning of IFRS 8.

Within Sanofi, responsibility for research and development (R&D) in their respective fields rests with Sanofi SA and Genzyme Corporation in Pharmaceuticals, and with Sanofi Pasteur and Sanofi Pasteur, Inc. in Vaccines. However, within our integrated R&D organization, strategic priorities are set and R&D efforts coordinated on a worldwide scale. In fulfilling their role in R&D, the aforementioned companies subcontract R&D to those of their subsidiaries that have the necessary resources. They also license patents, manufacturing know-how

## **Table of Contents**

### **ITEM 4. INFORMATION ON THE COMPANY**

and trademarks to certain of their French and foreign subsidiaries. Those licensee subsidiaries manufacture and distribute the majority of our products, either directly or via local distribution entities.

Our industrial property rights, patents and trademarks are mainly held by the following companies:

- Pharmaceuticals: Sanofi, Aventis Pharma SA, Sanofi Biotechnology SAS (France), Sanofi-Aventis Deutschland GmbH (Germany) and Genzyme Corporation (US);

- Vaccines: Sanofi Pasteur (France) and Sanofi Pasteur, Inc. (US).

For a description of our principal items of property, plant and equipment, see **D. Property, Plant and Equipment** below. Our property, plant and equipment is held mainly by the following companies:

- in France: Sanofi Pasteur SA, Sanofi Chimie, Sanofi Winthrop Industrie, Sanofi, Merial SAS France, and Sanofi-Aventis Recherche & Développement;

- in the United States: Sanofi Pasteur, Inc., Genzyme Corporation, and Genzyme Therapeutics Products LP;

- in Canada: Sanofi Pasteur Limited;

- in Germany: Sanofi-Aventis Deutschland GmbH;

- in Belgium: Genzyme Flanders BVBA Holding Co; and

- in Ireland: Genzyme Ireland Limited.

### **C.3. FINANCING AND FINANCIAL RELATIONSHIPS BETWEEN GROUP COMPANIES**

The Sanofi parent company raises the bulk of the Company's external financing and uses the funds raised to meet, directly or indirectly, the financing needs of its subsidiaries. The parent company operates a cash pooling arrangement under which any surplus cash held by subsidiaries is managed centrally. There is also a centralized foreign exchange risk management system in place, whereby the parent company contracts hedges to meet the needs of its principal subsidiaries.

Consequently, at December 31, 2016, the Sanofi parent company held 92% of our external financing and 83% of our surplus cash.

## Edgar Filing: Sanofi - Form 20-F

Sanofi European Treasury Center SA (SETC), a 100%-owned Sanofi subsidiary incorporated in 2012 under the laws of Belgium, is dedicated to providing financing and various financial services to our subsidiaries.

### D. PROPERTY, PLANT AND EQUIPMENT

#### D.1. OVERVIEW

Our headquarters are located in Paris, France. See D.4 Office Space below.

We operate our business through office premises and research, production and logistics facilities in approximately

100 countries around the world. Our office premises house all of our support functions, plus operational representatives from our subsidiaries and the Company.

A breakdown of our sites by use and by ownership status (owned versus leasehold) is provided below. This breakdown is based on surface area. All surface area figures are unaudited.

#### Breakdown of sites by use<sup>(a)</sup>

<i>Industrial</i>	59%
<i>Research</i>	14%
<i>Offices</i>	14%
<i>Logistics</i>	9%
<i>Other</i>	4%

<sup>(a)</sup> Includes sites of the Animal Health business.

#### Breakdown of sites by ownership status

<i>Leasehold</i>	27%
<i>Owned</i>	73%

<sup>(a)</sup> Includes sites of the Animal Health business.

We own most of our research & development and production facilities, either freehold or under finance leases with a purchase option exercisable on expiration of the lease.

#### D.2. DESCRIPTION OF OUR SITES

##### Sanofi industrial sites

As part of the process of transforming Sanofi and creating Global Business Units, we are continuing to adapt the organization of the Industrial Affairs department in support of our new business model. Since June 2013, the Industrial Affairs department has been responsible for all production and quality operations within Sanofi. The department focuses on customer needs and service quality, the sharing of lean manufacturing practices, the development of a common culture committed to quality and the pooling of expertise within technology platforms, particularly in biological, injectable and pharmaceutical products. Since January 2016, the Industrial Affairs department has also been responsible for Sanofi Global HSE and Global Supply Chain.

At the end of 2016, we were carrying out industrial production at 86 sites in 38 countries (including 35 sites in emerging markets):

74 sites for our Pharmaceuticals activity, including Sanofi Genzyme; and

12 sites for the industrial operations of Sanofi Pasteur in vaccines.

74

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

In 2016, we produced the following quantities:

· Pharmaceuticals: 4,292 million units, comprising:

    units manufactured and packaged: 2,956 million;

    units packaged only: 275 million;

    bulk products in unit equivalents: 396 million;

    outsourced units: 666 million; and

· Vaccines: 500 million containers (syringes and ampoules) filled, including outsourced production.

We believe that our production facilities are in compliance with all regulatory requirements, are properly maintained and are generally suitable for future needs. Nonetheless, we regularly inspect and evaluate those facilities with regard to environmental, health, safety and security matters, quality compliance and capacity utilization. For more information about our property, plant and equipment, see Note D.3 to our consolidated financial statements, included at Item 18 of this annual report, and section B.8 Production and Raw Materials above.

***Industrial Sites: Pharmaceuticals***

Production of chemical and pharmaceutical products is the responsibility of our Industrial Affairs department, which is also in charge of most of our logistics facilities (distribution and storage centers).

Major drugs, active ingredients, specialties and medical devices are manufactured at the following sites:

· France: Ambarès, Amilly, Aramon, Le Trait, Lyon Gerland, Maisons-Alfort, Sisteron, Tours, Vitry-sur-Seine and Vertolaye;

· Germany: Frankfurt Injectable, Frankfurt Pharma, Frankfurt Device and Frankfurt Chemistry;

· Ireland: Waterford;

## Edgar Filing: Sanofi - Form 20-F

- Italy: Scoppito, Anagni and Brindisi;
- United Kingdom: Haverhill and Holmes Chapel;
- Hungary: Ujpest and Csanyikvölgy;
- Japan: Kawagoe;
- Singapore: Jurong;
- China: Beijing and Hangzhou;
- Brazil: Campinas;
- Russia: Orel;
- India: Goa, Ankleshwar Pharma and Ankleshwar Chemistry;
- Belgium: Geel; and
- United States: Allston, Framingham Biologics, Framingham Biosurgery, Ridgefield, Northborough and Lynnwood, Washington State.

### ***Industrial sites: Consumer Healthcare***

Major drugs for our Consumer Healthcare portfolio are manufactured at the following sites:

- France: Compiègne and Lisieux;
- Germany: Cologne;
- Italy: Origgio;
- Hungary: Veres;
- Poland: Rzeszow;
- United States: Chattanooga;

- Brazil: Suzano;
- Mexico: Ocoyoacac;
- Vietnam: ACE; and
- Australia: Virginia.

***Industrial Sites: Vaccines (Sanofi Pasteur)***

The headquarters of our Vaccines division, Sanofi Pasteur, is located in Lyon, France. Sanofi Pasteur has 12 industrial sites in eight countries:

- France: Marcy l Étoile, Val de Reuil and Neuville;
- United States: Swiftwater, Canton and Rockville;
- Canada: Toronto;
- India: Hyderabad (Shantha);
- China: Shenzhen;
- Argentina: Pilar;
- Mexico: Ocoyoacac; and
- Thailand: Chachoengsao.

Sanofi Pasteur also has its own R&D and production sites, either freehold or under finance leases with a purchase option exercisable on expiration of the lease.

**Research & Development sites**

In Pharmaceuticals, research and development activities are conducted at 14 sites:

- six operational sites in France: Chilly/Longjumeau, Marcy l Etoile, Montpellier, Strasbourg, Toulouse and Vitry/ Alfortville;
- two sites in the rest of Europe (Germany and the Netherlands), the larger of which is in Frankfurt (Germany);



---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

· four sites in the United States, the Bridgewater, Cambridge, Framingham and Great Valley sites; and

· two sites in Asia (a clinical research unit in Beijing, China and a unit in Japan).  
Vaccines research and development sites are:

· United States: Swiftwater, Cambridge, Orlando;

· France: Marcy L Etoile/Lyon;

· Canada: Toronto.

**D.3. ACQUISITIONS, CAPITAL EXPENDITURES AND DIVESTITURES**

The carrying amount of our property, plant and equipment at December 31, 2016 was 10,019 million. During 2016, we invested 1,093 million (see Note D.3. to our consolidated financial statements, included at Item 18 of this annual report), mainly in increasing capacity and improving productivity at our various production and R&D sites.

Our principal acquisitions, capital expenditures and divestitures in 2014, 2015 and 2016 are described in Notes D.1. ( Impact of changes in the scope of consolidation ), D.3. ( Property, plant and equipment ) and D.4. ( Goodwill and other intangible assets ) to our consolidated financial statements, included at Item 18 of this annual report.

As of December 31, 2016, our firm commitments in respect of future capital expenditures amounted to 545 million. The principal locations involved were: for the Pharmaceuticals segment, the industrial facilities at Frankfurt (Germany), Framingham and Allston (United States), Geel (Belgium), Waterford (Ireland), Sisteron and Elbeuf (France) ; and for the Vaccines segment, the facilities at Swiftwater (United States), Toronto (Canada) and Marcy L Étoile (France).

In the medium term and assuming no changes in the scope of consolidation, we expect to invest on average some 1.8 billion a year in property, plant and equipment. We believe that our own cash resources and the undrawn portion of our existing credit facilities will be sufficient to fund these expenditures.

Our principal ongoing investments are described below.

**Pharmaceuticals**

The Frankfurt facility, our principal site for the manufacture of **diabetes** treatments, is now equipped with an additional aseptic filling unit that uses isolator technology. Toujeo®, launched in 2015, is among the diabetes products handled in this new filling unit. The Diabetes industrial network has a solid base in emerging markets, both in Russia with the Orel site (now our second largest insulin pen production site after Frankfurt) and at the Beijing site in China. As part of the integration of Shantha (India) into our Injectables platform, the Indian site uses our proprietary manufacturing technology to handle filling and packaging for insulin products.

## Edgar Filing: Sanofi - Form 20-F

Our prefilled syringes network mainly delivers Lovenox<sup>®</sup>/Clexane<sup>®</sup> from Le Trait (France) and Maisons Alfort (France) to global markets and from Csanyikvölgy (Hungary) to non-FDA/EMA regulated markets.

The pharmaceutical industrial operations of our **Consumer Healthcare** (CHC) business are spread across a dedicated network. Global markets are supplied from our facilities at Compiègne (France), Origgio (Italy), Cologne (Germany) and Veresegyház (Hungary). Regional markets are supplied from our Suzano facility in Brazil, our Rzeszow facility in Poland and our ACE facility in Vietnam. Our facilities at Lisieux (France, production of Doliprane<sup>®</sup> for the French market), Hangzhou (China), Virginia (Australia), and the Chattem facility in Tennessee (United States), mainly supply their local markets. We have recently invested heavily in major projects intended to build a specialist CHC industrial network. This has included switching some CHC products from non-CHC facilities to the dedicated CHC network, transferring some liquid and effervescent formulations of CHC products to the Cologne site, and transforming the Origgio site into a facility dedicated to a single product family (Enterogermina<sup>®</sup>).

In 2014, a dedicated **Biologics** platform was launched to develop synergies between Pharmaceuticals, Sanofi Pasteur, Sanofi Genzyme and our Biotherapeutic activities. This platform is helping us extend our footprint in biotechnologies by adopting a multi-disciplinary approach and improving capacity utilization. It also enables us to leverage our expertise in the production of biologics, from active ingredient through to integrated manufacturing, including both the medicine itself and associated medical devices.

Three dedicated biotechnology hubs have been developed: Paris/Lyon (France), Frankfurt (Germany) and Boston (United States). Piloting this technology, which relies on cell or microbiological culture or the development of viral vectors, calls for highly specific knowledge and expertise backed by dedicated production platforms to support global product launches.

The development of our **Emerging Markets** platform is built on a network of over 30 regional and local industrial sites in 25 countries, supporting growth in those markets.

At Sidi Abdellah in Algeria we are building a new facility that will become our largest industrial complex in Africa, mainly producing dry and liquid formulations.

In Vietnam, we have completed construction of our new facility in Ho Chi Minh City, which manufactures specialty pharmaceuticals and CHC products.

The Industrial Affairs Department has an ongoing policy of adapting our industrial facilities to market needs. As part of this process, we closed our facilities at Fawdon (United Kingdom) and Bogota (Colombia) in 2015 and at Kansas City (United States) in 2016, and we have announced the closure of our facility at Saint Louis (United States) in 2017. We sold our facilities at Quetigny (France) in 2015 and at

---

**Table of Contents**

**ITEM 4. INFORMATION ON THE COMPANY**

Mirador (Argentina) in 2016, and reached agreement with a third party to sell our facility at Dakar (Senegal) in 2016.

**Vaccines (Sanofi Pasteur)**

Sanofi Pasteur's industrial operations are in a major investment phase, preparing for the upcoming growth of our flu and Polio/Pertussis/Hib franchises. Major investments are being launched in France, Canada, the US and Mexico.

**Innovation and culture of industrial excellence**

In 2016, we highlighted industrial innovation in our various facilities by organizing our eighth annual round of Industrial Trophies, in five categories: Patient Needs, Technological Innovation, Operational Performance, Energy & Environment, and Young Industrial Innovation Talent.

The ambition of our Industrial Affairs department is to continue to raise quality standards in Sanofi's production activities, and to remain a world leader and a benchmark in the global pharmaceutical industry. To achieve this goal, all our activities share a common culture of industrial excellence, enshrined in the Sanofi Manufacturing System. This sets out a series of priorities (such as customer service, constant improvement, site network optimization and transverse optimization) that constitute our industrial vision and will be crucial to our mutual success.

**D.4. OFFICE SPACE**

As part of the worldwide rationalization of our office space we are reassessing our real estate needs across all our sites

to bring our people closer together, with a responsible environmental footprint and new working practices.

Following the completion in 2015 of our office space master plan for the Greater Paris area, which brought some 3,000 of our people together on our new urban campus at Gentilly, we are now rolling out a similar master plan for the Lyon area. This plan will bring teams from Sanofi Pasteur and support staff together on the Carteret campus, featuring environmentally-certified buildings with dynamic workspaces similar to those at Gentilly. The final spaces on this site are due to be delivered in 2017.

Further office space rationalization will be achieved by a master plan for Cambridge, Massachusetts (United States), under which Genzyme and Sanofi operations will be brought together under a single roof in an environmentally-certified building currently being developed for delivery in 2018. During 2016, other major projects designed to encourage new working practices and optimize our real estate footprint were delivered in Ireland, the Philippines, Bulgaria and Westborough (United States). Further projects launched in 2016 and due for delivery in 2017 at Sao Paulo (Brazil) and Tokyo (Japan) for example are intended to meet the same objectives: rationalizing space while promoting teamwork and innovation.

Over 25 non-operational sites were divested during 2016, the main ones being Romainville and Bagneux (France), Guadalajara (Mexico), Kansas City (United States) and Algiers (Algeria).

**Item 4A. Unresolved Staff Comments**

N/A

77

---

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

## **Item 5. Operating and Financial Review and Prospects**

You should read the following discussion in conjunction with our consolidated financial statements and the notes thereto included in this annual report at Item 18.

Our consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and with IFRS adopted by the European Union as of December 31, 2016.

The following discussion contains forward-looking statements that involve inherent risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See **Cautionary Statement Regarding Forward-Looking Statements** at the beginning of this document.

Unless otherwise stated, all financial variations in this item are given on a reported basis.

### **A. Operating results**

#### **A.1. SIGNIFICANT OPERATING INFORMATION**

##### **A.1.1. 2016 Overview**

Throughout 2016 we continued to make progress towards our key strategic objectives: reorganizing our operations, successfully launching new products, enhancing innovation in R&D and streamlining our organization.

During 2016, Sanofi and Boehringer Ingelheim (BI) finalized the negotiations initiated in December 2015 with a view to swapping our Animal Health business for BI's Consumer Healthcare business. This transaction closed on January 1, 2017, strengthening our position in the consumer healthcare market<sup>(1)</sup>. In 2016, the portfolio of BI Consumer Healthcare products acquired by Sanofi generated net sales estimated to be approximately 1.5 billion. Due to the closing of this transaction, the Animal Health business is no longer an operating segment within the meaning of IFRS 8. In the consolidated income statement, the net income or loss of this business is presented in a separate line item, ***Net income/(loss) of the held-for-exchange Animal Health business***, in accordance with IFRS 5 (see Notes B.7., D.2. and D.36. to the consolidated financial statements, included at Item 18 of this annual report).

At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their European joint venture Sanofi Pasteur MSD (SPMSD). This transaction involves the divestment of our share in the joint venture and the acquisition of the vaccines portfolio that

reverts to Sanofi. The derecognition of our interest in SPMSD generated a pre-tax gain on disposal of 211 million, included in our consolidated income statement within the line item ***Other gains and losses, and litigation*** (see Note D.28. to the consolidated financial statements). The consolidation of SPMSD's operations relating to the Sanofi vaccines portfolio led to the recognition of intangible assets of 465 million and goodwill of 5 million. We estimate that the additional annual net sales derived from this transaction will be approximately 280 million, based on 2016 figures.

## Edgar Filing: Sanofi - Form 20-F

During 2016, we continued our policy of securing research and development alliances and making targeted acquisitions. In immuno-oncology, we entered into a collaboration and license agreement with Innate Pharma, and extended our collaboration with Warp Drive Bio to discover novel oncology therapeutics and antibiotics. In diabetes, we joined forces with Verily Life Sciences LLC (formerly Google Life Sciences) to form Onduo, a joint venture to develop comprehensive diabetes management solutions.

Successes for our R&D efforts in 2016 included the entry into Phase III of dupilumab in nasal polyposis, sotagliflozin in type 2 diabetes, isatixumab for patients with relapsed and refractory multiple myeloma and GZ402666 (NeoGAA) in the treatment of Pompe disease which is a rare disease caused by the deficiency of the enzyme acid alpha-glucosidase. A number of launches were carried out during the year following the granting of regulatory approvals, in particular Praluent® (hypercholesterolemia) in Japan and Adlyxin (diabetes) in the United States, followed by Soliqua 100/33 (insulin glargine and lixisenatide for diabetes) in the United States at the start of 2017. The launch of Suliqua, the European trade name for the same association, is planned in Europe in 2017.

Since January 2016, we have been streamlining our organization and rolling out our new structure, composed of five global business units (GBUs): General Medicines & Emerging Markets, Sanofi Genzyme (Specialty Care), Diabetes & Cardiovascular, Sanofi Pasteur (Vaccines), and Animal Health. Following the transaction with BI, this last GBU has been replaced by the Consumer Healthcare GBU, which has been operational since January 1, 2017. To support this new organizational structure, we have embarked on a program to improve the excellence of our delivery by implementing a global information systems solution and by standardizing and consolidating our processes.

<sup>(1)</sup> *The closing of the acquisition of Merial in Mexico and the exchange of Merial with BI's Consumer Healthcare operations in India have been delayed, and should be finalized in 2017.*

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

Net sales for the year ended December 31, 2016 were 33,821 million, 0.7% lower than in 2015, but 1.2% higher at constant exchange rates (CER)<sup>(1)</sup>. This CER growth was driven mainly by the Sanofi Genzyme (Specialty Care) and Sanofi Pasteur (Vaccines) GBUs.

*Net income attributable to equity holders of Sanofi* reached 4,709 million, up 9.8% (on a reported basis) on 2015, while basic earnings per share was 11.6% higher year-on-year (on a reported basis) at 3.66. Business net income<sup>(2)</sup> totaled 7,308 million, 0.9% lower (+2.5% CER) than in 2015, while business earnings per share<sup>(2)</sup> was up 0.7% (+4.1% CER) at 5.68. For a further discussion and definition of business net income, and business earnings

per share for the years ended December 31, 2016, 2015 and 2014, see Business Net Income below.

Our debt, net of cash and cash equivalents<sup>(3)</sup> increased during 2016 and stood at 8,206 million as of December 31, 2016, compared with 7,254 million a year earlier, due largely to our share repurchase program of 2.9 billion (versus 1.8 billion in 2015), in anticipation of the cash to be received as part of the asset swap with Boehringer Ingelheim. The Annual General Meeting, to be held on May 10, 2017, will be asked to approve a dividend of 2.96 per share for the 2016 financial year, representing a payout of 52.1% of our business net income.

**A.1.2. Impacts of competition from generics and biosimilars**

Some of our flagship products continued to suffer sales erosion in 2016 due to competition from generics and biosimilars. While we do not believe it is possible to state with certainty what level of net sales would have been achieved in the absence of generic competition, we are able to estimate the impact that generic competition has had on each product.

A comparison of our consolidated net sales for the years ended December 31, 2016 and 2015 (see Results of Operations Year Ended December 31, 2016 Compared with Year Ended December 31, 2015 below) shows that in 2016, generic competition led to a loss of 676 million of net sales on a reported basis.

The table below sets forth the impact by product.

( million)	2016	2015	Change on a reported basis ( m)	Change on a reported basis (%)
Aprovel <sup>®</sup> Europe	127	148	(21)	-14.2%
Lantus <sup>®</sup> Europe	878	991	(113)	-11.4%
Lovenox <sup>®</sup> Europe	1,027	1,049	(22)	-2.1%
Plavix <sup>®</sup> Europe	162	184	(22)	-12.0%
Renagel <sup>®</sup> /Renvela <sup>®</sup> Europe	82	121	(39)	-32.2%
Ambien <sup>®</sup> United States	84	74	10	+13.5%
Lovenox <sup>®</sup> United States	54	77	(23)	-29.9%
Taxotere <sup>®</sup> United States	4	(1)	5	N/S
Allegra <sup>®</sup> Japan	174	180	(6)	-3.3%
Amaryl <sup>®</sup> Japan	36	46	(10)	-21.7%
Aprovel <sup>®</sup> Japan	82	94	(12)	-12.8%

Edgar Filing: Sanofi - Form 20-F

Lantus® Japan	74	112	(38)	-33.9%
Myslee® Japan	110	121	(11)	-9.1%
Plavix® Japan	355	695	(340)	-48.9%
Taxotere® Japan	26	60	(34)	-56.7%
<b>Total excluding Emerging Markets</b>	<b>3,275</b>	<b>3,951</b>	<b>(676)</b>	<b>-17.1%</b>

(1) See definition under A.1.6. Presentation of Net Sales below

(2) Non-GAAP financial measure: see definition under A.1.5. Segment information 3/ Business Net Income below

(3) Non-GAAP financial measure: see definition under B. Liquidity and Capital Resources below

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

We expect the erosion caused by generic competition to continue in 2017, with a negative impact on our net income. The products likely to be impacted are those that already faced generic competition in 2016, but whose sales can reasonably be expected to be subject to further sales erosion in 2017: Aprovel<sup>®</sup>, Lantus<sup>®</sup>, Lovenox<sup>®</sup>, Plavix<sup>®</sup> and Renagel<sup>®</sup>/Renvela<sup>®</sup> in Europe; Ambien<sup>®</sup>, Lantus<sup>®</sup>, Lovenox<sup>®</sup> and Taxotere<sup>®</sup> in the United States; and Allegra<sup>®</sup>, Amaryl<sup>®</sup>, Aprovel<sup>®</sup>, Myslee<sup>®</sup>, Lantus<sup>®</sup>, Plavix<sup>®</sup> and Taxotere<sup>®</sup> in Japan. We also anticipate generic competition for Renagel<sup>®</sup>/Renvela<sup>®</sup> in the United States in the first half of 2017.

Specifically as regards Lantus<sup>®</sup> in the United States, in September 2015 we reached an out-of-court settlement with Eli Lilly and Company (Lilly) regarding the patents for Lantus<sup>®</sup> SoloSTAR<sup>®</sup> (insulin glargine). This settlement brought an end to a patent infringement action in the United States relating to a new drug application by Lilly for a rival product to Lantus<sup>®</sup> SoloSTAR<sup>®</sup>. Sanofi and Lilly agreed to terminate that action and other similar proceedings worldwide. Under the terms of the settlement, Lilly will pay royalties to Sanofi in return for a license covering specified Sanofi patents. In the United States, Lilly began commercializing its insulin glargine in mid-December 2016. Lantus<sup>®</sup> in the United States is not shown in the table above because we believe it would be inaccurate to associate the decline in sales of this product in the United States during 2016 with competition from biosimilars, the decline having been primarily due to a fall in the average selling price of the product. The settlement does not include the injectable solution formulation of Lantus<sup>®</sup> in vials, Toujeo<sup>®</sup>, or combination products (for further information see Item 8 – Information on Legal or Arbitration Proceedings – Lantus and Lantus SoloSTAR<sup>®</sup> Patent Litigation ).

In 2016, the consolidated net sales of these products in countries where generic competition currently exists or is expected in 2017 amounted to 7,567 million; this comprises 4,434 million in the United States (including 3,528 million in net sales of Lantus<sup>®</sup> and 764 million in net sales of Renagel<sup>®</sup>/Renvela<sup>®</sup>); 2,276 million in Europe; and 857 million in Japan. The negative impact on our 2017 net sales is expected to represent a substantial proportion of this amount, but the actual impact will depend on a number of factors such as the actual launch dates of generic products in 2017, the prices at which they are sold, and potential litigation outcomes.

**A.1.3. Purchase Accounting Effects**

Our results of operations and financial condition for the years ended December 31, 2016, 2015 and 2014 have been significantly affected by our August 2004 acquisition of Aventis, our April 2011 acquisition of Genzyme and certain subsequent transactions. See – Critical accounting and reporting policies – Business combinations – below for an explanation of the impact of business combinations on our results of operations.

The Genzyme business combination has generated significant amortization of intangible assets ( 866 million in 2016, 890 million in 2015 and 811 million in 2014) and impairment of intangible assets (net reversal of 6 million in 2016, expenses of 214 million in 2015 and net reversal of 309 million in 2014). The Aventis business combination has also generated significant amortization expenses ( 482 million in 2016, 638 million in 2015 and 874 million in 2014).

In order to isolate the purchase accounting effects of all acquisitions and certain other items, we use a non-GAAP financial measure that we refer to as – business net income<sup>(b)</sup>.

**A.1.4. Sources of Revenues and Expenses**

**Revenues.** Revenue arising from the sale of goods is presented in the income statement within *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, human vaccines and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Returns, discounts, incentives and rebates are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. See Note B.13 to our consolidated financial statements included at Item 18 of this annual report. We sell pharmaceutical products and vaccines directly, through alliances, and by licensing arrangements throughout the world. When we sell products directly, we record sales revenues as part of our consolidated net sales. When we sell products

## Edgar Filing: Sanofi - Form 20-F

through alliances, the revenues reflected in our consolidated financial statements are based on the contractual arrangements governing those alliances. For more information about our alliances, see [Financial Presentation of Alliances](#) below. When our products are sold by licensing arrangements, we receive royalty income that we record in **Other revenues**. The sales of non-Sanofi products of our US based entity VaxServe are also presented in **Other revenues**; see Note B.14. to the consolidated financial statements included at Item 18 of this annual report.

**Cost of Sales.** Our cost of sales consists primarily of the cost of purchasing raw materials and active ingredients, labor and other costs relating to our manufacturing activities, packaging materials, payments made under licensing agreements and distribution costs. We have license agreements under which we manufacture, sell and distribute products that are patented by other companies and license

*(1) Non-GAAP financial measure: see definition under [A.1.5. Segment information](#) 3/Business Net Income below*

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

agreements under which other companies distribute products that we have patented. When we pay royalties, we record them in *Cost of sales*.

**Operating Income.** Our operating income reflects our revenues, our cost of sales and the remainder of our operating expenses, the most significant of which are research and development expenses and selling and general expenses. For our operating segments, we also measure our results of operations through an indicator referred to as Business Operating Income, which we describe below under Segment Information Business Operating Income of Segments.

**A.1.5. Segment information****1/ Operating segments**

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker. The performance of those segments is monitored individually using internal reports and common indicators. The operating segment disclosures required under IFRS 8 are provided in Note D.35. ( Segment Information ) to our consolidated financial statements, included at Item 18 of this annual report.

Sanofi now has two operating segments: Pharmaceuticals and Human Vaccines (Vaccines) (See Note B.26. to our consolidated financial statements). The Animal Health business was no longer an operating segment as of December 31, 2016, following the exchange deal with Boehringer Ingelheim that was finalized at the start of January 2017 (see Note D.2. to our consolidated financial statements).

The Pharmaceuticals segment comprises the commercial operations of the following franchises: Speciality Care (Rare Diseases, Multiple Sclerosis, Oncology), Diabetes & Cardiovascular, Established Prescription Products, Consumer Healthcare and Generics; and dedicated research and development, production and marketing activities for all of Sanofi's pharmaceuticals operations.

The Sanofi pharmaceuticals portfolio consists of flagship products (see A.2. Results of Operations A.2.2. Net Sales below), plus a broad range of prescription medicines, generic medicines, and Consumer Healthcare products. This segment also includes all associates whose activities are related to pharmaceuticals, in particular Regeneron Pharmaceuticals, Inc. and the entities majority owned by Bristol-Myers Squibb (BMS).

The Vaccines segment is wholly dedicated to vaccines and includes the commercial operations of Sanofi Pasteur and dedicated research and development, production and marketing activities for Sanofi's vaccines operations. This segment included the Sanofi Pasteur MSD joint venture until December 30, 2016, the date on which the joint venture ended.

Each segment includes global support function costs as allocated for internal reporting purposes within Sanofi.

The Other segment includes all activities that do not qualify as reportable segments under IFRS 8. This segment includes the effects of retained commitments in respect of divested activities.

Inter-segment transactions are not material.

**2/ Business Operating Income**

We report segment results on the basis of Business operating income. This indicator is used internally by the chief operating decision maker of the Company to measure the performance of each operating segment and to allocate resources, in accordance with IFRS 8. Business operating income is derived from *Operating income*, adjusted as follows:

## Edgar Filing: Sanofi - Form 20-F

- the amounts reported in the line items *Restructuring costs and similar items*, *Fair value remeasurement of contingent consideration liabilities* and *Other gains and losses, and litigation* are eliminated;
- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature) are eliminated;
- the share of profits/losses of associates and joint ventures (excluding restructuring costs relating to associates and joint ventures) is added;
- net income attributable to non-controlling interests is deducted; and
- other acquisition-related effects (primarily the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated.
- the non-recurring adjustment recognized in 2014 for the annual Branded Prescription Drug (BPD) Fee in the United States (following publication by the US Internal Revenue Service in July 2014 of the final regulations on that fee) is also eliminated.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The table below shows a reconciliation between total business operating income for our operating segments and *Income before tax and associates and joint ventures*, as required by IFRS 8.

( million)	2016	2015	2014
<b>Business operating income</b>	<b>9,285</b>	<b>9,313</b>	<b>8,957</b>
Share of (profit)/loss of associates and joint ventures <sup>(a)</sup>	(177)	(169)	(146)
Net income attributable to non-controlling interests <sup>(b)</sup>	113	126	126
Amortization of intangible assets	(1,692)	(2,137)	(2,081)
Impairment of intangible assets	(192)	(767)	31
Fair value remeasurement of contingent consideration liabilities	(135)	53	(303)
Restructuring costs and similar items	(879)	(795)	(404)
Additional year expense related to US Branded Prescription Drug Fee <sup>(c)</sup>	-	-	(116)
Other gains and losses, and litigation <sup>(d)</sup>	211	-	-
<b>Operating income</b>	<b>6,534</b>	<b>5,624</b>	<b>6,064</b>
Financial expenses <sup>(e)</sup>	(924)	(559)	(598)
Financial income	68	178	192
<b>Income before tax and associates and joint ventures</b>	<b>5,678</b>	<b>5,243</b>	<b>5,658</b>

(a) Excluding restructuring costs of associates and joint ventures and expenses arising from the impact of acquisitions on associates and joint ventures, and after elimination of Sanofi's share of the business net income of Sanofi Pasteur MSD from the date when Sanofi and Merck announced their intention to end their joint venture ( 52 million in 2016).

(b) Excluding restructuring costs and other adjustments attributable to non-controlling interests.

(c) Annual fee related to 2013 sales: the IRS reform of July 2014 altered the date on which the liability is recognized, such that the expense recognized during 2014 was based on both 2013 and 2014 sales.

(d) This line item consists of the pre-tax gain on divestment of Sanofi's interest in the Sanofi Pasteur MSD joint venture.

(e) In 2016, this line includes the impairment loss of 457 million taken against the investment in Alnylam.

**3/ Business Net Income**

We believe that understanding of our operational performance by our management and our investors is enhanced by reporting business net income. This non-GAAP financial measure represents business operating income, less financial income/(expense) and the relevant income tax effects. For the year ended December 31, 2016 and comparative periods, Business net income consists of

## Edgar Filing: Sanofi - Form 20-F

(i) Business net income excluding Animal Health, determined as described above and (ii) Animal Health business net income, determined on a similar and comparable basis.

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding.

The table below reconciles our business operating income to our business net income:

<i>( million)</i>	2016	2015	2014
<b>Business operating income</b>	<b>9,285</b>	<b>9,313</b>	<b>8,957</b>
Financial income/(expense)	(399)	(381)	(441)
Income tax expense	(2,054)	(1,929)	(2,033)
<b>Business net income excluding Animal Health</b>	<b>6,832</b>	<b>7,003</b>	<b>6,483</b>
Animal Health business net income	476	368	364
<b>Business net income</b>	<b>7,308</b>	<b>7,371</b>	<b>6,847</b>

---

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

Business net income is defined as *Net income attributable to equity holders of Sanofi* determined under IFRS, excluding the following items:

- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature);
- fair value remeasurements of contingent consideration liabilities relating to business combinations;
- other impacts associated with acquisitions (including impacts of acquisitions on associates and joint ventures);
- the non-recurring adjustment recognized in 2014 for the Annual Branded Prescription Drug (BPD) Fee in the United States (following publication by the US Internal Revenue Service in July 2014 of the final regulations on that fee);
- restructuring costs and similar items<sup>(1)</sup>;
- other gains and losses (including gains and losses on major disposals of non-current assets<sup>(2)</sup>);
- other costs and provisions related to litigation<sup>(2)</sup>;
- the tax effects related to the items listed above;
- the effects of major tax disputes;
- the 3% tax on the distribution of dividends to equity holders of Sanofi;
- those Animal Health items that are not included in business net income<sup>(3)</sup>;
- the portion attributable to non-controlling interests of the items listed above; and
-

## Edgar Filing: Sanofi - Form 20-F

the impairment loss taken against our shares in Alnylam in 2016 to reflect a decline in the market value of those shares as of the reporting date relative to their historical cost, mostly resulting from Alnylam's decision to discontinue the revusiran development program on October 5, 2016.

Business net income also includes our share of the business net income of the SPMSD joint venture with effect from the date on which Sanofi and Merck announced their intention to end the joint venture.

<sup>(1)</sup> Presented in the line item **Restructuring costs and similar items** in the consolidated income statement.

<sup>(2)</sup> Presented in the line item **Other gains and losses, and litigation** in the consolidated income statement.

<sup>(3)</sup> Impact of discontinuation of depreciation and impairment of property, plant and equipment from the start date of application of IFRS 5 (Non-current Assets Held for Sale and Discontinued Operations), amortization and impairment of intangible assets until the start date of IFRS 5 application, costs incurred as a result of the divestment, and the tax effects of these items.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The table below reconciles our business net income and business earnings per share to *Net income attributable to equity holders of Sanofi*:

( million)	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
<b>Business net income</b>	<b>7,308</b>	<b>7,371</b>	<b>6,847</b>
<b>Total reconciling items</b>	<b>(2,599)</b>	<b>(3,084)</b>	<b>(2,457)</b>
Amortization of intangible assets <sup>(b)</sup>	(1,692)	(2,137)	(2,081)
Impairment of intangible assets	(192)	(767)	31
Fair value remeasurement of contingent consideration liabilities	(135)	53	(303)
Restructuring costs and similar items	(879)	(795)	(404)
Other gains and losses, and litigation <sup>(c)</sup>	211	-	35
Additional year expense related to US Branded Prescription Drug Fee <sup>(d)</sup>	-	-	(116)
Tax effects <sup>(e)</sup> :	841	1,331	928
<i>Amortization of intangible assets</i>	647	757	564
<i>Impairment of intangible assets</i>	47	262	(18)
<i>Fair value remeasurement of contingent consideration liabilities</i>	24	39	254
<i>Restructuring costs and similar items</i>	95	273	141
<i>Other tax effects</i>	28	-	-
Other tax items	(113)	(111)	(110)
Share of items listed above attributable to non-controlling interests	22	25	8
Associates and joint ventures: restructuring costs and expenses arising from the impact of acquisitions	9	(191)	(198)
Items relating to the Animal Health business <sup>(f)</sup>	(162)	(492)	(247)
Other items relating to the Sanofi Pasteur MSD joint venture <sup>(g)</sup>	(52)	-	-
Impairment loss charged against the investment in Alnylam	(457)	-	-
<b>Net income attributable to equity holders of Sanofi</b>	<b>4,709</b>	<b>4,287</b>	<b>4,390</b>
Average number of shares outstanding (million)	1,286.6	1,306.2	1,315.8
Business earnings per share (in euros)	5.68	5.64	5.20
Reconciliation items per share (in euros)	(2.02)	(2.36)	(1.86)
Net income attributable to equity holders of Sanofi per share (in euros)	3.66	3.28	3.34

(a) The Animal Health business is presented separately in accordance with IFRS 5.

(b) Includes amortization expense generated by the remeasurement of intangible assets in connection with business combinations: 1,550 million in 2016 and 1,770 million 2015.

(c) Pre-tax gain on disposal of our interest in the Sanofi Pasteur MSD joint venture.

(d) Annual fee related to 2013 sales: the IRS reform of July 2014 altered the date on which the liability is recognized, such that the expense recognized during 2014 was based on both 2013 and 2014 sales.

## Edgar Filing: Sanofi - Form 20-F

- (e) *This line includes the impact on deferred tax assets and liabilities arising from the reconciling items (in particular amortization and impairment of intangible assets and restructuring costs) following the change in tax rates, mainly in France (28% standard rate effective as of January 1, 2020) and in Japan.*
- (f) *Impact of discontinuation of depreciation and impairment of property, plant and equipment from the start date of application of IFRS 5 (Non-current Assets Held for Sale and Discontinued Operations), amortization and impairment of intangible assets until the start date of IFRS 5 application, costs incurred as a result of the divestment, and the tax effects of these items.*
- (g) *Includes the following items: impact of the discontinuation of the equity accounting of the Sanofi Pasteur MSD business net income since the announcement by Sanofi and Merck of their intent to end their joint vaccine operations in Europe.*

The most significant reconciling items between our business net income and **Net income attributable to equity holders of Sanofi** relate to the purchase accounting effects of our acquisitions and business combinations, particularly the amortization and impairment of intangible assets (other than software and other rights of an industrial or operational nature). We believe that

excluding those non-cash charges enhances an investor's understanding of our underlying economic performance because we do not consider that the excluded charges reflect the combined entity's ongoing operating performance. Rather, we believe that each of the excluded charges reflects the decision to acquire the businesses concerned.

---

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The principal purchase accounting effects of acquisitions and business combinations on net income are:

- amortization and net impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature), net of taxes and non-controlling interests; and
- the incremental cost of sales incurred on the workdown of acquired inventories remeasured at fair value, net of taxes.

We believe (subject to the limitations described below) that disclosing our business net income enhances the comparability of our operating performance, for the following reasons:

- the elimination of charges related to the purchase accounting effect of our acquisitions (particularly amortization and impairment of finite-lived intangible assets, other than software and other rights of an industrial or operational nature) enhances the comparability of our ongoing operating performance relative to our peers in the pharmaceutical industry that carry these intangible assets (principally patents and trademarks) at low book values either because they are the result of in-house research and development that has already been expensed in prior periods or because they were acquired through business combinations that were accounted for as poolings-of-interest;
- the elimination of selected items such as the incremental cost of sales arising from the workdown of inventories remeasured at fair value, gains and losses on disposals of non-current assets, and costs and provisions associated with major litigation improves comparability from one period to the next; and
- the elimination of restructuring costs and similar items enhances comparability because those costs are directly and only incurred in connection with transformation and reorganization processes intended to optimize our operations.

We remind investors, however, that business net income should not be considered in isolation from, or as a substitute for, *Net income attributable to equity holders of Sanofi* reported in accordance with IFRS. In addition, we strongly encourage investors and potential investors not to rely on any single financial measure but to review our financial statements, including the notes thereto, and our other publicly filed reports, carefully and in their entirety.

We compensate for the material limitations described above by using business net income only to supplement our IFRS financial reporting and by ensuring that our disclosures provide sufficient information for a full understanding of all adjustments included in business net income.

Because our business net income is not a standardized measure, it may not be comparable with the non-GAAP financial measures of other companies using the same or a similar non-GAAP financial measure.

**A.1.6. Presentation of Net Sales**

In the discussion below, we present our consolidated net sales for 2016, 2015 and 2014. We analyze our net sales among various categories, including by business, product and geographical region. In addition to reported net sales, we analyze non-GAAP financial measures designed to isolate the impact on our net sales of currency exchange rates and changes in the structure of our group.

When we refer to changes in our net sales **at constant exchange rates (CER)**, that means that we have excluded the effect of exchange rates by recalculating net sales for the relevant period using the exchange rates that were used for the previous period.

When we refer to changes in our net sales on a **constant structure basis**, that means that we eliminate the effect of changes in structure by restating the net sales for the previous period as follows:

- by including sales generated by entities or product rights acquired in the current period for a portion of the previous period equal to the portion of the current period during which we owned them, based on sales information we receive from the party from whom we make the acquisition;
- similarly, by excluding sales for a portion of the previous period when we have sold an entity or rights to a product in the current period; and
- for a change in consolidation method, by recalculating the previous period on the basis of the method used for the current period.

#### **A.1.7. Financial Presentation of Alliances**

We have entered into a number of alliances for the development, co-promotion and/or co-marketing of our products. We believe that a presentation of our two principal alliances is useful to an understanding of our financial statements.

The financial impact of the alliances on the Company's income statement is described in Results of Operations Year Ended December 31, 2016 Compared with Year Ended December 31, 2015 and Year Ended December 31, 2015 Compared with Year Ended December 31, 2014, in particular in Net Sales, Other Revenues, Share of Profit/Loss of Associates and Joint Ventures and Net Income Attributable to Non-Controlling Interests.

##### *1/ Alliance Arrangements with Regeneron*

##### *Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies*

In November 2007, Sanofi and Regeneron signed agreements (amended in November 2009) for the discovery,

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

development and commercialization of fully human therapeutic antibodies. Under the 2009 amended agreements Sanofi committed to funding the discovery and pre-clinical development of fully human therapeutic antibodies by a maximum of \$160 million per year through 2017. Sanofi has an option to develop and commercialize antibodies discovered by Regeneron pursuant to the collaboration. Following the signature in July 2015 of the immuno-oncology collaboration agreement described below, \$75 million (spread over three years) was reallocated to that new agreement.

If the option is exercised, Sanofi co-develops the antibody with Regeneron and is responsible for funding. Sanofi and Regeneron share co-promotion rights and profits on sales of the co-developed antibodies. On receipt of the first positive Phase III trial results for any such antibody, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item **Research and development expenses**. Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties to the collaboration. In addition, Sanofi may be required to make milestone payments based on aggregate sales of all antibodies. As of December 31, 2016 the cumulative development costs incurred by the two parties were \$5.1 billion ( \$3.0 billion funded 100% by Sanofi, and \$2.1 billion funded 80% by Sanofi and 20% by Regeneron). On the later of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron will share the commercial expenses of the antibodies jointly developed under the license agreement. Sanofi recognizes all the sales of those antibodies. Profits and losses arising from commercial operations in the United States are split equally between the parties. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses attributable to Regeneron under the agreement is recognized in the line items **Other operating income** or **Other operating expenses**, which are components of **Operating income**. In addition, Regeneron is entitled to receive payments of up to \$250 million contingent on the attainment of specified levels of sales outside the United States.

If Sanofi opts not to exercise its license option for an antibody, it will receive a royalty from Regeneron on sales of that antibody.

***Collaboration agreement on the discovery, development and commercialization of antibodies in the field of immuno-oncology***

On July 28, 2015, Sanofi and Regeneron entered into a new global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology. As part of the agreement, the two companies will jointly develop a programmed cell death protein 1 (PD-1) inhibitor antibody currently in Phase II, and initiate clinical trials from 2016 with new therapeutic candidates based on ongoing innovative preclinical programs. Sanofi has made an upfront payment of \$640 million to Regeneron. The two companies will invest approximately \$1 billion from discovery through proof of concept (POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron (\$250 million) and 75% by Sanofi (\$750 million). Under the terms of the discovery program, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron's share of quarterly profits) until the payments from Regeneron reach 50% of the clinical development costs initially funded by Sanofi.

Sanofi and Regeneron also committed to provide additional funding of no more than \$650 million on an equal basis (\$325 million per company) for the development of REGN2810, a PD-1 inhibitor. In addition, Sanofi will make a one-time milestone payment of \$375 million to Regeneron in the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, \$2 billion in any consecutive 12-month period. Finally, the two companies agreed to reallocate \$75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi's \$160 million annual contribution to their existing antibody collaboration, which otherwise continues as announced in November 2009. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

Under the terms of the development program agreement, Sanofi can exercise its license option for candidates derived from the program.

Once Sanofi has exercised a license option for a candidate, future development of that candidate will be conducted either by Sanofi or Regeneron.

## Edgar Filing: Sanofi - Form 20-F

Where development is conducted by Sanofi, the entire cost of developing that candidate will be funded by Sanofi, and Regeneron will reimburse half of those costs, subject to a cap of 10% of Regeneron's quarterly profits.

Where development is conducted by Regeneron, the two parties will share the development costs equally.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS*****Investor Agreement***

In January 2014, Sanofi and Regeneron amended the investor agreement that has existed between the two companies since 2007 (the Amended Investor Agreement). Pursuant to the Amended Investor Agreement, Sanofi is bound by certain standstill provisions, which contractually prohibit Sanofi from seeking to directly or indirectly exert control of Regeneron or acquiring more than 30% of Regeneron's capital stock (consisting of the outstanding shares of common stock and the shares of Class A stock). This prohibition will remain in place until the earliest of (i) the later of the fifth anniversaries of the expiration or earlier termination of the Zaltrap® collaboration agreement with Regeneron (related to the development and Commercialization of Zaltrap®) or our License and Collaboration Agreement with Regeneron relating to our Antibody Collaboration (see Collaboration agreement on the discovery, development and commercialization of human therapeutics antibodies above), each as amended and (ii) other specified events. Sanofi has also agreed to vote as recommended by Regeneron's board of directors, except that it may elect to vote proportionally with the votes cast by all of Regeneron's other shareholders with respect to certain change-of-control transactions, and to vote in its sole discretion with respect to liquidation or dissolution, stock issuances equal to or exceeding 20% of the outstanding shares or voting rights of Regeneron's Class A Stock and Common Stock (taken together), and new equity compensation plans or amendments if not materially consistent with Regeneron's historical equity compensation practices. The rights and restrictions under the investor agreement are subject to termination upon the occurrence of certain events. Having passed the threshold of 20% ownership of the capital stock, Sanofi exercised its right under the Amended Investor Agreement to designate an independent director, who was appointed to the Board of Directors of Regeneron. The interest held by Sanofi in Regeneron has been consolidated by the equity method since the start of April 2014. In December 2015, Sanofi disclosed its intent to purchase, directly or through its subsidiaries, additional shares of Regeneron Common Stock to maintain and opportunistically increase its beneficial ownership without exceeding the maximum allowed under the Amended Investor Agreement entered into in January 2014 (30% of Shares of Then Outstanding Common Stock, as defined therein). Sanofi made no commitments concerning the price and availability of shares of Common Stock, the timing, or any other factors considered relevant to Sanofi. On December 31, 2016, Sanofi had an equity interest of 22.1% in Regeneron. On the conditions set out in the Amended Investor Agreement entered into in January 2014, Sanofi's right to designate a Regeneron board member is contingent on Sanofi maintaining its percentage share of Regeneron's outstanding capital stock (measured on a quarterly basis) at a level no lower than the highest percentage level previously achieved, with the maximum requirement capped at 25%.

In November 2015, the Independent Designee (as defined in the Amended Investor Agreement) designated by Sanofi as an independent director, resigned from the Regeneron Board of Directors. At Sanofi's request, pursuant to the Amended Investor Agreement, Regeneron appointed N. Anthony Tony Coles, M.D. to its Board of Directors in January 2017 as a successor Sanofi designee.

The Amended Investor Agreement also gives Sanofi the right to receive certain reasonable information as may be agreed upon by the parties and which will facilitate Sanofi's ability to account for their investment in Regeneron using the equity method of accounting under IFRS.

***2/ Alliance Arrangements with Bristol-Myers Squibb (BMS)***

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, which took effect on January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico, giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS will receive royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in the United States and Puerto Rico) until 2018, and will also receive a payment of \$200 million from Sanofi in December 2018, part of which will be used to buy out the non-controlling interests (see Note D.18.). Rights to Plavix® in the United States and Puerto Rico remain unchanged and continue to be governed by the terms of the original agreement until December 2019.

## Edgar Filing: Sanofi - Form 20-F

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro<sup>®</sup>/Avalide<sup>®</sup>) as defined in the new agreement, Sanofi recognizes in its consolidated financial statements the revenue and expenses generated by its own operations. The share of profits reverting to BMS subsidiaries is presented within *Net income attributable to non-controlling interests* in the income statement.

In the territory managed by BMS (United States and Puerto Rico for Plavix<sup>®</sup>), Sanofi recognizes its share of profits and losses within the line item *Share of profit/(loss) of associates and joint ventures*.

### **A.1.8. Impact of Exchange Rates**

We report our consolidated financial statements in euros. Because we earn a significant portion of our revenues in

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

countries where the euro is not the local currency, our results of operations can be significantly affected by exchange rate movements between the euro and other currencies, primarily the US dollar and, to a lesser extent, the Japanese yen, and currencies in emerging countries. We experience these effects even though certain of these countries do not account for a large portion of our net sales. In 2016, we earned 36.6% of our net sales in the United States. An increase in the value of the US dollar against the euro has a positive impact on both our revenues and our operating income. A decrease in the value of the US dollar against the euro has a negative impact on our revenues, which is not offset by an equal reduction in our costs and therefore negatively affects our operating income. A variation in the value of the US dollar has a particularly significant impact on our operating income, which is higher in the United States than elsewhere, and on the contribution to net income of our collaborations with Regeneron and BMS in the United States (see Financial Presentation of Alliances above).

For a description of arrangements entered into to manage operational foreign exchange risks as well as our hedging policy, see Item 11. Quantitative and Qualitative Disclosures about Market Risk, and Item 3. Key Information D. Risk Factors Risks Related to Financial Markets Fluctuations in currency exchange rates could adversely affect our results of operations and financial condition.

**A.1.9. Divestments**

At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their European joint venture Sanofi Pasteur MSD (SPMSD). This transaction involves the divestment of our share in the joint venture and the acquisition of the vaccines portfolio that reverts to Sanofi. The consideration for the transfer was (i) a fixed sum of 127 million received on January 4, 2017 and (ii) contingent consideration based on a percentage of MSD sales during the 2017-2024 period of specified products previously distributed by SPMSD, and receivable in annual installments over the same period. As of December 31, 2016, the fair value of the contingent consideration was measured at 458 million and recognized in the available-for-sale financial assets category.

There were no material divestments in 2015 and 2014.

For further details about the divestments mentioned above, see Note D.1.2. to our consolidated financial statements included at Item 18 of this annual report.

**A.1.10. Acquisitions**

In 2016, as part of the termination of the Sanofi Pasteur MSD joint venture, we acquired the vaccines portfolio that reverts to us. The purchase price essentially comprises (i) a fixed sum of 154 million paid on January 4, 2017 and (ii) contingent consideration of 354 million based on a percentage of future sales made by Sanofi Pasteur during

the 2017-2024 period of specified former SPMSD products, to be paid in installments over that period

The impact of acquisitions in 2015 on our consolidated financial statements is not material.

The principal acquisition during 2014 was Sanofi's acquisition of 7 million shares of Regeneron. As of December 31, 2014, Sanofi held 22.3% of Regeneron's share capital (versus 15.9% on December 31, 2013). The acquisition price amounted to 1,629 million.

The impact of other acquisitions in 2014 on our consolidated financial statements is not material.

For further information about the acquisitions mentioned above, see Note D.1. to our consolidated financial statements included at Item 18 of this annual report.

**A.1.11. Critical accounting and reporting policies**

Our consolidated financial statements are affected by the accounting and reporting policies that we use. Certain of our accounting and reporting policies are critical to an understanding of our results of operations and financial condition, and in some cases the application of these critical policies can be significantly affected by the estimates, judgments and assumptions made by management during the preparation of our consolidated financial statements. The accounting and reporting policies that we have identified as fundamental to a full understanding of our results of operations and financial condition are the following:

***1/ Revenue recognition***

Our policies with respect to revenue recognition are discussed in Note B.13. to our consolidated financial statements included at Item 18 of this annual report. Revenue arising from the sale of goods is presented in the income statement within *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, vaccines, and active ingredients, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities. Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; we no longer have effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to us.

We offer various types of price reductions on our products. In particular, products sold in the United States are covered by various programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

arrangements. Cash discounts may also be granted for prompt payment. The discounts, incentives and rebates described above are estimated on the basis of specific contractual arrangements with our customers or of specific terms of the relevant regulations and/or agreements applicable for transactions with healthcare authorities, and of assumptions about the attainment of sales targets. We also estimate the amount of sales returns, on the basis of contractual sales terms and reliable historical data. Discounts, incentives, rebates and sales returns are recognized in the period in which the underlying sales are recognized, as a reduction of sales revenue. For additional details regarding the financial impact of discounts, incentives, rebates and sales returns, see Note D.23. to our consolidated financial statements included at Item 18 of this annual report.

Non-Sanofi products revenues, mainly comprising royalty income from license arrangements and sales of non Sanofi products by our US-based entity VaxServe, are presented in *Other revenues*.

**2/ Business combinations**

As discussed in Note B.3. Business combinations and transactions with non-controlling interests to our consolidated financial statements included at Item 18 of this annual report, business combinations are accounted for by the acquisition method. The acquiree's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 Business Combinations are measured initially at their fair values as at the acquisition date, except for non-current assets classified as held for sale, which are measured at fair value less costs to sell. Business combinations completed on or after January 1, 2010 are accounted for in accordance with the revised IFRS 3 and the revised IAS 27, Consolidated and Individual Financial Statements, now superseded by IFRS 10 Consolidated Financial Statements. In particular, contingent consideration payable to former owners agreed in a business combination, e.g. in the form of payments upon the achievement of certain R&D milestones, is recognized as a liability at fair value as of the acquisition date. If the contingent consideration was originally recognized as a liability, subsequent adjustments to the liability are recognized in profit or loss (see Note D.18. Liabilities related to business combinations and non-controlling interests to our consolidated financial statements included at Item 18 of this annual report).

**3/ Goodwill impairment and intangible assets**

As discussed in Note B.6. Impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures and in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report, we test our intangible assets periodically for

impairment. We test for impairment on the basis of the same objective criteria that were used for the initial valuation. Our initial valuation and ongoing tests are based on the relationship of the value of our projected future cash flows associated with the asset to either the purchase price of the asset (for its initial valuation) or the carrying amount of the asset (for ongoing tests). The determination of the underlying assumptions relating to the recoverability of intangible assets is subjective and requires the exercise of considerable judgment. Key assumptions relating to goodwill impairment and intangible assets are the perpetual growth rate and the post-tax discount rate. Any changes in key assumptions could result in an impairment charge. A sensitivity analysis to the key assumptions is disclosed in Note D.5. Impairment of intangible assets and property, plant and equipment to our consolidated financial statements included at Item 18 of this annual report.

**4/ Venezuelan Subsidiaries**

As described in Note A.4. to our consolidated financial statements included at Item 18 of this annual report, Sanofi continues to account for subsidiaries based in Venezuela using the full consolidation method, on the basis that the criteria for control as specified in IFRS 10 (Consolidated Financial Statements) are met. In the context of the existence of several exchange rates in Venezuela, Sanofi has decided to use the new DICOM rate (established in February 2016) for the translation of transactions carried out by subsidiaries.

**5/ Contingent consideration receivable**

## Edgar Filing: Sanofi - Form 20-F

As described in Note B.8.6. and D.7. to our consolidated financial statements included at Item 18 of this annual report, contingent consideration receivable such as earn-outs on disposals, for example in the form of a percentage of future sales of the acquirer, are recognized as an asset at fair value at disposal date. Subsequent remeasurements of the fair value of the asset are recognized in profit or loss.

### *6/ Pensions and post-retirement benefits*

As described in Note B.23. Employee benefit obligations to our consolidated financial statements included at Item 18 of this annual report, we recognize our pension and retirement benefit commitments as liabilities on the basis of an actuarial estimate of the rights vested in employees and retirees at the end of the reporting period, net of the fair value of plan assets held to meet these obligations. We prepare this estimate at least on an annual basis taking into account financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

We recognize all actuarial gains and losses (including the impact of a change in discount rate) immediately through

---

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

equity. A sensitivity analysis to discount rate is set forth in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

Depending on the key assumptions used, the pension and post-retirement benefit expense could vary within a range of outcomes and have a material effect on reported earnings. A sensitivity analysis to these key assumptions is set forth in Note D.19.1. Provisions for pensions and other benefits to our consolidated financial statements included at Item 18 of this annual report.

***7/ Deferred taxes***

As discussed in Note B.22. Income tax expense to our consolidated financial statements included at Item 18 of this annual report, we recognize deferred income taxes on tax loss carry-forwards and on temporary differences between the tax base and carrying amount of assets and liabilities. We calculate our deferred tax assets and liabilities using enacted tax rates applicable for the years during which we estimate that the temporary differences are expected to reverse. We do not recognize deferred tax assets when it is more likely than not that the deferred tax assets will not be realized. The recognition of deferred tax assets is determined on the basis of profit forecasts for each tax group, and of the tax consequences of the strategic opportunities available to Sanofi.

***8/ Provisions for risks***

Sanofi and its subsidiaries and affiliates may be involved in litigation, arbitration or other legal proceedings. These proceedings typically are related to product liability claims,

intellectual property rights, compliance and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As discussed in Note B.12. Provisions for risks at Item 18 of this annual report, we record a provision where we have a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources. For additional details regarding the financial impact of provisions for risks see Notes D.19.3. Other provisions and D.22. Legal and Arbitral Proceedings to our consolidated financial statements included at Item 18 of this annual report.

***9/ Provisions for restructuring costs***

Provisions for restructuring costs include early retirement benefits, compensation for early termination of contracts, and rationalization costs relating to restructured sites. Refer to Note D.19.2 to our consolidated financial statements included in Item 18 of this annual report.

Provisions are estimated on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management's knowledge at the date of preparation of the financial statements. The assessment of provisions can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Given the inherent uncertainties related to these estimates and assumptions, the actual outflows resulting from the realization of those risks could differ from our estimates.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****A.2. RESULTS OF OPERATIONS YEAR ENDED DECEMBER 31, 2016 COMPARED WITH YEAR ENDED DECEMBER 31, 2015****A.2.1 Consolidated income statements**

The consolidated income statements for the years ended December 31, 2016 and December 31, 2015 are presented below:

( million)	2016 <sup>(a)</sup>	as % of net sales	2015 <sup>(a)(b)</sup>	as % of net sales
<b>Net sales</b>	<b>33,821</b>	<b>100.0%</b>	<b>34,060</b>	<b>100.0%</b>
Other revenues	887	2.6%	801	2.4%
Cost of sales	(10,702)	(31.6%)	(10,919)	(32.1%)
<b>Gross profit</b>	<b>24,006</b>	<b>71.0%</b>	<b>23,942</b>	<b>70.3%</b>
Research and development expenses	(5,172)	(15.3%)	(5,082)	(14.9%)
Selling and general expenses	(9,486)	(28.0%)	(9,382)	(27.5%)
Other operating income	355		254	
Other operating expenses	(482)		(462)	
Amortization of intangible assets	(1,692)		(2,137)	
Impairment of intangible assets	(192)		(767)	
Fair value remeasurement of contingent consideration liabilities	(135)		53	
Restructuring costs and similar items	(879)		(795)	
Other gains and losses, and litigation	211		-	
<b>Operating income</b>	<b>6,534</b>	<b>19.3%</b>	<b>5,624</b>	<b>16.5%</b>
Financial expenses	(924)		(559)	
Financial income	68		178	
<b>Income before tax and associates and joint ventures</b>	<b>5,678</b>	<b>16.8%</b>	<b>5,243</b>	<b>15.4%</b>
Income tax expense	(1,326)		(709)	
Share of profit/(loss) of associates and joint ventures	134		(22)	
<b>Net income excluding the held-for-exchange Animal Health business</b>	<b>4,486</b>	<b>13.3%</b>	<b>4,512</b>	<b>13.2%</b>
Net income/(loss) of the held-for-exchange Animal Health business	314		(124)	
<b>Net income</b>	<b>4,800</b>	<b>14.2%</b>	<b>4,388</b>	<b>12.9%</b>
Net income attributable to non-controlling interests	91		101	
<b>Net income attributable to equity holders of Sanofi</b>	<b>4,709</b>	<b>13.9%</b>	<b>4,287</b>	<b>12.6%</b>
Average number of shares outstanding (million)	1,286.6		1,306.2	
Average number of shares outstanding after dilution (million)	1,296.0		1,320.7	
Basic earnings per share (in euros)	3.66		3.28	
Basic earnings per share excluding the held-for-exchange Animal Health business (in euros)	3.42		3.38	
Diluted earnings per share (in euros)	3.63		3.25	
Diluted earnings per share excluding the held-for-exchange Animal Health business (in euros)	3.39		3.34	

(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36. to our consolidated financial statements.

## Edgar Filing: Sanofi - Form 20-F

(b) *Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly; refer to Note A.5. to our consolidated financial statements.*

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****A.2.2. Net sales**

Net sales for the year ended December 31, 2016 were 33,821 million, 0.7% lower than in 2015. Exchange rate fluctuations had a negative effect of 1.9 percentage points overall, with adverse trends in the Argentine peso, Chinese yuan renminbi, Mexican peso and pound sterling outweighing the positive effect of the Japanese yen and US dollar. At constant exchange rates (CER), net sales rose by 1.2%.

This performance includes the negative effects of a change in the exchange rate applied in translating the results of our

Venezuelan operations into euros. This change reflects reforms to the Venezuelan foreign exchange system in February 2016, and the continued impossibility of converting bolivars to US dollars at the official preferential exchange rate<sup>(1)</sup>. In addition, in the first half of 2015, Sanofi benefited from a significant increase in product demand in Venezuela, due to buying patterns associated with local market conditions. As a result, our net sales in Venezuela amounted to 18 million in 2016, compared with 455 million in 2015. Excluding Venezuela, our net sales increased by 2.6% CER.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2016 and December 31, 2015 to our net sales at constant exchange rates:

( million)	2016 <sup>(a)</sup>	2015 <sup>(a)(b)</sup>	Change
<b>Net sales</b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>
Effect of exchange rates	661		
<b>Net sales at constant exchange rates</b>	<b>34,482</b>	<b>34,060</b>	<b>+1.2%</b>

(a) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business.

(b) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

**I/ Net Sales by Operating Segment**

Our net sales comprise the net sales generated by our Pharmaceuticals and Human Vaccines (Vaccines) segments, in accordance with IFRS 5.

The following table sets forth our 2016 and 2015 net sales by operating segment:.

## Edgar Filing: Sanofi - Form 20-F

( million)	2016 <sup>(a)</sup>	2015 <sup>(a)(b)</sup>	Change
Pharmaceuticals	29,244	29,799	-1.9%
Vaccines	4,577	4,261	+7.4%
<b>Net sales</b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>

(a) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business.

(b) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

During 2016, Sanofi and Boehringer Ingelheim (BI) finalized the negotiations initiated in December 2015 with a view to swapping Sanofi's Animal Health business for BI's Consumer Healthcare business. This transaction having closed on January 1, 2017, the Animal Health business ceased to be an operating segment within the meaning of IFRS 8. In the consolidated income statement, the net income/(loss) of this business is presented in a separate line

item, **Net income/(loss) of the held-for-exchange Animal Health business**, in accordance with IFRS 5 (see Notes B.7., D.2. and D.36. to our consolidated financial statements, included at Item 18 of this annual report). Consequently, the net sales as presented above and as reported in our consolidated income statement do not include the net sales of the Animal Health business.

<sup>(1)</sup> The exchange rate used in 2016 was the DICOM rate of 710 bolivars per US dollar, as opposed to the SICAD administered exchange rate of 13.5 bolivars per US dollar used in 2015.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The Animal Health business generated net sales of 2,708 million in the year ended December 31, 2016.

( million)	2016	2015
Companion Animals	1,781	1,629
Production Animals	927	886
<b>Total Animal Health</b>	<b>2,708</b>	<b>2,515</b>
<i>of which fipronil products</i>	546	627
<i>of which vaccines</i>	845	804
<i>of which avermectin products</i>	520	498

**2/ Net Sales by Global Business Unit (GBU)**

The table below presents net sales for our Global Business Units (GBUs) reflecting the new structure intended to streamline our organization, sharpen our focus and concentrate our efforts on growth drivers. Within this new structure, Emerging Markets sales of Diabetes & Cardiovascular and Specialty Care products are included in the General Medicines & Emerging Markets GBU. Following the creation of the Consumer Healthcare GBU, sales of that GBU's products previously included in the General Medicines & Emerging Markets GBU are presented for information purposes on a separate line for 2016 and prior periods, in the interests of comparability.

Net sales by Global Business Unit (GBU)			Change on	
	2016	2015	a reported	Change at constant exchange rates
( million)			basis	
Sanofi Genzyme GBU <sup>(a)</sup> (Specialty Care) <sup>(b)</sup>	5,019	4,275	+17.4%	+17.3%
Diabetes & Cardiovascular GBU <sup>(a)</sup>	6,397	6,517	-1.8%	-2.0%
General Medicines & Emerging Markets GBU <sup>(c)(d)</sup>	14,498	15,515	-6.6%	-3.3%
Consumer Healthcare GBU	3,330	3,492	-4.6%	-1.6%
<b>Total Pharmaceuticals</b>	<b>29,244</b>	<b>29,799</b>	<b>-1.9%</b>	<b>+0.2%</b>
<b>Sanofi Pasteur (Vaccines) GBU<sup>(e)</sup></b>	<b>4,577</b>	<b>4,261</b>	<b>+7.4%</b>	<b>+8.8%</b>
<b>Total Net Sales<sup>(f)</sup></b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>	<b>+1.2%</b>

(a) Does not include Emerging Markets net sales.

(b) Rare Diseases, Multiple Sclerosis, Oncology and Immunology.

(c) Includes net sales in Emerging Markets of Specialty Care and Diabetes & Cardiovascular products.

## Edgar Filing: Sanofi - Form 20-F

- (d) *Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.*
- (e) *Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.*
- (f) *In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business. The net sales of the Animal Health business (equivalent to the net sales of the Animal Health GBU) are presented for information purposes in *1/ Net Sales by Operating Segment* above.*

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****3/ Net Sales by Franchise**

The table below sets forth our 2016 net sales by franchise in order to facilitate comparisons with our peers. For a detailed reconciliation of net sales by franchise and net sales by GBU for our Pharmaceuticals segment, refer to the table showing Pharmaceuticals segment net sales by geographical region.

<i>Net Sales by Franchise</i>	2016	2015	Change on  a reported	Change  at constant  exchange rates
( million)	2016	2015	basis	rates
Rare Diseases	2,777	2,550	+8.9%	+11.7%
Multiple Sclerosis	1,720	1,114	+54.4%	+56.1%
Oncology	1,453	1,504	-3.4%	-2.2%
<b>Total Specialty Care</b>	<b>5,950</b>	<b>5,168</b>	<b>+15.1%</b>	<b>+17.2%</b>
<i>of which Developed Markets (Sanofi Genzyme GBU)</i>	<i>5,019</i>	<i>4,275</i>	<i>+17.4%</i>	<i>+17.3%</i>
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	<i>931</i>	<i>893</i>	<i>+4.3%</i>	<i>+16.7%</i>
Diabetes	7,341	7,580	-3.2%	-1.8%
Cardiovascular	458	350	+30.9%	+31.1%
<b>Total Diabetes &amp; Cardiovascular</b>	<b>7,799</b>	<b>7,930</b>	<b>-1.7%</b>	<b>-0.4%</b>
<i>of which Developed Markets (Diabetes &amp; Cardiovascular GBU)</i>	<i>6,397</i>	<i>6,517</i>	<i>-1.8%</i>	<i>-2.0%</i>
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	<i>1,402</i>	<i>1,413</i>	<i>-0.8%</i>	<i>+7.2%</i>
Established Prescription Products <sup>(a)</sup>	10,311	11,292	-8.7%	-6.8%
Consumer Healthcare (Consumer Healthcare GBU)	3,330	3,492	-4.6%	-1.6%
Generics <sup>(a)</sup>	1,854	1,917	-3.3%	+0.7%
<b>Total Pharmaceuticals</b>	<b>29,244</b>	<b>29,799</b>	<b>-1.9%</b>	<b>+0.2%</b>
<b>Vaccines (Sanofi Pasteur GBU)<sup>(c)</sup></b>	<b>4,577</b>	<b>4,261</b>	<b>+7.4%</b>	<b>+8.8%</b>
<b>Total Net Sales<sup>(d)</sup></b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>	<b>+1.2%</b>

(a) These items are aggregated to form the General Medicines and Emerging Markets GBU.

(b) Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(c) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

## Edgar Filing: Sanofi - Form 20-F

(d) *In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business. The net sales of the Animal Health business (equivalent to the net sales of the Animal Health GBU) are presented for information purposes in [1/ Net Sales by Operating Segment](#) above.*

### **4/ Net Sales - Pharmaceuticals Segment**

In 2016, net sales for the Pharmaceuticals segment were 29,244 million, down 1.9% on a reported basis and up 0.2% at constant exchange rates (CER). The year-on-year decrease of 555 million reflects the negative effect of exchange rates (604 million), and the following impacts at CER:

- growth in net sales for the Multiple Sclerosis franchise (up 625 million), the Rare Diseases franchise (up 298 million) and the Cardiovascular franchise (up 109 million); and
  - lower net sales for Established Prescription Products (down 770 million), the Diabetes franchise (down 137 million), Consumer Healthcare (down 56 million) and the Oncology franchise (down 33 million).
- Excluding Venezuela, pharmaceuticals net sales rose by 1.6% CER. Comments on the performances of major Pharmaceuticals segment products are provided below.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****Pharmaceuticals segment net sales, 2016 and 2015**

Net sales by product and franchise				Change on	Change at
		2016	2015	a reported	constant
( million)	Indication			basis	exchange
				rates	rates
Cerezyme®	Gaucher disease	748	757	-1.2%	+5.3%
Cerdelga®	Gaucher disease	106	66	+60.6%	+59.1%
Myozyme® /Lumizyme®	Pompe disease	725	650	+11.5%	+13.5%
Fabrazyme®	Fabry disease	674	592	+13.9%	+14.7%
Aldurazyme®	Mucopolysaccharidosis	201	195	+3.1%	+7.7%
Other		323	290	+11.4%	+10.0%
<b>Total Rare Diseases</b>		<b>2,777</b>	<b>2,550</b>	<b>+8.9%</b>	<b>+11.7%</b>
Aubagio®	Multiple sclerosis	1,295	871	+48.7%	+49.7%
Lemtrada®	Multiple sclerosis	425	243	+74.9%	+79.0%
<b>Total Multiple sclerosis</b>		<b>1,720</b>	<b>1,114</b>	<b>+54.4%</b>	<b>+56.1%</b>
Jevtana®	Prostate cancer	358	321	+11.5%	+11.5%
Thymoglobulin®	Organ rejection	281	256	+9.8%	+10.9%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	179	222	-19.4%	-17.1%
Eloxatin®	Colorectal cancer	170	227	-25.1%	-21.6%
Mozobil®	Hematologic malignancies	152	143	+6.3%	+7.0%
Zaltrap®	Colorectal cancer	65	77	-15.6%	-14.3%
Other		248	258	-3.9%	-3.9%
<b>Total Oncology</b>		<b>1,453</b>	<b>1,504</b>	<b>-3.4%</b>	<b>-2.2%</b>
<b>Total Specialty Care</b>		<b>5,950</b>	<b>5,168</b>	<b>+15.1%</b>	<b>+17.2%</b>
Lantus®	Diabetes	5,714	6,390	-10.6%	-9.4%
Toujeo®	Diabetes	649	164	+295.7%	+294.5%
Amaryl®	Diabetes	362	393	-7.9%	-3.8%
Apidra®	Diabetes	367	376	-2.4%	-1.1%
Insuman®	Diabetes	129	141	-8.5%	-3.5%
Blood glucose meters	Diabetes	66	63	+4.8%	+4.8%
Lyxumia®	Diabetes	33	38	-13.2%	-13.2%
Other	Diabetes	21	15	+40.0%	+26.7%
<b>Total Diabetes</b>		<b>7,341</b>	<b>7,580</b>	<b>-3.2%</b>	<b>-1.8%</b>
Multaq®	Atrial fibrillation	353	341	+3.5%	+3.8%
Praluent®	Hypercholesterolemia	105	9	+1,066.7%	+1,066.7%
<b>Total Cardiovascular</b>		<b>458</b>	<b>350</b>	<b>+30.9%</b>	<b>+31.1%</b>

<b>Total Diabetes &amp; Cardiovascular</b>	<b>7,799</b>	<b>7,930</b>	<b>-1.7%</b>	<b>-0.4%</b>
--	--------------	--------------	--------------	--------------

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

Net sales by product and franchise ( million)		2016	2015	Change on	Change at
				a reported	constant
Indication				basis	exchange rates
Lovenox <sup>®</sup>	Thrombosis	1,636	1,719	-4.8%	-1.7%
Plavix <sup>®</sup>	Atherothrombosis	1,544	1,929	-20.0%	-18.8%
Renagel <sup>®</sup> /Renvela <sup>®</sup>	Hyperphosphatemia	922	935	-1.4%	-1.1%
Aprovel <sup>®</sup> / Avapro <sup>®</sup>	Hypertension	681	762	-10.6%	-7.0%
Depakine <sup>®</sup>	Epilepsy	416	422	-1.4%	+3.3%
Synvisc <sup>®</sup> / Synvisc-One <sup>®</sup>	Arthritis	408	413	-1.2%	-0.2%
Stilnox <sup>®</sup> /Ambien <sup>®</sup> /Myslee <sup>®</sup>	Sleep disorders	304	306	-0.7%	-2.9%
Tritace <sup>®</sup>	Hypertension	245	274	-10.6%	-7.7%
Allegra <sup>®</sup>	Allergic rhinitis, urticaria	186	194	-4.1%	-11.9%
Targocid <sup>®</sup>	Bacterial infections	149	160	-6.9%	-3.8%
Lasix <sup>®</sup>	Edema, hypertension	148	162	-8.6%	-6.2%
Cordarone <sup>®</sup>	Arrhythmia	122	130	-6.2%	-4.6%
Xatral <sup>®</sup>	Benign prostatic hypertrophy	100	95	+5.3%	+8.4%
Orudis <sup>®</sup>	Rheumatoid arthritis, osteoarthritis	103	156	-34.0%	-30.1%
Other		3,347	3,635	-7.9%	-5.9%
<b>Total Established Prescription Products</b>		<b>10,311</b>	<b>11,292</b>	<b>-8.7%</b>	<b>-6.8%</b>
<b>Consumer Healthcare</b>		<b>3,330</b>	<b>3,492</b>	<b>-4.6%</b>	<b>-1.6%</b>
<b>Generics</b>		<b>1,854</b>	<b>1,917</b>	<b>-3.3%</b>	<b>+0.7%</b>
<b>Total Pharmaceuticals</b>		<b>29,244</b>	<b>29,799</b>	<b>-1.9%</b>	<b>+0.2%</b>
<b>Rare Diseases franchise</b>					

Net sales for the **Rare Diseases** franchise reached 2,777 million in 2016, up 8.9% on a reported basis and 11.7% CER.

In Gaucher disease, net sales of **Cerezyme**<sup>®</sup> advanced by 5.3% CER to 748 million, as strong growth in Emerging Markets<sup>(1)</sup> (+27.1% CER, at 239 million) more than compensated for lower sales in the United States (-10% CER, at 181 million) due to the launch of Cerdelga<sup>®</sup>. **Cerdelga**<sup>®</sup> reported net sales of 106 million, of which 85 million were generated in the United States. In Europe, where Cerdelga<sup>®</sup> is now available in a number of countries (including Germany, France, Italy and some Nordic countries), net sales of the product were 17 million.

Net sales of **Myozyme**<sup>®</sup> / **Lumizyme**<sup>®</sup> in Pompe disease rose by 13.5% CER to 725 million, driven by sales in the United States (+16.6% CER, at 240 million) and Europe (+8.5% CER, at 327 million). Net sales also rose sharply in

Emerging Markets (+20.2% CER, at 102 million) and in the Rest of the World region<sup>(2)</sup> (+20.5% CER, at 56 million). This performance is mainly due to increased worldwide diagnosis.

In Fabry disease, **Fabrazyme**<sup>®</sup> posted net sales growth of 14.7% CER to 674 million. The product reported growth in many countries due to an increase in the number of patients treated, with notable performances in the United States (+12.8% CER, at 345 million), Europe (+13.6% CER, at 156 million), but also in Japan (+14% CER, at 73 million), and in Emerging Markets (+25.4% CER, at 68 million).

#### Multiple Sclerosis franchise

Net sales for the Multiple Sclerosis franchise reached 1,720 million in 2016, up 54.4% on a reported basis and 56.1% CER. This progression is mainly due to the net sales of **Aubagio**<sup>®</sup> which advanced by 49.7% CER to

<sup>(1)</sup> World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

<sup>(2)</sup> Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

1,295 million. In the United States, net sales reached 908 million, up 46.6% CER. In Europe, the product continued to extend its geographical reach, and net sales rose by 56.9% CER to 308 million. Aubagio® is currently the fastest-growing oral treatment in the multiple sclerosis market, with a patient market share of 8.8% in the United States (IMS NSP TRX Q4 2016).

Net sales of **Lemtrada**® amounted to 425 million (+79% CER), including 233 million in the United States and 151 million in Europe, mainly in Germany and the United Kingdom.

**Oncology franchise**

The Oncology franchise generated net sales of 1,453 million, down 3.4% on a reported basis and 2.2% CER, reflecting lower sales of Taxotere®, Eloxatin® and Zaltrap®, though the effect was partially compensated by increased sales of Jevtana®, Thymoglobulin® and Mozobil®.

Net sales of **Jevtana**® totaled 358 million in 2016, up 11.5% CER, driven by a strong performance in the United States (+18.9% CER, at 152 million) and in Japan (+85% CER, at 41 million).

Net sales of **Thymoglobulin**® rose by 10.9% CER to 281 million on good performances in Emerging Markets (+23.5% CER, at 59 million), the United States (+10.3% CER, at 160 million) and the Rest of the World region (+10% CER, at 24 million).

**Taxotere**® saw net sales fall by 17.1% CER to 179 million, reflecting competition from generics in Emerging Markets (-3.5% CER, at 130 million) and in Japan (-60% CER, at 26 million), though the effect was partly offset by stronger sales in China (+26.5% CER, at 59 million).

Net sales of **Eloxatin**® were down 21.6% CER at 170 million, hit by a slump in sales in Canada (-86.2% CER, at 8 million) due to competition from generics.

Net sales of **Mozobil**® reached 152 million, up 7% CER, mainly on sales growth in the United States (+14.5% CER, at 95 million).

**Zaltrap**® (afibercept, developed in collaboration with Regeneron) reported a decline in net sales of 14.3% CER to 65 million. This reflects lower sales in the United States (-33.3% CER, at 14 million) and also in Europe (-7.8% CER, at 47 million).

**Diabetes franchise**

Net sales for the Diabetes franchise amounted to 7,341 million in 2016, down 3.2% on a reported basis and 1.8% CER. The main factor was reduced sales of Lantus® in the United States, where net sales for the Diabetes franchise fell by 4.6% CER to 4,127 million. Outside the United States, Diabetes franchise net sales reached 3,214 million,

driven by Emerging Markets (+7% CER at 1,395 million, or +10.7% CER excluding Venezuela). In Europe, net sales were 1,319 million, down 0.4% CER, as a strong performance from Toujeo® canceled out lower sales of Lantus®.

Net sales of **insulin glargines** (Lantus® and Toujeo®) fell by 1.8% CER to 6,363 million.

Net sales of **Lantus**® were down 9.4% CER in 2016, at 5,714 million. In the United States, sales were down 12.5% CER at 3,528 million, mainly due to a decrease in the average selling price and patients switching to Toujeo®. Net sales in Europe fell by 10.3% CER to 878 million, due largely to the launch of a biosimilar of Lantus® in July 2015. Over the same period, sales of Lantus® in Emerging Markets reached 953 million, up 6.0% CER (+8.5% CER excluding Venezuela), driven largely by Asia (+13.6% CER, at 351 million) and especially China.

**Toujeo**<sup>®</sup>, a new-generation basal insulin which saw its first launches in 2015, posted net sales of 649 million, including 475 million in the United States and 120 million in Europe. Worldwide rollout is ongoing, and Toujeo is now available in more than 40 countries including United States, Germany, Spain, France, the United Kingdom and Japan. The product is scheduled to launch in around 20 more countries during 2017 including Italy, Mexico and Russia. In Japan, the two-week prescription limit was lifted in September 2016, resulting in a significant increase in market share (10.8% in December 2016, based on IMS basal insulin market share by value).

Given the recent performance of our diabetes franchise in the EU and Emerging Markets, as well as the aforementioned coverage in the US, Sanofi continues to expect global diabetes sales over the period from 2015 to 2018 to decline at an average annualized rate of between 4% and 8% at CER. (For information about factors that may impact forward-looking statements, see Cautionary Statement Regarding Forward-Looking Statements ).

Net sales of **Amaryl**<sup>®</sup> fell by 3.8% CER to 362 million, mainly due to a drop in sales in Japan (-30.4% CER, at 36 million) due to competition from generics. This was to some extent compensated for by sales growth in Europe (+3.8% CER, at 27 million) and the United States (+50% CER, at 3 million). In Emerging Markets, the product's sales held steady at 92 million, although if Venezuela is excluded sales grew by 8.4%.

Net sales of **Apidra**<sup>®</sup> fell by 1.1% CER to 367 million. Sales declined in the United States (-20.7% CER, at 115 million), reflecting a tougher competitive and pricing environment. However, the effect was partly cushioned by increased sales in Emerging Markets (+32.4% CER, at 81 million) and Europe (+2.4% CER, at 127 million).

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

**Lyxumia**<sup>®</sup> generated 33 million of net sales in 2016, down 13.2% CER.

**Cardiovascular franchise**

Net sales of **Praluent**<sup>®</sup> (alirocumab, developed in collaboration with Regeneron) reached 105 million in 2016, of which 85 million was generated in the United States and 18 million in Europe, where the product is now available in a number of countries including Germany, Spain, the Netherlands, the United Kingdom, and some Nordic countries. Praluent<sup>®</sup> has also been launched in Japan, Canada and Mexico. Amgen initiated patent infringement proceedings in several countries against Sanofi and Regeneron relating to Praluent<sup>®</sup> in which Amgen has requested injunctive relief (see Note D.22. to the consolidated financial statements included at Item 18 and Item 8 Updates to Note D.22 of the annual report for more information).

Net sales of **Multaq**<sup>®</sup> were 353 million (+3.8% CER), of which 299 million was generated in the United States (+4.2% CER) and 44 million in Europe (+2.3% CER).

**Established Prescription Products**

Net sales of established prescription products in 2016 amounted to 10,311 million, down 8.7% on a reported basis and 6.8% CER. This mainly reflects the situation in Venezuela (net sales were down 4.9% CER excluding Venezuela), and competition from generics of Plavix<sup>®</sup> in Japan. In Europe and the United States, net sales of established prescription products fell by 4.8% (to 3,642 million) and 2.4% (to 1,490 million), respectively.

Net sales of **Lovenox**<sup>®</sup> were 1,636 million, down 1.7% CER, due largely to competition from generics in the United States (-29.9% CER, at 54 million). In Europe, sales

of Lovenox<sup>®</sup> were 1.1% lower CER at 1,027 million, as a result of competition from two biosimilars containing enoxaparin sodium that received a positive opinion from the CHMP (Committee for Medicinal Products for Human Use) of the EMA (European Medicines Agency) in July 2016. Net sales of the product rose by 1.6% CER in Emerging Markets (to 462 million), or by 3.7% CER if Venezuela is excluded.

Net sales of **Plavix**<sup>®</sup> were 1,544 million (-18.8% CER), reflecting generic competition in Japan (-54% CER, at 355 million) and Europe (-11.4% CER, at 162 million). The effect was partly offset by growth in sales of Plavix<sup>®</sup> in Emerging Markets (+3.4% CER, at 970 million, or 7.9% excluding Venezuela), especially in China where the product posted net sales of 701 million (+12.3% CER). Sales of Plavix<sup>®</sup> in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see Note C.2., Alliance Arrangements with Bristol-Myers Squibb (BMS) , to our consolidated financial statements).

Net sales of **Renvela**<sup>®</sup>/**Renagel**<sup>®</sup> fell by 1.1% CER to 922 million. In the United States, net sales advanced by 5.5% CER to 764 million. Generics of this product are now being sold in some European countries, as a result of which net sales of Renvela<sup>®</sup>/**Renagel**<sup>®</sup> in Europe slipped by 31.4% to 82 million. We expect potential generic competition in the United States in the first half of 2017.

**Aprovel**<sup>®</sup>/**Avapro**<sup>®</sup> reported a drop in net sales of 7.0% CER to 681 million, mainly as a result of competition from generics in Europe (-13.5% CER, at 127 million) and Japan (-10.6% CER, at 82 million). In Emerging Markets (excluding Venezuela), net sales rose by 6.4% CER to 410 million, mainly on a good performance in China (+9.1% CER, at 239 million).

We have no comments on sales of our other prescription products.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****Consumer Healthcare**

**Consumer Healthcare** products generated net sales of 3,330 million, down 4.6% on a reported basis and 1.6% CER. Excluding Venezuela, net sales of Consumer Healthcare products were up 1.4% CER.

( million)	2016	2015	Change on a reported basis	Change at constant exchange rates
Allegra®	417	424	-1.7%	-0.2%
Doliprane®	309	303	+2.0%	+2.6%
Essentiale®	145	196	-26.0%	-20.9%
Enterogermina®	159	161	-1.2%	+2.5%
Nasacort®	108	122	-11.5%	-10.7%
Maalox®	85	97	-12.4%	-8.2%
Lactacyd®	80	114	-29.8%	-25.4%
Dorflex®	75	81	-7.4%	-2.5%
No-Spa®	82	88	-6.8%	0.0%
Magné B6®	73	82	-11.0%	-6.1%
Other products	1,797	1,824	-1.5%	+1.7%
<b>Total Consumer Healthcare</b>	<b>3,330</b>	<b>3,492</b>	<b>-4.6%</b>	<b>-1.6%</b>

Net sales in the United States were 938 million, up 3.8% CER, despite lower sales of Allegra® OTC (-4.7% CER, at 243 million) and Nasacort® (-9.2% CER, at 90 million) due to an increased competitive environment. In Emerging Markets, net sales slipped by 7.9% CER to 1,238 million, reflecting the impact of Venezuela but also lower sales in Russia and China. In Russia, net sales mainly decreased due to the challenging local economic situation. In the Rest of the World region, net sales were up 9.9% at 275 million, driven by sales in Australia (+10.2% CER, at 203 million). In Europe, net sales were stable year-on-year at 879 million.

During 2016, Sanofi and BI finalized the negotiations initiated in December 2015 with a view to swapping Sanofi's Animal Health business for BI's Consumer Healthcare business. This transaction closed on January 1, 2017 in most markets, strengthening our position in the consumer healthcare market. We have established a dedicated Consumer Healthcare Global Business Unit (GBU) which has been operational since January 1, 2017. The transaction enhanced our position in four of our strategic categories – Vitamins, Minerals and Supplements, Cough & Cold Care, Digestive Health, and Pain Care – by bringing in major BI brands (Pharmatof®, Bisolvon®, Mucosolvan®, Buscopan®,

Dulcolax®, Lysopaine®/Mucoangin®), and enabled us to achieve critical scale in key geographies.

**Generics**

Net sales of **Generics** amounted to 1,854 million, down 3.3% on a reported basis but up 0.7% CER and 2.5% CER if Venezuela is excluded.

## Edgar Filing: Sanofi - Form 20-F

Emerging Markets generated net sales of 785 million (+1.8% CER, or +6.1% CER excluding Venezuela), boosted by Latin America (other than Venezuela), Turkey and China. In Europe, net sales were flat at 802 million. In the United States, net sales increased by 1.8% CER to 175 million. In the Rest of the World region, sales reached 92 million (+1.2% CER), mainly on increased sales of generics in Japan (+1.5% CER, at 74 million).

In line with our Strategic Roadmap 2020 , we have been examining all options and have decided to initiate a carve-out process in order to divest our European Generics business. We will be looking for a potential purchaser who can leverage the mid-to-long-term sustainable growth opportunities for this business. We have also confirmed our commitment to our Generics business in other parts of the world, and will focus more on Emerging Markets in order to develop the business in those countries.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The following table breaks down 2016 net sales of our Pharmaceuticals segment products by geographical region:

( million)	Total GBUs	Europe <sup>(a)</sup>	Change at		Change at		Rest of the world <sup>(b)</sup>	Change at		Total Franchise	Change at	
			constant exchange rates	United States	constant exchange rates	Emerging Markets <sup>(c)</sup>		constant exchange rates	constant exchange rates			
Cerezyme®	509	280	+0.0%	181	-10.0%	48	-2.1%	239	+27.1%	748	+5.3%	
Cerdelga®	106	17	+183.3%	85	+41.7%	4	-	-	-	106	+59.1%	
Myozyme®/Lumizyme®	623	327	+8.5%	240	+16.6%	56	+20.5%	102	+20.2%	725	+13.5%	
Fabrazyme®	606	156	+13.6%	345	+12.8%	105	+15.5%	68	+25.4%	674	+14.7%	
Aldurazyme®	141	75	+2.7%	42	+5.0%	24	+9.1%	60	+15.5%	201	+7.7%	
Other	285	67	+30.8%	121	+6.1%	97	+2.2%	38	+11.1%	323	+10.0%	
<b>Total Rare Diseases</b>	<b>2,270</b>	<b>922</b>	<b>+8.6%</b>	<b>1,014</b>	<b>+9.4%</b>	<b>334</b>	<b>+9.8%</b>	<b>507</b>	<b>+22.9%</b>	<b>2,777</b>	<b>+11.7%</b>	
Aubagio®	1,261	308	+56.9%	908	+46.6%	45	+46.9%	34	+75.0%	1,295	+49.7%	
Lemtrada®	407	151	+73.6%	233	+82.0%	23	+64.3%	18	+110.0%	425	+79.0%	
<b>Total Multiple Sclerosis</b>	<b>1,668</b>	<b>459</b>	<b>+62.2%</b>	<b>1,141</b>	<b>+52.7%</b>	<b>68</b>	<b>+52.2%</b>	<b>52</b>	<b>+85.3%</b>	<b>1,720</b>	<b>+56.1%</b>	
Jevtana®	335	139	+0.0%	152	+18.9%	44	+53.8%	23	-3.7%	358	+11.5%	
Thymoglobulin®	222	38	-2.5%	160	+10.3%	24	+10.0%	59	+23.5%	281	+10.9%	
Taxotere®	49	4	-42.9%	4	-500.0%	41	-47.3%	130	-3.5%	179	-17.1%	
Eloxatin®	36	4	0.0%	-	-100.0%	32	-60.7%	134	+8.5%	170	-21.6%	
Mozobil®	145	42	+4.9%	95	+14.5%	8	0.0%	7	-33.3%	152	+7.0%	
Zaltrap®	61	47	-7.8%	14	-33.3%	-	-50.0%	4	+33.3%	65	-14.3%	
Other	233	52	-3.6%	157	-3.1%	24	0.0%	15	-15.8%	248	-3.9%	
<b>Total Oncology</b>	<b>1,081</b>	<b>326</b>	<b>-2.4%</b>	<b>582</b>	<b>+6.4%</b>	<b>173</b>	<b>-30.3%</b>	<b>372</b>	<b>+2.9%</b>	<b>1,453</b>	<b>-2.2%</b>	
<b>Sanofi Genzyme (Specialty Care)</b>	<b>5,019</b>	<b>1,707</b>	<b>+16.4%</b>	<b>2,737</b>	<b>+23.2%</b>	<b>575</b>	<b>-3.4%</b>	<b>931</b>	<b>+16.7%</b>	<b>5,950</b>	<b>+17.2%</b>	
Lantus®	4,761	878	-10.3%	3,528	-12.5%	355	-12.9%	953	+6.0%	5,714	-9.4%	
Toujeo®	630	120	+566.7%	475	+246.0%	35	+775.0%	19	+260.0%	649	+294.5%	
Amaryl®	70	27	+3.8%	3	+50.0%	40	-32.7%	292	+0.3%	362	-3.8%	
Apidra®	286	127	+2.4%	115	-20.7%	44	+2.6%	81	+32.4%	367	-1.1%	
Insuman®	85	82	-11.7%	3	+50.0%	-	-100.0%	44	+13.6%	129	-3.5%	
Blood glucose meters	65	64	+6.7%	-	-	1	0.0%	1	-50.0%	66	+4.8%	
Lyxumia®	30	21	-8.3%	-	-	9	-11.1%	3	-40.0%	33	-13.2%	
Other	19	-	-	3	-57.1%	16	+75.0%	2	-	21	+26.7%	
<b>Total Diabetes</b>	<b>5,946</b>	<b>1,319</b>	<b>-0.4%</b>	<b>4,127</b>	<b>-4.6%</b>	<b>500</b>	<b>-6.5%</b>	<b>1,395</b>	<b>+7.0%</b>	<b>7,341</b>	<b>-1.8%</b>	
Multaq®	347	44	+2.3%	299	+4.2%	4	-25.0%	6	+16.7%	353	+3.8%	
Praluent®	104	18	+1700.0%	85	+855.6%	1	-100.0%	1	-	105	+1,066.7%	
<b>Total Cardiovascular</b>	<b>451</b>	<b>62</b>	<b>+40.0%</b>	<b>384</b>	<b>+30.1%</b>	<b>5</b>	<b>0.0%</b>	<b>7</b>	<b>+33.3%</b>	<b>458</b>	<b>+31.1%</b>	
<b>Total Diabetes &amp; Cardiovascular</b>	<b>6,397</b>	<b>1,381</b>	<b>+0.9%</b>	<b>4,511</b>	<b>-2.3%</b>	<b>505</b>	<b>-6.5%</b>	<b>1,402</b>	<b>+7.2%</b>	<b>7,799</b>	<b>-0.4%</b>	

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

( million)	Total GBUs	Europe <sup>(a)</sup>	Change at constant exchange rates	United States	Change at constant exchange rates	Rest of the world <sup>(b)</sup>	Change at constant exchange rates	Emerging Markets <sup>(c)</sup>	Change at constant exchange rates	Total Franchise	Change at constant exchange rates
Lovenox <sup>®</sup>	1,636	1,027	-1.1%	54	-29.9%	93	-2.1%	462	+1.6%	1,636	-1.7%
Plavix <sup>®</sup>	1,544	162	-11.4%	1	+0.0%	411	-50.0%	970	+3.4%	1,544	-18.8%
Renage <sup>®</sup> /Renvela <sup>®</sup>	922	82	-31.4%	764	+5.5%	33	+6.5%	43	-23.3%	922	-1.1%
Aprovel <sup>®</sup> /CoAprovel <sup>®</sup>	681	127	-13.5%	15	0.0%	127	-7.9%	412	-4.8%	681	-7.0%
Depakine <sup>®</sup>	416	161	-1.2%	-	-	15	+7.1%	240	+6.3%	416	+3.3%
Synvisc <sup>®</sup> / Synvisc-One <sup>®</sup>	408	33	+3.1%	313	-2.8%	14	-12.5%	48	+20.9%	408	-0.2%
Allegra <sup>®</sup>	186	9	-18.2%	-	-	177	-11.5%	-	-	186	-11.9%
Stilnox <sup>®</sup> /Ambien <sup>®</sup> / Myslee <sup>®</sup>	304	44	-6.4%	84	+13.5%	120	-16.0%	56	+9.3%	304	-2.9%
Tritace <sup>®</sup>	245	154	-4.9%	-	-	4	-20.0%	87	-11.3%	245	-7.7%
Targocid <sup>®</sup>	149	74	-8.4%	-	-	7	-25.0%	68	+4.3%	149	-3.8%
Lasix <sup>®</sup>	148	75	-2.6%	-	-100.0%	19	-34.6%	54	+7.1%	148	-6.2%
Cordarone <sup>®</sup>	122	28	-6.7%	-	-	31	-9.4%	63	-1.5%	122	-4.6%
Xatral <sup>®</sup>	100	38	0.0%	-	-	4	-20.0%	58	+17.3%	100	+8.4%
Orudis <sup>®</sup>	103	17	-5.3%	-	-	7	+50.0%	79	-36.1%	103	-30.1%
Other	3,347	1,611	-4.1%	259	-16.6%	358	-5.7%	1,119	-5.8%	3,347	-5.9%
<b>Total Established Prescription Products</b>	<b>10,311</b>	<b>3,642</b>	<b>-4.8%</b>	<b>1,490</b>	<b>-2.4%</b>	<b>1,420</b>	<b>-25.7%</b>	<b>3,759</b>	<b>-2.0%</b>	<b>10,311</b>	<b>-6.8%</b>
<b>Generics</b>	<b>1,854</b>	<b>802</b>	<b>-0.7%</b>	<b>175</b>	<b>+1.8%</b>	<b>92</b>	<b>+1.2%</b>	<b>785</b>	<b>+1.8%</b>	<b>1,854</b>	<b>+0.7%</b>
<b>Total Emerging Markets - Specialty Care</b>	<b>931</b>							<b>931</b>	<b>+16.7%</b>		
<b>Total Emerging Markets - Diabetes &amp; Cardiovascular General Medicines &amp; Emerging Markets</b>	<b>14,498</b>	<b>4,444</b>	<b>-4.1%</b>	<b>1,665</b>	<b>-1.9%</b>	<b>1,512</b>	<b>-24.5%</b>	<b>6,877</b>	<b>+2.5%</b>	<b>14,498</b>	<b>-3.3%</b>
<b>Consumer Healthcare<sup>(d)</sup></b>	<b>3,330</b>	<b>879</b>	<b>0.0%</b>	<b>938</b>	<b>+3.8%</b>	<b>275</b>	<b>+9.9%</b>	<b>1,238</b>	<b>-7.9%</b>	<b>3,330</b>	<b>-1.6%</b>
<b>Total Pharmaceuticals</b>	<b>29,244</b>	<b>8,411</b>	<b>+0.8%</b>	<b>9,851</b>	<b>+4.3%</b>	<b>2,867</b>	<b>-15.2%</b>	<b>8,115</b>	<b>+0.8%</b>	<b>29,244</b>	<b>+0.2%</b>

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(d) Following the creation of the Consumer Healthcare GBU, sales of that GBU's products previously included in the General Medicines & Emerging Markets GBU are presented for information purposes on a separate line for 2016 and prior periods, in the interests of comparability.



**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****5/ Net Sales Human Vaccines (Vaccines) Segment**

In 2016, net sales for the Vaccines segment were 4,577 million, up 7.4% on a reported basis and 8.8% CER. This rise was driven mainly by sales of influenza vaccines in the United States and Polio/Pertussis/Hib vaccines in Emerging Markets plus sales of Dengvaxia®, the world's first dengue vaccine.

The table below sets forth 2016 and 2015 net sales for our Vaccines segment by product range:

			Change on a reported basis	Change at constant exchange rates
( million)	2016	2015		
Polio/Pertussis/Hib Vaccines (including Pentacel®, Pentaxim®, Imovax® and Hexaxim®)	1,495	1,348	+10.9%	+12.7%
Influenza Vaccines (including Vaxigrip® and Fluzone®)	1,521	1,322	+15.1%	+16.6%
Meningitis/Pneumonia Vaccines (including Menactra®)	633	614	+3.1%	+4.1%
Adult Booster Vaccines (including Adacel®)	417	496	-15.9%	-15.5%
Travel and Other Endemics Vaccines	368	375	-1.9%	-0.8%
Dengvaxia®	55	-	-	-
Other vaccines <sup>(a)</sup>	88	106	-17.0%	-17.0%
<b>Total Vaccines segment<sup>(a)</sup></b>	<b>4,577</b>	<b>4,261</b>	<b>+7.4%</b>	<b>+8.8%</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

**Polio/Pertussis/Hib** vaccines posted net sales of 1,495 million (+12.7% CER). In Emerging Markets, sales for this franchise reached 832 million (+18.2% CER) due to sales growth for Hexaxim® in the Middle East and Africa (+238.1% CER, at 205 million). This more than compensated for local disruption in the Chinese market, which hampered sales for the franchise (-59.9% CER, at 112 million). In the United States, net sales amounted to 405 million (+2.5% CER), with an expected decline in sales of Pentacel® (-2.0% CER, at 246 million) more than compensated for by stronger sales of Imovax® (+22.2% CER, at 55 million). During 2016, Sanofi Pasteur experienced delays in production of Pentacel®, which eased during the fourth quarter.

Net sales of **Influenza** vaccines rose by 16.6% CER, to 1,521 million. This performance was mainly driven by higher sales for this franchise in the United States (+24.4% CER, at 1,117 million), supporting Sanofi Pasteur's differentiation strategy in influenza vaccines. Sales of influenza vaccines also rose in Emerging Markets (+3.7% CER, at 282 million) and in the Rest of the World region (+8.3% CER, at 39 million), but fell in Europe (-13.5% CER, at 83 million) mainly due to Sanofi sales to Sanofi Pasteur MSD being deferred to 2017 as a result of inventory repurchases in connection with the termination of Sanofi Pasteur MSD joint venture.

## Edgar Filing: Sanofi - Form 20-F

Net sales of **Meningitis/Pneumonia** vaccines reached 633 million (+4.1% CER). **Menactra**® generated net sales of 586 million (+4.8% CER); sales in the United States rose by +4.4% CER to 516 million largely as a result of trends in orders from the Centers for Disease Control and Prevention (CDC), a US federal agency.

**Dengvaxia**®, the world's first dengue vaccine, is now licensed in 14 countries (Bolivia, Brazil, Cambodia, Costa Rica, Guatemala, Indonesia, Mexico, Paraguay, Peru, Philippines, El Salvador, Singapore, Thailand and Venezuela). Net sales of Dengvaxia® amounted to 55 million, reflecting two deliveries for the public dengue vaccination program in the Philippines, the first dose for the public vaccination program in Paraná state (Brazil), and sales to the private sector.

Net sales of **Adult Booster** vaccines fell by 15.5% CER to 417 million, reflecting lower sales in the United States (-16.4% CER, at 302 million) due to increased competition for Adacel®. The franchise also recorded a drop in sales in Europe (-29% CER, at 44 million) mainly driven by supply issues with Repevax® and Emerging Markets (-7.4% CER, at 48 million).

Net sales of **Travel and Other Endemics** vaccines were relatively stable year-on-year at 368 million.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The following table presents the 2016 net sales of our Vaccines segment by geographical region:

( million)	Europe <sup>(a)</sup>	Change at constant exchange rates	United States	Change at constant exchange rates	Rest of the world <sup>(b)</sup>	Change at constant exchange rates	Emerging Markets <sup>(c)</sup>	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (including Pentacel <sup>®</sup> and Pentaxim <sup>®</sup> )	105	+16.7%	405	+2.5%	153	+9.3%	832	+18.2%
Influenza Vaccines (including Vaxigrip <sup>®</sup> and Fluzone <sup>®</sup> )	83	-13.5%	1,117	+24.4%	39	+8.3%	282	+3.7%
Meningitis/Pneumonia Vaccines (including Menactra <sup>®</sup> )	5	+66.7%	518	+4.6%	16	+88.9%	94	-7.5%
Adult Booster Vaccines (including Adacel <sup>®</sup> )	44	-29.0%	302	-16.4%	23	+20.0%	48	-7.4%
Travel and Other Endemics Vaccines	26	-13.3%	126	+13.5%	50	-5.7%	166	-6.1%
Dengvaxia <sup>®</sup>	-	-	-	-	-	-	55	-
Other vaccines <sup>(a)</sup>	5	+100.0%	72	-16.7%	10	-9.1%	1	-75.0%
<b>Total Vaccines segment<sup>(a)</sup></b>	<b>268</b>	<b>-5.3%</b>	<b>2,540</b>	<b>+8.3%</b>	<b>291</b>	<b>+8.9%</b>	<b>1,478</b>	<b>+12.4%</b>

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(d) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

Sanofi Pasteur MSD (SPMSD), our joint venture with Merck & Co. in Europe, reported net sales (not included in our consolidated net sales) of 940 million, up 14.1% on a reported basis. The main drivers were growth in sales of Gardasil<sup>®</sup> (+30.6%, at 214 million), the new hexavalent pediatric vaccine Hexyon<sup>®</sup> (+201% on a reported basis, at

110 million), and the chickenpox vaccine Varivax<sup>®</sup> (+73.0% on a reported basis, at 54 million). In March 2016, Sanofi Pasteur and Merck announced their intention to end the SPMSD joint venture, in order to pursue their own distinct growth strategies in Europe. Sanofi Pasteur and MSD ended their joint venture at the end of December 2016.

6/ Net Sales by Geographical Region

The following table presents our net sales by geographical region for the years ended December 31, 2016 and 2015:

			Change on	Change at
			a reported	constant
( million)	2016	2015	basis	exchange
				rates
<b>United States</b>	12,391	11,764	+5.3%	+5.1%
<b>Emerging Markets<sup>(a)</sup></b>	9,593	10,072	-4.8%	+2.4%
<i>Of which Latin America</i>	2,503	3,047	-17.9%	-7.1%
<i>Of which Asia (excluding South Asia)</i>	3,109	3,101	+0.3%	+4.5%
<i>Of which Africa, Middle East and South Asia</i>	2,764	2,657	+4.0%	+9.9%
<i>Of which Eurasia<sup>(b)</sup></i>	1,090	1,132	-3.7%	+5.2%
<b>Europe<sup>(c)</sup></b>	8,679	8,729	-0.6%	+0.6%
<b>Rest of the world<sup>(d)</sup></b>	3,158	3,495	-9.6%	-13.4%
<i>Of which Japan</i>	1,688	2,034	-17.0%	-24.8%
<b>Total net sales</b>	<b>33,821</b>	<b>34,060</b>	<b>-0.7%</b>	<b>+1.2%</b>

(a) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(b) Russia, Ukraine, Georgia, Belarus, Armenia and Turkey.

(c) Western Europe and Eastern Europe (excluding Eurasia).

(d) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

## Table of Contents

### ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

In the **United States**, net sales rose by 5.1% CER to 12,391 million. Lower sales for the Diabetes franchise (-4.6% CER, at 4,127 million) and Established Prescription Products (-2.4% CER, at 1,490 million) were more than compensated for by solid performances for the Vaccines segment (+8.3% CER, at 2,540 million), and for the Multiple Sclerosis (+52.7% CER, at 1,141 million) and Rare Diseases (+9.4% CER, at 1,014 million) franchises.

In **Emerging Markets**, net sales reached 9,593 million, up 2.4% CER (but +7% CER excluding Venezuela). Growth in Emerging Markets was driven by increased sales for Vaccines (+12.4% CER, at 1,478 million), and the Rare Diseases (+22.9% CER, at 507 million), and Diabetes (+7% CER, at 1,395 million) franchises. In **Asia**, net sales amounted to 3,109 million (including 2,039 million in China), representing a rise of 4.5% CER; a good performance in Pharmaceuticals (+8.4% CER, at 2,711 million) more than offset a decline in Vaccines sales (-16.4% CER, at 398 million), especially in China (-52.6% CER, at 153 million) due to disruption in the local market. In the **Africa, Middle East and South Asia** region, net sales were up 9.9% at 2,764 million, driven by the Middle East (+8.5% CER, at 1,226 million) and South Africa (+26.2% CER, at 253 million). Net sales in **Latin America** totaled 2,503 million, a fall of 7.1% CER, due mainly to the situation in Venezuela; excluding Venezuela, net sales were up 8.5% CER. The main driver of Latin American sales growth (excluding Venezuela) was the increase in sales in Mexico (+5.8% CER, at 548 million), Argentina (+47.3% CER, at 267 million), and Colombia (+10% CER, at 268 million). In Brazil, net sales were 983 million (+1.7% CER) thanks to the performances of the Rare Diseases franchise, Generics, and the contribution from Dengvaxia. In the **Eurasia** region net sales were up 5.2% CER at 1,090 million, reflecting strong sales growth in Turkey and Ukraine, which more than compensated for lower sales in Russia (-7.1% CER, at 499 million). Net sales in Russia were adversely affected by a dip in sales for Consumer Healthcare and the Oncology franchise, partially offset by strong performances from Established Prescription Products, Vaccines, and the Diabetes franchise.

In **Europe**, net sales reached 8,679 million (+0.6% CER). Positive performances from the Multiple Sclerosis franchise (+62.2% CER, at 459 million) and the Rare Diseases franchise (+8.6% CER, at 922 million) offset weaker sales in Established Prescription Products (-4.8% CER, at 3,642 million) and Vaccines (-5.3% CER, at 268 million). Net sales in France were 2,206 million, down 1.9% CER, mainly reflecting lower sales of Lantus®, Plavix® and Aprovel®.

In the Rest of the World region, net sales fell by 13.4% CER to 3,158 million. This reflects negative performances for Established Prescription Products (-25.7% CER, at 1,420 million), and the Diabetes (-6.5% CER, at 500 million) and Oncology (-30.3% CER, at 173 million) franchises, partially offset by positive performances for the Multiple Sclerosis and

Rare Diseases franchises and for Consumer Healthcare. In Japan, net sales were 1,688 million (-24.8% CER) reflecting the negative impact of competition from generics of Plavix® (-54% CER, at 355 million), though the effect was somewhat cushioned by the performances of the Rare Diseases franchise and Consumer Healthcare.

#### A.2.3. Other Revenues

Other revenues mainly comprise royalties under licensing agreements contracted in the ordinary course of business. Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

Other revenues rose by 10.7% to 887 million in 2016, compared with 801 million in 2015. This year-on-year increase reflects a higher level of sales of non-Sanofi products by VaxServe.

#### A.2.4. Gross Profit

Gross profit reached 24,006 million in 2016 (71.0% of net sales), versus 23,942 million in 2015 (70.3% of net sales), a rise of 0.3%.

## Edgar Filing: Sanofi - Form 20-F

The gross margin ratio for the Pharmaceuticals segment was 0.9 of a point higher at 72.4%, mainly due to improved productivity in our industrial facilities. Other factors included a positive impact from the Sanofi Genzyme GBU and the cardiovascular franchise in the United States, which more than offset weaker sales for the Diabetes franchise in the United States and competition from generics of Plavix®.

The gross margin ratio for the Vaccines segment was unchanged year-on-year at 62%.

### A.2.5. Research and Development Expenses

Research and development (R&D) expenses amounted to 5,172 million in 2016 (versus 5,082 million in 2015) and represented 15.3% of net sales (versus 14.9% in 2015). The overall year-on-year rise of 90 million (+1.8%) included 88 million for the Pharmaceuticals segment (+1.9%) and 2 million for the Vaccines segment (+0.4%).

This slight overall increase reflects cost control measures and reduced spending on Praluent® and dupilumab, but also higher costs linked to the commencement of a number of Phase III studies, in particular on isatuximab.

### A.2.6. Selling and General Expenses

Selling and general expenses totaled 9,486 million (28.0% of net sales), compared with 9,382 million in 2015 (27.5% of net sales). This represents a year-on-year rise of 104 million (+1.1%).

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

By segment, the year on-year increase was 87 million (+1.0%) for Pharmaceuticals and 17 million (+2.3%) for Vaccines. The rise in costs was mainly due to preparations for the launches of sarilumab (Kevzara ) and dupilumab (Dupixent ).

**A.2.7. Other Operating Income and Expenses**

In 2016, other operating income totaled 355 million (versus 254 million in 2015), and other operating expenses 482 million (versus 462 million in 2015). Overall, this represents a net expense of 127 million in 2016, versus a net expense of 208 million in 2015.

These items included gains on disposal amounting to 40 million in 2016; this compares with 146 million in 2015, which mainly related to intangible assets in the United States.

In 2016, they also included 192 million received under an arbitration settlement of a contractual dispute, and a payment of 90 million in settlement of litigation regarding generics of Cipro®.

The net overall improvement of 81 million in other operating income and expenses also reflects a reduction in operating foreign exchange losses on our Venezuelan operations, which fell from 240 million in 2015 to 102 million in 2016 (see Note D.26. to our consolidated financial statements).

**A.2.8. Amortization of Intangible Assets**

Amortization charged against intangible assets amounted to 1,692 million in 2016, versus 2,137 million in 2015.

This year-on-year decrease of 445 million reflects (i) the amortization in full, in December 2015, of a priority review voucher acquired in May 2015 for \$245 million and used for the filing of a new drug application with the FDA for LixiLan; and (ii) a decrease in amortization charged against the intangible assets recognized on the acquisition of Aventis ( 482 million in 2016, versus 637 million in 2015) as some products reached the end of their life cycles.

**A.2.9. Impairment of Intangible Assets**

In 2016, this line item showed impairment losses of 192 million against intangible assets, compared with 767 million in 2015.

In 2016, this line item includes (i) a net impairment loss of 58 million on R&D projects in the Pharmaceuticals and Vaccines segments; and (ii) impairment losses of 134 million taken against rights relating to a number of marketed products in the Pharmaceuticals segment.

In 2015, this line item included (i) a net impairment loss of 340 million on R&D projects in the Pharmaceuticals and Vaccines segments, primarily Synvisc-One® in osteoarthritis of the hip and the rotavirus vaccine project (Shantha); and (ii) impairment losses of 427 million taken against rights

relating to a number of marketed products in the Pharmaceuticals segment, mainly Afrezza® in the United States (following termination of the license and collaboration agreement with MannKind Corporation) and Auvi-Q®/Allerject® in the United States and Canada (following the voluntary recall of this product in the fourth quarter of 2015).

**A.2.10. Fair Value Remeasurement of Contingent Consideration Liabilities**

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net expense of 135 million in 2016, versus a net gain of 53 million in 2015.

These remeasurements mainly relate to (i) the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi (expense of 78 million in 2016 and of 104 million in 2015); and (ii) an increase in the market value of the contingent value rights (CVRs) issued by Sanofi in connection with the Genzyme acquisition, which represented a net expense of 58 million in 2016 and a net gain of 143 million in 2015 (see Note D.18. to our consolidated financial statements).

#### **A.2.11. Restructuring Costs and Similar Items**

Restructuring costs and similar items amounted to 879 million in 2016, compared with 795 million in 2015.

The restructuring costs recognized in 2016 related mainly to the implementation of an organizational transformation program in France (457 million) and in the rest of the world as part of the 2020 strategic roadmap. With effect from January 1, 2016, this line item includes expenses regarded as equivalent to restructuring costs that have arisen from certain transformation programs implemented by Sanofi as part of the transformation strategy announced in November 2015, and more specifically programs intended to deliver a global information systems solution, to standardize and consolidate processes, and to transition towards a worldwide services platform. See Note D.27. to our consolidated financial statements.

#### **A.2.12. Other Gains and Losses, and Litigation**

At the end of December 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) ended their joint venture Sanofi Pasteur MSD (SPMSD). The derecognition of Sanofi's investment in SPMSD generated a pre-tax gain on disposal of 211 million.

#### **A.2.13. Operating Income**

Operating income totaled 6,534 million for 2016, versus 5,624 million for 2015, an improvement of 16.2%; this was attributable mainly to lower charges for amortization and impairment of intangible assets, and the gain on disposal of the investment in the SPMSD joint venture.

---

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

**A.2.14. Financial Income and Expenses**

Net financial expenses for 2016 were 856 million in 2016, compared with 381 million in 2015, an increase of 475 million. This increase was mainly a result of an impairment loss of 457 million taken against our shares in Alnylam, which reflects a decline in the market value of those shares as of the reporting date relative to their historical cost; most of that decline occurred when Alnylam decided to discontinue the revusiran development program on October 5, 2016.

Financial expenses directly related to our debt, net of cash and cash equivalents (see the definition in Consolidated Balance sheet below) amounted to 218 million in 2016, compared with 274 million in 2015, in line with a reduction in the cost of debt.

Interest expenses relating to post-employment benefit obligations amounted to 114 million in 2016, the same as in 2015.

**A.2.15. Income before Tax and Associates and Joint Ventures**

Income before tax and associates and joint ventures totaled 5,678 million in 2016, versus 5,243 million in 2015, a rise of 8.3%.

**A.2.16. Income Tax Expense**

Income tax expense totaled 1,326 million in 2016, versus 709 million in 2015, giving an effective tax rate (based on consolidated net income) of 23.4% in 2016 compared with 13.5% in 2015 (see Note D.30. to our consolidated financial statements). The year-on-year trend in the effective tax rate is mainly attributable to changes in the geographical mix of our profits and of local tax rates in the territories where we operate, and changes in tax rates notably in France and Japan (see Note D.30. to our consolidated financial statements).

Changes in the level of income tax expense are significantly impacted by the tax effects of the amortization and impairment of intangible assets ( 694 million in 2016, versus 1,019 million in 2015) and of restructuring costs ( 95 million in 2016, versus 273 million in 2015).

The effective tax rate on our business net income<sup>(1)</sup> is a non-GAAP financial measure. It is calculated on the basis of

business operating income, minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. We believe the presentation of this measure, used by our management, is also useful for investors as it provides a means to analyze the effective tax cost of our current business activities. It should not be seen as a substitute for the effective tax rate on consolidated net income.

Our effective tax rate was 23.3% in 2016, compared with 21.7% in 2015. The main impacts on this tax rate were the geographical mix of the profits of Sanofi entities; the tax effects of the elimination of intragroup margin on inventory; favorable settlements of recent proceedings involving the tax authorities in various countries; and changes in tax rates, particularly in Italy, Japan, Hungary and France. In 2015, there was also a favorable effect as a result of changes in the taxation of dividends in France following a ruling by the Court of Justice of the European Union and the resulting amendments to the 2015 Finance Act.

The table below reconciles our effective tax rate (based on consolidated net income) and the effective tax rate on our business net income:

<i>(as a percentage)</i>	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>
<b>Effective tax rate on consolidated net income</b>	<b>23.4</b>	<b>13.5</b>
<i>Tax effects:</i>		
Amortization and impairment of intangible assets	3.7	6.5
Restructuring costs and similar items	(1.3)	2.9
Impairment loss charged against the investment of Alnylam	(1.5)	0
Other items	(1.0)	(1.2)
<b>Effective tax rate on business net income</b>	<b>23.3</b>	<b>21.7</b>

(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36.

<sup>(1)</sup> See definition under section A.1.5. Segment information 3/ Business Net Income .

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****A.2.17. Share of Profit/(Loss) of Associates and Joint Ventures**

Associates and joint ventures contributed net income of 134 million in 2016, compared with a net loss of 22 million in 2015.

This line item mainly comprises our share of the profits and losses of Regeneron, which represented net income of 126 million in 2016 and a net loss of 54 million in 2015.

**A.2.18. Net Income Excluding the Held-for-Exchange Animal Health Business**

Net income excluding the held-for-exchange Animal Health business amounted to 4,486 million in 2016, versus 4,512 million in 2015.

**A.2.19. Net Income/(Loss) of the Held-for-Exchange Animal Health Business**

In accordance with IFRS 5, the net income or loss of the Animal Health business is presented in a separate line item, *Net income/(loss) of the held-for-exchange Animal Health business* (see Notes D.2. and D.36. to our consolidated financial statements). This business reported net income of 314 million in 2016, compared with a net loss of 124 million in 2015. The Animal Health business generated operating income of 678 million in 2016, against 101 million in 2015. The year-on-year increase was mainly due to the discontinuation of depreciation of property, plant and equipment and amortization of intangible assets with effect from the end of 2015, when these non-current assets of the Animal Health business were reclassified as *Assets*

*held for sale or exchange* in accordance with IFRS 5. Income tax expense for the year was 359 million, compared with 216 million in 2015.

**A.2.20. Net Income**

Net income amounted to 4,800 million in 2016, compared with 4,388 million in 2015.

**A.2.21. Net Income Attributable to Non-Controlling Interests**

Net income attributable to non-controlling interests was 91 million in 2016, versus 101 million in 2015. This line

item mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi ( 86 million, versus 94 million in 2015). The year-on-year fall was directly related to competition from generics of clopidogrel (active ingredient of Plavix®) and irbesartan (active ingredient of Aprovel®) in Europe.

**A.2.22. Net Income Attributable to Equity Holders of Sanofi**

Net income attributable to equity holders of Sanofi amounted to 4,709 million, versus 4,287 million in 2015.

Basic earnings per share for 2016 was 3.66, 11.6% higher than the 2015 figure of 3.28, based on an average number of shares outstanding of 1,286.6 million in 2016 (1,306.2 million in 2015). Diluted earnings per share for 2016 was 3.63, 11.7% higher than the 2015 figure of 3.25, based on an average number of shares outstanding after dilution of 1,296 million in 2016 and 1,320.7 million in 2015.



**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****A.2.23. Segment Results*****1/ Business Operating Income***

We report our segmental results on the basis of business operating income. This indicator is used internally to measure our operational performance and to allocate resources. See Segment Information Business Operating Income of Segments above for the definition of business operating income and a reconciliation to **Income before tax and associates and joint ventures**. Business operating income amounted to 9,285 million in 2016 (27.5% of net sales), 0.3% lower than the 2015 figure of 9,313 million (27.3% of net sales).

Business operating income by segment for 2016 and 2015 is set forth below:

( million)	December 31, 2016	December 31, 2015	Change
Pharmaceuticals	7,824	8,013	-2.4%
Vaccines <sup>(a)</sup>	1,573	1,414	+11.2%
Other	(112)	(114)	-1.8%
<b>Business operating income</b>	<b>9,285</b>	<b>9,313</b>	<b>-0.3%</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

The following tables set forth our segment results and business operating income for the years ended December 31, 2016 and 2015:

**Year ended December 31, 2016**

( million)	Pharmaceuticals	Vaccines <sup>(a)</sup>	Other	Total
<b>Net sales</b>	<b>29,244</b>	<b>4,577</b>	-	<b>33,821</b>
Other revenues	274	613	-	887
Cost of sales	(8,349)	(2,353)	-	(10,702)
Research and development expenses	(4,618)	(554)	-	(5,172)
Selling and general expenses	(8,743)	(743)	-	(9,486)
Other operating income and expenses	(1)	(14)	(112)	(127)
Share of profit/(loss) of associates and joint ventures	129	48	-	177
Net income attributable to non-controlling interests	(112)	(1)	-	(113)
<b>Business operating income</b>	<b>7,824</b>	<b>1,573</b>	<b>(112)</b>	<b>9,285</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

**Year ended December 31, 2015**

Edgar Filing: Sanofi - Form 20-F

<i>( million)</i>	<b>Pharmaceuticals</b>	<b>Vaccines<sup>(a)</sup></b>	<b>Other</b>	<b>Total</b>
<b>Net sales</b>	<b>29,799</b>	<b>4,261</b>	<b>-</b>	<b>34,060</b>
Other revenues	288	513	-	801
Cost of sales	(8,788)	(2,131)	-	(10,919)
Research and development expenses	(4,530)	(552)	-	(5,082)
Selling and general expenses	(8,656)	(726)	-	(9,382)
Other operating income and expenses	(121)	27	(114)	(208)
Share of profit/(loss) of associates and joint ventures	146	23	-	169
Net income attributable to non-controlling interests	(125)	(1)	-	(126)
<b>Business operating income</b>	<b>8,013</b>	<b>1,414</b>	<b>(114)</b>	<b>9,313</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The tables below provide an analysis of business operating income for our Pharmaceuticals and Vaccines segments.

**Business operating income: Pharmaceuticals segment**

( million)	2016	as % of net sales	2015	as % of net sales	Change 2016/2015
<b>Net sales</b>	<b>29,244</b>	<b>100.0%</b>	<b>29,799</b>	<b>100.0%</b>	<b>-1.9%</b>
Other revenues	274	0.9%	288	1.0%	-4.9%
Cost of sales	(8,349)	(28.5)%	(8,788)	(29.5)%	-5.0%
<b>Gross profit</b>	<b>21,169</b>	<b>72.4%</b>	<b>21,299</b>	<b>71.5%</b>	<b>-0.6%</b>
Research and development expenses	(4,618)	(15.8)%	(4,530)	(15.2)%	+1.9%
Selling and general expenses	(8,743)	(29.9)%	(8,656)	(29.0)%	+1.0%
Other operating income and expenses	(1)		(121)		
Share of profit/(loss) of associates and joint ventures	129		146		
Net income attributable to non-controlling interests	(112)		(125)		
<b>Business operating income</b>	<b>7,824</b>	<b>26.8%</b>	<b>8,013</b>	<b>26.9%</b>	<b>-2.4%</b>

**Business operating income: Vaccines segment**

( million)	2016 <sup>(a)</sup>	as % of net sales	2015 <sup>(a)</sup>	as % of net sales	Change 2016/2015
<b>Net sales</b>	<b>4,577</b>	<b>100%</b>	<b>4,261</b>	<b>100.0%</b>	<b>+7.4%</b>
Other revenues	613	13.4%	513	11.9%	+19.5%
Cost of sales	(2,353)	(51.4)%	(2,131)	(50.0)%	+10.4%
<b>Gross profit</b>	<b>2,837</b>	<b>62.0%</b>	<b>2,643</b>	<b>62.0%</b>	<b>+7.3%</b>
Research and development expenses	(554)	(12.1)%	(552)	(13.0)%	+0.4%
Selling and general expenses	(743)	(16.2)%	(726)	(17.0)%	+2.3%
Other operating income and expenses	(14)		27		
Share of profit/(loss) of associates and joint ventures	48		23		
Net income attributable to non-controlling interests	(1)		(1)		
<b>Business operating income</b>	<b>1,573</b>	<b>34.4%</b>	<b>1,414</b>	<b>33.2%</b>	<b>+11.2%</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

**2/ Business Net Income**

Business net income is a non-GAAP financial measure that we use to evaluate our performance. See Business Net Income above for the definition of this measure, and for a reconciliation to *Net income attributable to equity holders of Sanofi*.

## Edgar Filing: Sanofi - Form 20-F

Our business net income for 2016 was 7,308 million, 0.9% lower than in 2015 (7,371 million). These figures include the business net income of the Animal Health business (476 million in 2016, 368 million in 2015). Excluding Animal Health, our business net income was 6,832 million in 2016 (20.2% of net sales) and 7,003 million in 2015 (20.6% of net sales).

### ***3/ Business Earnings Per Share***

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding.

Business earnings per share was 5.68 in 2016, 0.7% higher than the 2015 figure of 5.64, based on an average number of shares outstanding of 1,286.6 million in 2016 and 1,306.2 million in 2015.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****A.3. RESULTS OF OPERATIONS YEAR ENDED DECEMBER 31, 2015 COMPARED WITH YEAR ENDED DECEMBER 31, 2014****A.3.1. Consolidated income statements**

The consolidated income statements for the years ended December 31, 2015 and December 31, 2014 break down as follows:

(under IFRS)	as % of		as % of	
( million)	2015 <sup>(a)(b)</sup>	net sales	2014 <sup>(a)(b)</sup>	net sales
<b>Net sales</b>	<b>34,060</b>	<b>100.0%</b>	<b>31,380</b>	<b>100.0%</b>
Other revenues	801	2.4%	619	2.0%
Cost of sales	(10,919)	(32.1%)	(10,230)	(32.6%)
<b>Gross profit</b>	<b>23,942</b>	<b>70.3%</b>	<b>21,769</b>	<b>69.4%</b>
Research & development expenses	(5,082)	(14.9%)	(4,667)	(14.9%)
Selling & general expenses	(9,382)	(27.5%)	(8,425)	(26.8%)
Other operating income	254		301	
Other operating expenses	(462)		(157)	
Amortization of intangible assets	(2,137)		(2,081)	
Impairment of intangible assets	(767)		31	
Fair value remeasurement of contingent consideration liabilities	53		(303)	
Restructuring costs	(795)		(404)	
Other gains and losses, and litigation	-		-	
<b>Operating income</b>	<b>5,624</b>	<b>16.5%</b>	<b>6,064</b>	<b>19.3%</b>
Financial expenses	(559)		(598)	
Financial income	178		192	
<b>Income before tax and associates and joint ventures</b>	<b>5,243</b>	<b>15.4%</b>	<b>5,658</b>	<b>18.0%</b>
Income tax expense	(709)		(1,214)	
Share of profit/(loss) of associates and joint ventures	(22)		(52)	
<b>Net income excluding the held-for-exchange Animal Health business<sup>(a)</sup></b>	<b>4,512</b>	<b>13.2%</b>	<b>4,392</b>	<b>14.0%</b>
Net income/(loss) of the held-for-exchange Animal Health business	(124)		117	
<b>Net income</b>	<b>4,388</b>	<b>12.9%</b>	<b>4,509</b>	<b>14.4%</b>
Net income attributable to non-controlling interests	101		119	
<b>Net income attributable to equity holders of Sanofi</b>	<b>4,287</b>	<b>12.6%</b>	<b>4,390</b>	<b>14.0%</b>
Average number of shares outstanding (million)	1,306.2		1,315.8	
Average number of shares outstanding after dilution (million)	1,320.7		1,331.1	
Basic earnings per share (in euros)	3.28		3.34	
Basic earnings per share excluding the held-for-exchange Animal Health business (in euros)	3.38		3.25	
Diluted earnings per share (in euros)	3.25		3.30	
Diluted earnings per share excluding the held-for-exchange Animal Health business(in euros)	3.34		3.21	

## Edgar Filing: Sanofi - Form 20-F

- (a) *The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36. to our consolidated financial statements.*
- (b) *Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly; refer to Note A.5. to our consolidated financial statements.*

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****A.3.2. Net Sales**

Net sales for the year ended December 31, 2015 were 34,060 million, 8.5% higher than in 2014. Exchange rate movements had a favorable effect of 7.1 percentage points. At constant exchange rates (CER), net sales rose by 1.4% year-on-year.

The following table sets forth a reconciliation of our reported net sales for the years ended December 31, 2015 and December 31, 2014 to our net sales at CER:

( million)	2015 <sup>(a)(b)</sup>	2014 <sup>(a)(b)</sup>	Change
<b>Net sales</b>	<b>34,060</b>	<b>31,380</b>	<b>+8.5%</b>
Effect of exchange rates	(2,256)		
<b>Net sales at constant exchange rates (CER)</b>	<b>31,804</b>	<b>31,380</b>	<b>+1.4%</b>

(a) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business.

(b) Due to a change in accounting presentation, Vaxserve sales of non-Sanofi are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.1.2).

**1/ Net Sales by Operating Segment**

Our net sales comprise the net sales generated by our Pharmaceuticals and Human Vaccines (Vaccines) segments, in accordance with IFRS 5.

The following table sets forth our 2015 and 2014 net sales by operating segment:

( million)	2015 <sup>(a)(b)</sup>	2014 <sup>(a)(b)</sup>	Change	Change at constant exchange rates
Pharmaceuticals	29,799	27,720	+7.5%	+0.8%
Vaccines <sup>(a)</sup>	4,261	3,660	+16.4%	+5.4%
<b>Net sales</b>	<b>34,060</b>	<b>31,380</b>	<b>+8.5%</b>	<b>+1.4%</b>

(a) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business.

(b) Due to a change in accounting presentation, Vaxserve sales of non-Sanofi are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.1.2).

The Animal Health business generated net sales of 2,515 million in the year ended December 31, 2015.

<i>( million)</i>	<b>2015</b>	<b>2014</b>
Companion Animals	1,629	1,281
Production Animals	886	795
<b>Total Animal Health</b>	<b>2,515</b>	<b>2,076</b>
<i>of which fipronil products</i>	627	597
<i>of which vaccines</i>	804	720
<i>of which avermectin products</i>	498	398

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****2/ Net Sales by Global Business Unit (GBU)**

The table below presents net sales for our Global Business Units (GBUs) reflecting the new structure intended to streamline our organization, sharpen our focus and concentrate our efforts on growth drivers. Within this new structure, Emerging Markets sales of Diabetes & Cardiovascular and Specialty Care products are included in the General Medicines & Emerging Markets GBU. Following the creation of the Consumer Healthcare GBU, sales of that GBU's products previously included in the General Medicines & Emerging Markets GBU are presented for information purposes on a separate line for 2016 and prior periods, in the interests of comparability.

Net sales by Global Business Unit (GBU)			Change on	Change at
	2015	2014	a reported	constant
( million)			basis	exchange rates
Sanofi Genzyme GBU <sup>(a)</sup> (Specialty Care) <sup>(b)</sup>	4,275	3,228	+32.4%	+19.9%
Diabetes & Cardiovascular GBU <sup>(a)</sup>	6,517	6,395	+1.9%	-10.6%
General Medicines & Emerging Markets GBU <sup>(c)(d)</sup>	15,515	14,760	+5.1%	+1.1%
Consumer Healthcare GBU	3,492	3,337	+4.6%	+2.8%
<b>Total Pharmaceuticals</b>	<b>29,799</b>	<b>27,720</b>	<b>+7.5%</b>	<b>+0.8%</b>
<b>Sanofi Pasteur GBU (Vaccines)<sup>(e)</sup></b>	<b>4,261</b>	<b>3,660</b>	<b>+16.4%</b>	<b>+5.4%</b>
<b>Total Net Sales<sup>(f)</sup></b>	<b>34,060</b>	<b>31,380</b>	<b>+8.5%</b>	<b>+1.4%</b>

(a) Does not include Emerging Markets net sales.

(b) Rare Diseases, Multiple Sclerosis, Oncology and Immunology.

(c) Includes net sales in Emerging Markets of Specialty Care and Diabetes & Cardiovascular products.

(d) Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(e) Due to a change in accounting presentation, Vaxserve sales of non-Sanofi are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.1.2).

(f)

## Edgar Filing: Sanofi - Form 20-F

*In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business. The net sales of the Animal Health business (equivalent to the net sales of the Animal Health GBU) are presented for information purposes in [1/ Net Sales by Operating Segment](#) above.*

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****3/ Net Sales by Franchise**

The table below sets forth our 2015 net sales by franchise in order to facilitate comparisons with our peers. For a detailed reconciliation of net sales by franchise and net sales by GBU for our Pharmaceuticals segment, refer to the table showing Pharmaceuticals segment net sales by geographical region.

Net sales by franchise	2015	2014	Change on a reported	Change at constant
( million)	Reported	Reported	basis	exchange rates
Rare Diseases	2,550	2,137	+19.3%	+11.4%
Multiple Sclerosis	1,114	467	+138.5%	+112.2%
Oncology	1,504	1,401	+7.4%	-1.9%
<b>Total Specialty Care</b>	<b>5,168</b>	<b>4,005</b>	<b>+29.0%</b>	<b>+18.5%</b>
<i>of which Developed Markets (Sanofi Genzyme GBU)</i>	4,275	3,228	+32.4%	+19.9%
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	893	777	+14.9%	+12.7%
Diabetes	7,580	7,273	+4.2%	-6.8%
Cardiovascular	350	290	+20.7%	+3.4%
<b>Total Diabetes &amp; Cardiovascular</b>	<b>7,930</b>	<b>7,563</b>	<b>+4.9%</b>	<b>-6.4%</b>
<i>of which Developed Markets (Diabetes &amp; Cardiovascular GBU)</i>	6,517	6,395	+1.9%	-10.6%
<i>of which Emerging Markets<sup>(a)(b)</sup></i>	1,413	1,168	+21.0%	+16.5%
Established Prescription Products <sup>(a)</sup>	11,292	11,010	+2.6%	-2.4%
Consumer Healthcare franchise (Consumer Healthcare GBU)	3,492	3,337	+4.6%	+2.8%
Generics <sup>(a)</sup>	1,917	1,805	+6.2%	+7.6%
<b>Total Pharmaceuticals</b>	<b>29,799</b>	<b>27,720</b>	<b>+7.5%</b>	<b>+0.8%</b>
<b>Vaccines (Sanofi Pasteur GBU)<sup>(c)</sup></b>	<b>4,261</b>	<b>3,660</b>	<b>+16.4%</b>	<b>+5.4%</b>
<b>Total Net Sales<sup>(d)</sup></b>	<b>34,060</b>	<b>31,380</b>	<b>+8.5%</b>	<b>+1.4%</b>

(a) These items are aggregated to form the General Medicines and Emerging Markets GBU.

(b) Emerging Markets: World excluding United States, Canada, Western and Eastern Europe (apart from Russia, Ukraine, Georgia, Belarus, Armenia and Turkey), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(c) Due to a change in accounting presentation, Vaxserve sales of non-Sanofi are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.1.2)

(d) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business. The net sales of the Animal Health business (equivalent to the net sales of the Animal Health GBU) are presented for information purposes in 1/ Net Sales by Operating Segment above.

**4/ Net Sales - Pharmaceuticals Segment**

In 2015, net sales for the Pharmaceuticals segment were 29,799 million, up 7.5% on a reported basis and 0.8% at constant exchange rates (CER). The year-on-year increase of 2,079 million includes favorable exchange rate effects of 1,854 million, along with the following main effects at CER:

- growth in net sales for the Rare Diseases and Multiple Sclerosis franchises (up 768 million), Generics (up 138 million), and Consumer Healthcare (up 92 million);
  - lower net sales for the Diabetes franchise (down 496 million) and for Established Prescription Products (down 261 million).
- Our flagship Pharmaceuticals segment products are discussed below.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The following table presents 2015 and 2014 net sales for the Pharmaceuticals segment by product and franchise:

		2015	2014	Change on	Change at
( million)	Indication	Reported	Reported	a reported	constant
				basis	exchange
					rates
Cerezyme®	Gaucher disease	757	715	+5.9%	+1.3%
Cerdelga®	Gaucher disease	66	4	-	-
Myozyme® /Lumizyme®	Pompe disease	650	542	+19.9%	+12.4%
Fabrazyme®	Fabry disease	592	460	+28.7%	+17.2%
Aldurazyme®	Mucopolysaccharidosis	195	172	+13.4%	+8.7%
Other		290	244	+18.9%	+8.6%
<b>Total Rare Diseases franchise</b>		<b>2,550</b>	<b>2,137</b>	<b>+19.3%</b>	<b>+11.4%</b>
Aubagio®	Multiple sclerosis	871	433	+101.2%	+77.8%
Lemtrada®	Multiple sclerosis	243	34	+614.7%	+550.0%
<b>Total Multiple Sclerosis franchise</b>		<b>1,114</b>	<b>467</b>	<b>+138.5%</b>	<b>+112.2%</b>
Jevtana®	Prostate cancer	321	273	+17.6%	+9.5%
Thymoglobulin®	Organ rejection	256	217	+18.0%	+6.0%
Taxotere®	Breast, lung, prostate, stomach, and head & neck cancer	222	266	-16.5%	-22.2%
Eloxatin®	Colorectal cancer	227	210	+8.1%	-0.5%
Mozobil®	Hematologic malignancies	143	111	+28.8%	+16.2%
Zaltrap®	Colorectal cancer	77	69	+11.6%	+5.8%
Other		258	255	+1.2%	-10.6%
<b>Total Oncology franchise</b>		<b>1,504</b>	<b>1,401</b>	<b>+7.4%</b>	<b>-1.9%</b>
<b>Total Specialty Care franchise</b>		<b>5,168</b>	<b>4,005</b>	<b>+18.5%</b>	<b>+29.0%</b>
Lantus®	Diabetes	6,390	6,344	+0.7%	-10.8%
Toujeo®	Diabetes	164	-	-	-
Amaryl®	Diabetes	393	360	+9.2%	+1.7%
Apidra®	Diabetes	376	336	+11.9%	+4.8%
Insuman®	Diabetes	141	137	+2.9%	+2.9%
Blood glucose meters	Diabetes	63	64	-1.6%	-1.6%
Lyxumia®	Diabetes	38	27	+40.7%	+37.0%
Other	Diabetes	15	5	+200.0%	+180.0%
<b>Total Diabetes franchise</b>		<b>7,580</b>	<b>7,273</b>	<b>+4.2%</b>	<b>-6.8%</b>
Multaq®	Atrial fibrillation	341	290	+17.6%	+0.7%
Praluent®	Hypercholesterolemia	9	-	-	-
<b>Total Cardiovascular franchise</b>		<b>350</b>	<b>290</b>	<b>+20.7%</b>	<b>+3.4%</b>
<b>Total Diabetes &amp; Cardiovascular franchise</b>		<b>7,930</b>	<b>7,563</b>	<b>+4.9%</b>	<b>-6.4%</b>



**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

		2015	2014	Change on a reported basis	Change at constant exchange rates
( million)	Indication	Reported	Reported		
Plavix®	Atherothrombosis	1,929	1,862	+3.6%	-4.1%
Lovenox®	Thrombosis	1,719	1,699	+1.2%	-0.5%
Renagel®/Renvela®	Hyperphosphatemia	935	684	+36.7%	+18.9%
Aprovel® / Avapro®	Hypertension	762	727	+4.8%	-3.7%
Depakine®	Epilepsy	422	395	+6.8%	+2.8%
Synvisc® / Synvisc-One®	Arthritis	413	352	+17.3%	+2.3%
Stilnox®/Ambien®/Myslee®	Sleep disorders	306	306	0.0%	-6.2%
Tritace®	Hypertension	274	281	-2.5%	-3.9%
Allegra®	Allergic rhinitis, urticaria	194	192	+1.0%	-3.6%
Lasix®	Edema, hypertension	162	164	-1.2%	-3.7%
Targocid®	Bacterial infections	160	162	-1.2%	-4.3%
Orudis®	Rheumatoid arthritis, osteoarthritis	156	160	-2.5%	+3.8%
Cordarone®	Arrhythmia	130	129	+0.8%	-0.8%
Xatral®	Benign prostatic hypertrophy	95	94	+1.1%	-3.2%
Other		3,635	3,803	-4.4%	-6.6%
<b>Total Established Prescription Products franchise</b>		<b>11,292</b>	<b>11,010</b>	<b>+2.6%</b>	<b>-2.4%</b>
<b>Consumer Healthcare franchise</b>		<b>3,492</b>	<b>3,337</b>	<b>+4.6%</b>	<b>+2.8%</b>
<b>Generics franchise</b>		<b>1,917</b>	<b>1,805</b>	<b>+6.2%</b>	<b>+7.6%</b>
<b>Total Pharmaceuticals</b>		<b>29,799</b>	<b>27,720</b>	<b>+7.5%</b>	<b>+0.8%</b>

**Rare Diseases franchise**

Net sales for the **Rare Diseases** franchise reached 2,550 million in 2015, up 19.3% on a reported basis and 11.4% at constant exchange rates.

In Gaucher disease, net sales of **Cerezyme**® advanced by 1.3% CER to 757 million, as strong growth in Emerging Markets (+13.3% CER, at 225 million) more than compensated for lower sales in the United States (-9.1% CER, at 201 million) due to the launch of **Cerdelga**® in September 2014. **Cerdelga**® reported net sales of 66 million, of which 60 million were generated in the United States.

Net sales of **Myozyme**®/**Lumizyme**® rose by 12.4% CER to 650 million, driven by further growth in patient numbers in the United States (+20.4% CER, at 205 million) and Emerging Markets (+22.7% CER, at 94 million).

**Fabrazyme**® achieved net sales growth of 17.2% CER, to 592 million. The product reported growth in all regions on a rise in the number of patients treated, with notable performances in the United States (+14.3% CER, at 305 million), Europe (+17.9% CER, at 140 million) and Emerging Markets (+26.9% CER, at 63 million).

**Multiple Sclerosis franchise**

The Multiple Sclerosis franchise generated net sales of 1,114 million, up 112.2% CER year-on-year. Net sales of **Aubagio**® surged by 77.8% CER in 2015 to 871 million. In the United States, net sales reached 618 million, up 59.2% CER. In Europe, the product continued to extend its geographical reach, and full-year net sales rose by 136.1% CER at 197 million. Net sales of **Lemtrada**® amounted to 243 million (+550.0%

## Edgar Filing: Sanofi - Form 20-F

CER), including 91 million in Europe (mainly in Germany and the United Kingdom) and 128 million in the United States, where the product was launched at the end of 2014.

### **Oncology franchise**

Net sales for the **Oncology** business were 1,504 million, down 1.9% CER. Good performances from Jevtana® and Mozobil® were offset by the impact of generic versions of Taxotere® in Japan.

Net sales of **Jevtana**® totaled 321 million in 2015, up 9.5% CER, driven by a strong performance in the United States (+16.5% CER, at 127 million) and by sales in Japan (+533.3% CER, at 20 million) where the product was launched in September 2014.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

Net sales of **Thymoglobulin**<sup>®</sup> rose by 6.0% CER to 256 million, as sales advanced in the United States (+12.0% CER, at 145 million) but fell in Emerging Markets (-5.6% CER, at 51 million).

**Taxotere**<sup>®</sup> saw net sales fall sharply by 22.2% CER, to 222 million. The product is facing competition from generics in Emerging Markets (-8.4% CER, at 142 million) and in Japan (-34.5% CER, at 60 million).

**Eloxatin**<sup>®</sup> net sales decreased by 0.5% CER to 227 million, hit by a sharp decline in U.S. sales (-68.2% CER, at 9 million) but boosted by growth in Emerging Markets (+14.6% CER, at 130 million), especially in China.

Net sales of **Mozobil**<sup>®</sup> reached 143 million, up 16.2% CER, mainly on sales growth in the United States (+11.3% CER, at 83 million).

**Zaltrap**<sup>®</sup> (aflibercept, developed in collaboration with Regeneron) recorded net sales of 77 million, up 5.8% CER. A surge in sales in Europe (+34.2% CER, at 51 million) following recent launches more than offset lower sales in the United States (-37.0% CER, at 21 million).

**Diabetes franchise**

Net sales for the **Diabetes** franchise were 7,580 million, down 6.8% CER, mainly due to lower sales of Lantus<sup>®</sup> in the United States. In the United States, Diabetes division net sales totaled 4,316 million, down 17.3% CER. Outside the United States, the division posted 8.9% net sales growth CER, to 3,264 million.

The effects of a strong performance in Emerging Markets (+16.6% CER, at 1,407 million) were attenuated by slower sales growth in Europe (+3.8% CER, at 1,337 million), mainly on the entry of a biosimilar of insulin glargine into the market in the second half of the year.

Net sales for the **glargine franchise** (Lantus<sup>®</sup> and Toujeo<sup>®</sup>) fell by 8.5% CER to 6,554 million.

Net sales of **Lantus**<sup>®</sup> were 10.8% lower CER in 2015, at 6,390 million. This decline in net sales of Lantus<sup>®</sup> during 2015 reflected higher volumes (+4.6%), but also a generally unfavorable price effect (-15.4% CER), primarily in the United States. Net sales in the United States decreased by 20.5% CER to 4,023 million, due mainly to three factors: slower growth in the basal insulins market, further rises in the level of rebates compared with 2014, and the fact that a higher proportion of sales passed through governmental channels such as Medicaid. In Emerging Markets, sales increased by 17.3% CER to 972 million, driven by growth in China, the Middle East and Latin America. In Europe, where a biosimilar of Lantus<sup>®</sup> was launched in the second half of 2015, net sales increased by 2.9% CER.

**Toujeo**<sup>®</sup>, a new-generation basal insulin which saw its first launches in 2015 (late March in the United States, from April onwards in Europe, and subsequently in Japan and

Canada), posted net sales of 164 million, including 137 million in the United States.

Net sales of **Apidra**<sup>®</sup> totaled 376 million in 2015, up 4.8% CER, reflecting a strong performance in Emerging Markets (+25.5% CER, at 68 million) but lower sales in the United States (-7.6% CER, at 145 million).

Net sales of **Amaryl**<sup>®</sup> rose by 1.7% CER to 393 million. On the upside, Emerging Markets performed well (+8.3% CER, at 310 million), but sales were affected by generic competition in Japan (-18.5% CER, at 46 million).

**Cardiovascular franchise**

**Praluent**<sup>®</sup> reported net sales of 9 million, mainly in the United States where the product was launched in July 2015.

## Edgar Filing: Sanofi - Form 20-F

Net sales of **Multaq**<sup>®</sup> were 341 million (+0.7% CER), of which 287 million was generated in the United States (+2.1% CER) and 44 million in Europe (-6.4% CER).

### Established Prescription Products

Net sales of **Plavix**<sup>®</sup> declined by 4.1% CER to 1,929 million, impacted by generic competition in Europe (-22.1% CER, at 184 million) and also, from June 2015, in Japan (-12.5% CER, at 695 million). In Emerging Markets, Plavix<sup>®</sup> reported net sales growth of 9.7% CER to 992 million, driven by China (+13.1% CER, at 660 million). Sales of Plavix<sup>®</sup> in the United States and Puerto Rico are handled by BMS under the terms of the Sanofi-BMS alliance (see Financial presentation of alliances Alliance Arrangements with Bristol-Myers Squibb above).

Full-year net sales of **Lovenox**<sup>®</sup> were virtually unchanged in 2015, slipping just 0.5% CER to 1,719 million. Net sales in Europe rose by 1.5% CER to 1,049 million. Lower net sales in the United States due to generic competition (-50.8% CER, at 77 million) were offset by a good performance in Emerging Markets (+8.9% CER, at 496 million), especially in Latin America and Africa. Sales of the generic version of Lovenox<sup>®</sup> launched by Sanofi in 2012 are recorded by our Generics business (see below).

Net sales of **Renagel**<sup>®</sup>/**Renvela**<sup>®</sup> rose by 18.9% CER to 935 million on a strong performance in the United States (+30.8% CER, at 723 million), reflecting reduced competition from Impax which for a few months beginning April 2014 had the right to sell a limited number of authorized generics of Renvela<sup>®</sup>. In Europe, sales fell year-on-year (-16.1% CER, at 121 million) as a result of competition from generics.

**Aprovel**<sup>®</sup>/**Avapro**<sup>®</sup> reported a drop in net sales of 3.7% CER to 762 million, mainly as a result of competition from generics in Europe, where sales fell by 25.5% CER to 148 million. Net sales in Emerging Markets rose by 8.9% CER to 459 million, mainly on a good performance in China.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

Net sales of **Auvi-Q®/Allerject** (epinephrine auto-injectors) fell by 113.9% CER to negative 5 million (versus positive 72 million in 2014) due to the voluntary recall in October 2015 of all batches of the product marketed in the United States and Canada. This recall had a negative effect of 122 million on net sales, largely as a result of the reversal of all sales of the product since the start of 2015. It was discovered that the product could potentially have inaccurate dosage delivery, which may include failure to deliver the drug. Sanofi has ultimately decided to return all US and Canadian rights to Auvi-Q® to the developer of Auvi-Q®.

We have no comments on sales of our other established prescription products.

**Consumer Healthcare**

Net sales for the **Consumer Healthcare** business rose by 2.8% CER in 2015 to 3,492 million. The main growth drivers were the United States (+6.1% CER, at 902 million) largely due to a strong performance from Allegra® OTC following the launch of a new formulation, and Australia/New Zealand (+18.5% CER, at 191 million).

Net sales in Emerging Markets reached 1,453 million, up 0.7% CER. In Europe, net sales rose by 0.6% CER to 885 million. French sales of Doliprane® fell following two price cuts in January 2015 and November 2015. In the Rest of the World region, net sales rose by 15.8% CER to 252 million, reflecting good performances in Australia/New Zealand.

The following table breaks down our 2015 and 2014 net sales for the Consumer Healthcare by product:

( million)			Change	Change at
	2015	2014	on	constant
Product	Reported	Reported	a	exchange rates
			reported	
			basis	
Allegra®	424	350	+21.1%	+8.0%
Doliprane®	303	310	-2.3%	-2.3%
Essentiale®	196	235	-16.6%	-6.4%
Enterogermina®	161	156	+3.2%	+1.3%
Nasacort®	122	114	+7.0%	-8.8%
No-Spa®	88	109	-19.3%	-5.5%
Lactacyd®	114	104	+9.6%	+10.6%
Maalox®	97	98	-1.0%	+4.1%
Dorflex®	81	90	-10.0%	+6.7%
Magné B6®	82	88	-6.8%	+9.1%
Other products	1,824	1,683	+8.4%	+4.2%
<b>Total: Consumer Healthcare</b>	<b>3,492</b>	<b>3,337</b>	<b>+4.6%</b>	<b>+2.8%</b>

**Generics**

**Generics** recorded 2015 net sales of 1,917 million, up 7.6% CER.

In Emerging Markets, Generics generated net sales of 839 million, a rise of 6.9% CER, driven by Eurasia/Middle East and Venezuela. Net sales in Europe increased by 2.8% CER to 823 million, boosted by a good performance in Germany. In the United States, net sales advanced by

15.4% CER to 171 million, mainly due to increased sales of the authorized generic of Lovenox®. In the Rest of the World region, net sales rose by 86.4% CER to 84 million, due mainly to the performance in Japan of the authorized generic of Allegra® and of the authorized generic of Plavix® launched by Sanofi and our partner Nichi-Iko Pharmaceuticals Co., Ltd at the end of the second quarter of 2015.

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The following table presents the 2015 net sales of our Pharmaceutical segment products by geographical region:

( million)	Total GBUs	Europe <sup>(a)</sup>	Change at constant exchange rates	United States	Change at constant exchange rates	Rest		Emerging Markets <sup>(c)</sup>	Change at constant exchange rates	Total Franchise	Change at constant exchange rates
						of the world (b)	Change at constant exchange rates				
Cerezyme®	532	283	+0.4%	201	-9.1%	48	-4.3%	225	+13.3%	757	+1.3%
Cerdelga®	66	6	-	60	+1150.0%	-	-	-	-	66	+1325.0%
Myozyme®/Lumizyme®	556	307	+4.8%	205	+20.4%	44	+19.4%	94	+22.7%	650	+12.4%
Fabrazyme®	529	140	+17.9%	305	+14.3%	84	+17.6%	63	+26.9%	592	+17.2%
Aldurazyme®	137	75	+4.2%	40	0.0%	22	+5.0%	58	+22.9%	195	+8.7%
Other	255	52	+10.9%	114	+9.0%	89	+1.2%	35	+25.9%	290	+8.6%
<b>Total Rare Diseases</b>	<b>2,075</b>	<b>863</b>	<b>+6.4%</b>	<b>925</b>	<b>+14.5%</b>	<b>287</b>	<b>+7.5%</b>	<b>475</b>	<b>+18.8%</b>	<b>2,550</b>	<b>+11.4%</b>
Aubagio®	847	197	+136.1%	618	+59.2%	32	+121.4%	24	+140.0%	871	+77.8%
Lemtrada®	233	91	+217.9%	128	+5300.0%	14	+366.7%	10	+900.0%	243	+550.0%
<b>Total Multiple Sclerosis</b>	<b>1,080</b>	<b>288</b>	<b>+156.8%</b>	<b>746</b>	<b>+91.2%</b>	<b>46</b>	<b>+164.7%</b>	<b>34</b>	<b>+209.1%</b>	<b>1,114</b>	<b>+112.2%</b>
Jevtana®	294	141	-4.8%	127	+16.5%	26	+225.0%	27	0.0%	321	+9.5%
Thymoglobulin®	205	40	+8.3%	145	+12.0%	20	0.0%	51	-5.6%	256	+6.0%
Taxotere®	80	7	-62.5%	-1	-112.5%	74	-28.3%	142	-8.4%	222	-22.2%
Eloxatin®	97	4	-20.0%	9	-68.2%	84	0.0%	130	+14.6%	227	-0.5%
Mozobil®	131	41	+11.1%	83	+11.3%	7	+60.0%	12	+50.0%	143	+16.2%
Zaltrap®	74	51	+34.2%	21	-37.0%	2	+100.0%	3	0.0%	77	+5.8%
Other	239	56	-10.0%	162	-10.6%	21	-4.5%	19	-18.2%	258	-10.6%
<b>Total Oncology</b>	<b>1,120</b>	<b>340</b>	<b>-1.2%</b>	<b>546</b>	<b>-3.2%</b>	<b>234</b>	<b>-3.0%</b>	<b>384</b>	<b>0.0%</b>	<b>1,504</b>	<b>-1.9%</b>
<b>Sanofi Genzyme (Specialty Care)</b>	<b>4,275</b>	<b>1,491</b>	<b>+17.6%</b>	<b>2,217</b>	<b>+25.9%</b>	<b>567</b>	<b>+8.2%</b>	<b>893</b>	<b>+12.7%</b>	<b>5,168</b>	<b>+18.5%</b>
Lantus®	5,418	991	+2.9%	4,023	-20.5%	404	+4.1%	972	+17.3%	6,390	-10.8%
Toujeo®	159	18	-	137	-	4	-	5	-	164	-
Amaryl®	83	26	-13.3%	2	-50.0%	55	-16.1%	310	+8.3%	393	+1.7%
Apidra®	308	124	+6.9%	145	-7.6%	39	+11.8%	68	+25.5%	376	+4.8%
Insuman®	97	94	-7.8%	2	+100.0%	1	-200.0%	44	+39.4%	141	+2.9%
Blood glucose meters	61	60	+1.7%	-	-	1	-33.3%	2	-33.3%	63	-1.6%
Lyxumia®	33	24	+35.3%	-	-	9	+28.6%	5	+66.7%	38	+37.0%
Other	14	-	-	7	-	7	+75.0%	1	0.0%	15	+180.0%
<b>Total Diabetes</b>	<b>6,173</b>	<b>1,337</b>	<b>+3.8%</b>	<b>4,316</b>	<b>-17.3%</b>	<b>520</b>	<b>+3.4%</b>	<b>1,407</b>	<b>+16.6%</b>	<b>7,580</b>	<b>-6.8%</b>
Multaq®	335	44	-6.4%	287	+2.1%	4	0.0%	6	0.0%	341	+0.7%
Praluent®	9	1	-	9	-	-1	-	-	-	9	-
<b>Total Cardiovascular</b>	<b>344</b>	<b>45</b>	<b>-4.3%</b>	<b>296</b>	<b>+5.1%</b>	<b>3</b>	<b>0.0%</b>	<b>6</b>	<b>0.0%</b>	<b>350</b>	<b>+3.4%</b>
<b>Total Diabetes &amp; Cardiovascular</b>	<b>6,517</b>	<b>1,382</b>	<b>+3.6%</b>	<b>4,612</b>	<b>-16.1%</b>	<b>523</b>	<b>+3.4%</b>	<b>1,413</b>	<b>+16.5%</b>	<b>7,930</b>	<b>-6.4%</b>
Plavix®	1,929	184	-22.1%	1	0.0%	752	-12.5%	992	+9.7%	1,929	-4.1%
Lovenox®	1,719	1,049	+1.5%	77	-50.8%	97	+3.3%	496	+8.9%	1,719	-0.5%
Renage®/Renvela®	935	121	-16.1%	723	+30.8%	31	+7.7%	60	+13.7%	935	+18.9%
Aprovel®/CoAprovel®	762	148	-25.5%	15	-33.3%	140	-3.8%	459	+8.9%	762	-3.7%
Depakine®	422	168	-1.2%	-	-	14	-6.7%	240	+6.5%	422	+2.8%



**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

( million)	Total GBUs	Change at constant exchange rates		United States	Change at constant exchange rates		Rest of the world (b)	Change at constant exchange rates		Emerging Markets(c)	Change at constant exchange rates		Total Franchise	Change at constant exchange rates
		Europe(a)												
Synvisc® / Synvisc-One®	413	32	+3.2%	322	-1.5%	16	+25.0%	43	+22.9%		413	+2.3%		
Stilnox®/Ambien®/Myslee®	306	47	-6.0%	74	-16.2%	131	-7.4%	54	+12.8%		306	-6.2%		
Tritace®	274	163	-6.9%	-	-	5	-50.0%	106	+6.3%		274	-3.9%		
Allegra®	194	11	0.0%	-	-	183	-3.9%	-	-		194	-3.6%		
Targocid®	160	83	-5.7%	-	-	8	-22.2%	69	0.0%		160	-4.3%		
Lasix®	162	77	-2.5%	3	-33.3%	26	-18.8%	56	+6.0%		162	-3.7%		
Orudis®	156	19	-9.5%	-	-	4	0.0%	133	+5.9%		156	+3.8%		
Cordarone®	130	30	-6.5%	-	-	32	-11.4%	68	+7.9%		130	-0.8%		
Xatral®	95	38	-5.0%	-	-	5	+25.0%	52	-4.0%		95	-3.2%		
Other	3,635	1,694	-2.0%	307	-37.3%	367	-20.2%	1,267	+1.8%		3,635	-6.6%		
<b>Total Established Prescription Products</b>	<b>11,292</b>	<b>3,864</b>	<b>-4.3%</b>	<b>1,522</b>	<b>-7.1%</b>	<b>1,811</b>	<b>-11.4%</b>	<b>4,095</b>	<b>+6.2%</b>		<b>11,292</b>	<b>-2.4%</b>		
<b>Generics</b>	<b>1,917</b>	<b>823</b>	<b>+2.8%</b>	<b>171</b>	<b>+15.4%</b>	<b>84</b>	<b>+86.4%</b>	<b>839</b>	<b>+6.9%</b>		<b>1,917</b>	<b>+7.6%</b>		
<b>Total Emerging Markets Specialty Care</b>	<b>893</b>							<b>893</b>	<b>+12.7%</b>					
<b>Total Emerging Markets Diabetes &amp; Cardiovascular</b>	<b>1,412</b>							<b>1,413</b>	<b>+16.5%</b>					
<b>General Medicines &amp; Emerging Markets</b>	<b>15,515</b>	<b>4,687</b>	<b>-3.1%</b>	<b>1,693</b>	<b>-5.2%</b>	<b>1,895</b>	<b>-9.2%</b>	<b>7,240</b>	<b>+8.9%</b>		<b>15,515</b>	<b>+1.1%</b>		
<b>Consumer Healthcare(d)</b>	<b>3,492</b>	<b>885</b>	<b>+0.6%</b>	<b>902</b>	<b>+6.1%</b>	<b>252</b>	<b>+15.8%</b>	<b>1,453</b>	<b>+0.7%</b>		<b>3,492</b>	<b>+2.8%</b>		
<b>Total Pharmaceuticals</b>	<b>29,799</b>	<b>8,445</b>	<b>+1.5%</b>	<b>9,424</b>	<b>-4.8%</b>	<b>3,237</b>	<b>-2.9%</b>	<b>8,693</b>	<b>+7.3%</b>		<b>29,799</b>	<b>+0.8%</b>		

(a) Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).

(b) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(d) Following the creation of the Consumer Healthcare GBU, sales of that GBU's products previously included in the General Medicines & Emerging Markets GBU are presented for information purposes on a separate line for 2016 and prior periods, in the interests of comparability.

#### 5/ Net Sales - Human Vaccines (Vaccines) Segment

In 2015, net sales for the Vaccines segment were 4,261 million, up 16.4% on a reported basis and 5.4% at constant exchange rates (CER). Year-on-year growth was driven by sales of Polio/Pertussis/Hib vaccines in Emerging Markets, and in the United States by sales of Menactra®.

The table below sets forth 2015 and 2014 net sales of our Vaccines segment by product range:

Edgar Filing: Sanofi - Form 20-F

	2015	2014	Change on	Change at
( million)	Reported	Reported	a	constant
			reported	exchange rates
			basis	
Polio/Pertussis/Hib Vaccines (including <i>Pentacel</i> <sup>®</sup> and <i>Pentaxim</i> <sup>®</sup> )	1,348	1,154	+16.8%	+8.1%
Influenza Vaccines (including <i>Vaxigrip</i> <sup>®</sup> and <i>Fluzone</i> <sup>®</sup> )	1,322	1,178	+12.2%	+2.0%
Meningitis/Pneumonia Vaccines (including <i>Menactra</i> <sup>®</sup> )	614	454	+35.2%	+16.7%
Adult Booster Vaccines (including <i>Adacel</i> <sup>®</sup> )	496	398	+24.6%	+10.1%
Travel and Other Endemics Vaccines	375	377	-0.5%	-6.9%
Other Vaccines	106	99	+7.1%	-8.1%
<b>Total: Vaccines<sup>(a)</sup></b>	<b>4,261</b>	<b>3,660</b>	<b>+16.4%</b>	<b>+5.4%</b>

(a) Due to a change in accounting presentation, Vaxserve sales of non-Sanofi are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.1.2)

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

Net sales of **Polio/Pertussis/Hib** vaccines rose by 8.1% CER to 1,348 million, boosted by the performances of Pentaxim® and Hexaxim®. Net sales in Emerging Markets grew strongly by 31.7% CER to 736 million, due to sales of Pentaxim® and polio vaccines in China. The Shan5 pentavalent pediatric vaccines generated net sales of 33 million, mainly to world healthcare organizations. In the United States, sales declined by 20.2% CER to 393 million, due to lower sales of Pentacel® caused by manufacturing delays.

Net sales of **Influenza** vaccines rose by 2.0% CER to 1,322 million. Sales were strong in the United States (+11.8% CER, at 896 million), justifying Sanofi Pasteur's differentiation strategy in influenza vaccines. In Emerging Markets, sales declined by 14.8% CER to 294 million, due mainly to shipment delays in Brazil and Mexico.

Net sales of **Meningitis/Pneumonia** vaccines reached 614 million, up 16.7% CER. Menactra® generated net sales of 563 million, up 18.2% CER, driven by public-sector sales in the United States.

**Adult booster** vaccines saw net sales increase by 10.1% CER to 496 million, as strong performances in the United States (+9.8% CER, at 360 million) and Emerging Markets (+38.5% CER, at 54 million) more than offset lower sales in Europe (-8.8% CER, at 62 million) due to the timing of shipments.

Net sales of **Travel and Other Endemics** vaccines declined by 6.9% CER to 375 million.

Net sales of **Other Vaccines** declined by 8.1% CER to 106 million.

In addition to the Vaccines activity reflected in our consolidated net sales, sales generated by Sanofi Pasteur MSD, our joint venture with Merck in Europe, fell by 2.8% on a reported basis in 2015 to 824 million. The main factors were a decline in sales of Gardasil® (-11.7% on a reported basis) and Adult Booster vaccines (-16.5% on a reported basis), partly offset by a good performance from hepatitis A vaccines. Sales generated by Sanofi Pasteur MSD are not included in our consolidated net sales.

The following table presents the 2015 net sales of our Vaccines segment by product range and by region:

( million)	Europe <sup>(a)</sup>	Change at constant exchange rates	United States	Change at constant exchange rates	Rest of the world <sup>(b)</sup>	Change at constant exchange rates	Emerging Markets <sup>(c)</sup>	Change at constant exchange rates
Polio/Pertussis/Hib Vaccines (including Pentacel® and Pentaxim®)	90	+50.0%	393	-20.2%	129	-16.4%	736	+31.7%
Influenza Vaccines (including Vaxigrip® and Fluzone®)	96	-5.9%	896	+11.8%	36	-2.7%	294	-14.8%
Meningitis/Pneumonia Vaccines (including Menactra®)	3	-25.0%	496	+15.0%	9	-11.1%	106	+29.6%
Adult Booster Vaccines (including Adacel®)	62	-8.8%	360	+9.8%	20	+26.7%	54	+38.5%
Travel and Other Endemics Vaccines	30	0.0%	111	-2.1%	53	-3.6%	181	-11.2%
Dengvaxia®	-	-	-	-	-	-	-	-
Other vaccines <sup>(d)</sup>	3	-25.0%	84	-10.0%	11	+42.9%	8	-25.0%
<b>Total Vaccines segment<sup>(d)</sup></b>	<b>284</b>	<b>+6.0%</b>	<b>2,340</b>	<b>+3.7%</b>	<b>258</b>	<b>-7.8%</b>	<b>1,379</b>	<b>+11.1%</b>

## Edgar Filing: Sanofi - Form 20-F

- (a) *Western Europe and Eastern Europe excluding Eurasia (Russia, Ukraine, Georgia, Belarus, Armenia and Turkey).*
- (b) *Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.*
- (c) *World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.*
- (d) *Due to a change in accounting presentation, Vaxserve sales of non-Sanofi are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.1.2)*

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****6/ Net Sales by Geographical Region**

The following table presents our 2015 and 2014 net sales by region:

( million)	2015 <sup>(a)(b)</sup>	2014 <sup>(a)(b)</sup>	Change on  a reported  basis	Change at  constant  exchange rates
United States	11,764	10,186	+15.5%	-3.2%
Emerging Markets <sup>(c)</sup>	10,072	9,240	+9.0%	+7.8%
Of which Latin America	3,047	3,113	-2.1%	+3.8%
Of which Asia (excluding South Asia)	3,101	2,375	+30.6%	+13.9%
Of which Africa, Middle East and South Asia	2,657	2,354	+12.9%	+7.1%
Of which Eurasia <sup>(d)</sup>	1,132	1,324	-14.5%	+4.0%
Europe <sup>(e)</sup>	8,729	8,511	+2.6%	+1.6%
Rest of the world <sup>(f)</sup>	3,495	3,443	+1.5%	-3.3%
Of which Japan	2,034	2,083	-2.4%	-7.2%
<b>Total net sales</b>	<b>34,060</b>	<b>31,380</b>	<b>+8.5%</b>	<b>+1.4%</b>

(a) Due to a change in accounting presentation, Vaxserve sales of non-Sanofi are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.1.2)

(b) In accordance with the presentation requirements of IFRS 5, the consolidated income statement line item **Net sales** does not include the net sales of the Animal Health business.

(c) World excluding United States, Canada, Western and Eastern Europe (apart from Eurasia), Japan, South Korea, Australia, New Zealand and Puerto Rico.

(d) Russia, Ukraine, Georgia, Belarus, Armenia and Turkey.

(e) Western Europe and Eastern Europe (excluding Eurasia).

(f) Japan, South Korea, Canada, Australia, New Zealand and Puerto Rico.

In the United States, net sales declined by 3.2% CER to 11,764 million, reflecting reduced sales for the Diabetes division (-17.3% CER), though the effect was partly offset by solid performances by Specialty Care franchise (+25.9% CER) and Vaccines (+3.7% CER).

## Edgar Filing: Sanofi - Form 20-F

In Emerging Markets, net sales reached 10,072 million, up 7.8% CER, driven by the Diabetes franchise (+16.6% CER), the Specialty Care franchise (+12.7% CER) and Vaccines (+11.1% CER).

Net sales in Latin America advanced by 3.8% CER to 3,047 million. In Asia, net sales rose by 13.9% CER to 3,101 million. In Africa, Middle East and South Asia net sales increased by 7.1% CER to 2,657 million. Growth in Eurasia reached 4.0% CER to 1,132 million.

Net sales in Europe rose by 1.6% CER to 8,729 million. The effects of ongoing generic competition for Plavix® and Aprovel® were more than compensated for by the performances of the Specialty Care franchise (+17.6% CER) and the Diabetes (+3.8% CER) franchise.

In the Rest of the World region, net sales amounted to 3,495 million, down 3.3% CER. Lower sales of established prescription products (-11.4% CER) and in Vaccines (-7.8% CER) were not fully offset by positive performances from the Specialty Care franchise, Generics and Consumer Healthcare. In Japan, net sales totaled 2,034 million (-7.2% CER) due to the adverse impact of competition from

generics of Taxotere®, Myslee® and Amaryl® combined with lower polio vaccine sales, partly offset by good performances in Generics.

### A.3.3. Other Revenues

Other revenues mainly comprise royalties under licensing agreements contracted in the ordinary course of business. Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

Other revenues rose to 801 million in 2015, compared with 619 million in 2014. This year-on-year increase reflects a higher level of sales of non-Sanofi products by VaxServe.

### A.3.4. Gross Profit

Gross profit reached 23,942 million in 2015 (70.3% of net sales), versus 21,769 million in 2014 (69.4% of net sales).

The gross margin ratio for the Pharmaceuticals segment was 0.4 of a percentage point higher at 71.5%. The main factor was an improvement in the ratio of cost of sales to net sales, due largely to the favorable effect of exchange rates. Other factors included a positive impact from the Genzyme business and a negative impact from the Diabetes division in the United States.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

The gross margin ratio for the Vaccines segment rose by 5.7 percentage points to 62.0%, reflecting a more favorable product mix and favorable exchange rate effects.

**A.3.5. Research and Development Expenses**

Research and development (R&D) expenses amounted to 5,082 million in 2015, compared with 4,667 million in 2014 and represented 14.9% of net sales (versus 14.9% in 2014). The overall year-on-year increase of 415 million included 356 million for the Pharmaceuticals segment (+8.5%) and 59 million for the Vaccines segment (+12.0%).

The majority of this increase was attributable to the adverse impact of exchange rates. At constant exchange rates, R&D expenses rose only modestly, reflecting increased expenditure on dupilumab and Praluent® and the initiation of the new alliance with Regeneron in immuno-oncology in the second half of 2015.

**A.3.6. Selling and General Expenses**

Selling and general expenses totaled 9,382 million (27.5% of net sales) in 2015, compared with 8,425 million (26.8% of net sales) in 2014. This represents a year-on-year rise of 957 million.

By segment, the year on-year increase was 964 million (+12.5%) for Pharmaceuticals and 112 million (+18.2%) for Vaccines. In addition to unfavorable exchange rate effects, the overall increase also reflects investment in new product launches in the Specialty Care, Diabetes, and Cardiovascular (Praluent®) franchises.

**A.3.7. Other Operating Income and Expenses**

In 2015, other operating income totaled 254 million (versus 301 million in 2014), and other operating expenses 462 million (versus 157 million in 2014).

This year-on-year adverse movement of 352 million was attributable mainly to the operating foreign exchange loss on our Venezuelan operations, which reached 240 million in 2015 compared with 47 million in 2014 (see Note D.26. to our consolidated financial statements included at Item 18 of this annual report).

**A.3.8. Amortization of Intangible Assets**

Amortization charged against intangible assets totaled 2,137 million in 2015, versus 2,081 million in 2014.

This overall year-on-year increase of 56 million reflects a number of factors: (i) an increase in amortization charged against the intangible assets recognized on the acquisition of Genzyme ( 890 million in 2015, versus 811 million in 2014), due to new product launches and unfavorable exchange rate effects; (ii) the amortization in full, in December 2015, of a priority review voucher acquired in May 2015 for \$245 million and used for the filing of a new drug application with the FDA

for LixiLan; and (iii) a reduction in amortization charged against the intangible assets recognized on the acquisition of Aventis ( 637 million in 2015, versus 874 million in 2014) as some products reached the end of their life cycles.

**A.3.9. Impairment of Intangible Assets**

In 2015, this line item showed impairment losses of 767 million against intangible assets, versus a net reversal of 31 million in 2014.

In 2015, this line item includes (i) a net impairment loss of 340 million on research projects in the Pharmaceuticals and Vaccines segments, primarily Synvisc-One® in osteoarthritis of the hip and the rotavirus vaccine project (Shantha); and (ii) impairment losses of 427 million taken against rights relating to a number of marketed products in the Pharmaceuticals segment, mainly Afrezza® in the United States (following termination of the license and collaboration agreement with MannKind Corporation) and Auvi-Q®/Allerject® in the United States and Canada (following the voluntary recall of this product in the fourth quarter of 2015).

The 2014 figure includes a gain of 356 million arising because the impairment loss taken in 2013 against Lemtrada® (alemtuzumab) was reversed following approval of the product by the FDA in November 2014. It also includes the negative effects of (i) a net impairment loss of 203 million arising from various research projects in Pharmaceuticals and Vaccines, in particular the discontinuation of collaborative development programs with Alopexx (SAR 279 356) and Kalobios (*Pseudomonas aeruginosa* vaccine), and from revised commercial prospects (especially for the rotavirus vaccine project); and (ii) the impairment losses of 123 million taken against rights to a number of marketed products in the Pharmaceuticals and Vaccines segments (mainly Consumer Healthcare assets in the Emerging Markets region).

### **A.3.10. Fair Value Remeasurement of Contingent Consideration Liabilities**

Fair value remeasurements of contingent consideration liabilities recognized on acquisitions in accordance with the revised IFRS 3 represented a net gain of 53 million in 2015, versus a net expense of 303 million in 2014.

These remeasurements mainly relate to the contingent consideration payable to Bayer as a result of an acquisition made by Genzyme prior to the latter's acquisition by Sanofi, and to the contingent value rights (CVRs) issued by Sanofi in connection with the Genzyme acquisition (see Note D.18. to our consolidated financial statements included at Item 18 of this annual report).

### **A.3.11. Restructuring Costs and similar items**

Restructuring costs and similar items amounted to 795 million in 2015, compared with 404 million in 2014.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

In 2015, restructuring costs related mainly to (i) employee-related expenses arising from headcount adjustment plans in the United States and the rest of the world; (ii) the reorganization of the Company's R&D activities, especially in France following signature of the agreement with Evotec; and (iii) impairment losses taken against industrial assets in Europe. In 2014, these costs mainly comprised employee-related expenses arising from headcount adjustment plans in France and the rest of Europe. See Note D.27. to our consolidated financial statements included at Item 18 of this annual report.

**A.3.12. Other Gains and Losses, and Litigation**

Nothing was recognized on this line in either 2015 or 2014.

**A.3.13. Operating Income**

Operating income totaled 5,624 million for 2015, compared with 6,064 million for 2014. The year-on-year decline of 7.3% was attributable mainly to the higher levels of research and development expenses, selling and general expenses, impairment of intangible assets and restructuring costs, which were not wholly offset by the growth in net sales and gross profit.

**A.3.14. Financial Income and Expenses**

Net financial expenses for 2015 were 381 million, compared with 406 million for 2014, a decrease of 25 million.

**A.3.15. Income before Tax and Associates and Joint Ventures**

Income before tax and associates and joint ventures amounted to 5,243 million in 2015, versus 5,658 million in 2014, a fall of 7.3%.

**A.3.16. Income Tax Expense**

Income tax expense represented 709 million in 2015, versus 1,214 million in 2014, giving an effective tax rate (based on consolidated net income) of 13.5% in 2015, versus 21.5% in 2014 (see Note D.30. to our consolidated financial statements included at Item 18 of this annual report).

The level of income tax expense was significantly impacted by the positive tax effects arising on the amortization and impairment of intangible assets ( 1,019 million in 2015, versus 546 million in 2014) and on restructuring costs ( 273 million in 2015, versus 441 million in 2014). In

addition, the tax effect of the fair value remeasurement of contingent consideration liabilities represented a gain of 39 million in 2015, compared with a gain of 254 million in 2014. Overall, these effects reduced our income tax expense by 403 million.

The effective tax rate on our business net income<sup>(1)</sup> is a non-GAAP financial measure. It is calculated on the basis of business operating income, minus net financial expenses and before the share of profit/loss of associates and joint ventures and net income attributable to non-controlling interests. We believe the presentation of this measure, used by our management, is also useful for investors as it provides a means to analyze the effective tax cost of our current business activities. It should not be seen as a substitute for the effective tax rate on consolidated net income.

This effective tax rate was 21.7% in 2015 and 23.9% in 2014. The main impacts on this tax rate are the geographical mix of the results from Sanofi entities, the tax effects of the elimination of intragroup margin on inventory, and settlements of recent proceedings involving the tax authorities in various countries that had a positive effect in 2014. In 2015, there was also a favorable effect as a result of changes in the taxation of dividends in France following a ruling by the Court of Justice of the European Union and the resulting amendments to the 2015 Finance Act.

## Edgar Filing: Sanofi - Form 20-F

The table below reconciles our effective tax rate (based on consolidated net income) and the effective tax rate on our business net income:

<i>(as a percentage)</i>	<b>2015<sup>(a)</sup></b>	<b>2014<sup>(a)</sup></b>
<b>Effective tax rate on consolidated net income</b>	<b>13.5</b>	<b>21.5</b>
<i>Tax effects:</i>		
Amortization and impairment of intangible assets	6.5	0.8
Restructuring costs and similar items	2.9	0.8
Other items	(1.2)	0.8
<b>Effective tax rate on business net income</b>	<b>21.7</b>	<b>23.9</b>

<sup>(a)</sup> The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36.

<sup>(1)</sup> See definition under section A.1.5. Segment information 3/ Business Net Income.

---

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

**A.3.17. Share of Profit/(Loss) of Associates and Joint Ventures**

Associates and joint ventures contributed a net loss of 22 million in 2015, versus a net loss of 52 million in 2014.

Beginning April 2014, this line item includes our share of the profits and losses of Regeneron (impact: losses of 54 million in 2015, and 126 million in 2014), including the impact of the fair value remeasurement of our share of the acquired intangible assets of Regeneron. It also includes our share of after-tax profits from territories managed by BMS under the Plavix® and Avapro® alliance ( 36 million in 2015, versus 31 million in 2014), plus immaterial amounts for our share of profits and losses from other associates and joint ventures.

**A.3.18. Net Income Excluding the Held-For-Exchange Animal Health Business**

Net income excluding the held-for-exchange Animal Health business amounted to 4,512 million in 2015, versus 4,392 million in 2014.

**A.3.19. Net Income/(Loss) of the Held-For-Exchange Animal Health Business**

In accordance with IFRS 5, the net income or loss of the Animal Health business is presented in a separate line item, *Net income/(loss) of the held-for-exchange Animal Health business* (see Notes D.2. and D.36. to our consolidated financial statements included at Item 18 of this annual report). This business reported a net loss of 124 million in 2015, compared with net income of

117 million in 2014. In 2015, this line item includes income tax expense of 149 million arising from taxable temporary differences relating to holdings in subsidiaries, because it has become probable that those differences will reverse.

**A.3.20. Net Income**

Net income amounted to 4,388 million in 2015, compared with 4,509 million in 2014.

**A.3.21. Net Income Attributable to Non-Controlling Interests**

Net income attributable to non-controlling interests was 101 million in 2015, versus 119 million in 2014. This line mainly comprises the share of pre-tax profits paid to BMS from territories managed by Sanofi ( 94 million, versus 109 million in 2014). The year-on-year decrease was directly related to competition from generics of clopidogrel (active ingredient of Plavix®) and irbesartan (active ingredient of Aprovel®) in Europe.

**A.3.22. Net Income Attributable to Equity Holders of Sanofi**

Net income attributable to equity holders of Sanofi amounted to 4,287 million, versus 4,390 million in 2014.

Basic earnings per share for 2015 was 3.28, 1.8% lower than the 2014 figure of 3.34, based on an average number of shares outstanding of 1,306.2 million in 2015 (1,315.8 million in 2014). Diluted earnings per share for 2015 was 3.25, 1.5% lower than the 2014 figure of 3.30), based on an average number of shares outstanding after dilution of 1,320.7 million in 2015 and 1,331.1 million in 2014.



**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS****A.3.23. Segment results**

We report segment results on the basis of Business Operating Income. This indicator, adopted in compliance with IFRS 8, is used internally to measure operational performance and to allocate resources. See Segment information above for the definition of business operating income and a reconciliation to Income before tax and associates and joint ventures.

**1/ Business Operating Income**

Business operating income amounted to 9,313 million in 2015, 4.0% higher than in 2014 ( 8,957 million) and represented 27.3% of net sales, versus 28.5% in 2014.

Business operating income for 2015 and 2014 is set forth below:

( million)	2015	2014	Change
Pharmaceuticals	8,013	8,018	-0.1%
Vaccines <sup>(a)</sup>	1,414	994	+42.3%
Other	(114)	(55)	-107.3%
<b>Business operating income</b>	<b>9,313</b>	<b>8,957</b>	<b>+4.0%</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

The following table presents our segment results for the year ended December 31, 2015:

( million)	Pharmaceuticals	Vaccines <sup>(a)</sup>	Other	Total
<b>Net sales</b>	<b>29,799</b>	<b>4,261</b>	-	<b>34,060</b>
Other revenues	288	513	-	801
Cost of sales	(8,788)	(2,131)	-	(10,919)
Research and development expenses	(4,530)	(552)	-	(5,082)
Selling and general expenses	(8,656)	(726)	-	(9,382)
Other operating income and expenses	(121)	27	(114)	(208)
Share of profit/(loss) of associates and joint ventures	146	23	-	169
Net income attributable to non-controlling interests	(125)	(1)	-	(126)
<b>Business operating income</b>	<b>8,013</b>	<b>1,414</b>	<b>(114)</b>	<b>9,313</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

The following table presents our segment results for the year ended December 31, 2014:

( million)	Pharmaceuticals	Vaccines <sup>(a)</sup>	Other	Total
------------	-----------------	-------------------------	-------	-------

Edgar Filing: Sanofi - Form 20-F

<b>Net sales</b>	<b>27,720</b>	<b>3,660</b>	<b>-</b>	<b>31,380</b>
Other revenues	272	347	-	619
Cost of sales	(8,282)	(1,948)	-	(10,230)
Research and development expenses	(4,174)	(493)	-	(4,667)
Selling and general expenses	(7,692)	(614)	(3)	(8,309)
Other operating income and expenses	194	2	(52)	144
Share of profit/(loss) of associates and joint ventures	106	40	-	146
Net income attributable to non-controlling interests	(126)	-	-	(126)
<b>Business operating income</b>	<b>8,018</b>	<b>994</b>	<b>(55)</b>	<b>8,957</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly.

---

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

***2/ Business Net Income***

Business net income is a non-GAAP financial measure that we use to evaluate our performance. See **Business Net Income** above for the definition of business net income and a reconciliation to *Net income attributable to equity holders of Sanofi*.

Business net income totaled 7,371 million in 2015, versus 6,847 million in 2014, an increase of 7.7%; it represented 21.6% of net sales in 2015 versus 21.8% of net sales in 2014.

***3/ Business Earnings Per Share***

We also report business earnings per share, a non-GAAP financial measure which we define as business net income divided by the weighted average number of shares outstanding (see **Business Net Income** above).

Business earnings per share was 5.64 in 2015, 8.5% higher than the 2014 figure of 5.20, based on an average number of shares outstanding of 1,306.2 million in 2015 and 1,315.8 million in 2014.

**B. Liquidity and Capital Resources**

Our operations generate significant positive cash flows. We fund our day-to-day investments (with the exception of significant acquisitions) primarily with operating cash flow,

and pay regular dividends on our shares. Our net debt increased in 2016, mainly due to share repurchases made at the end of 2016, carried out in anticipation of the net proceeds from the transaction with BI finalized in most markets in early 2017. In 2015, the net debt was relatively stable compared to 2014.

We define **debt, net of cash and cash equivalents** as (i) the sum total of short-term debt, long-term debt and interest rate and currency derivatives used to hedge debt, minus (ii) the sum total of cash and cash equivalents and interest rate and currency derivatives used to hedge cash and cash equivalents. We believe the presentation of this non-GAAP financial indicator reviewed by our management is useful as it provides information to measure overall liquidity and capital resources. As of December 31, 2016, our debt, net of cash and cash equivalents stood at 8,206 million versus 7,254 million as of December 31, 2015 and 7,171 million as of December 31, 2014. See Note D.17. to our consolidated financial statements.

In order to assess the Company's financing risk, we also use the **gearing ratio**, a non-GAAP financial measure (see table in section **B.2. Consolidated Balance Sheet and Debt** below). The gearing ratio is defined as the ratio of debt, net of cash and cash equivalents, to total equity. As of December 31, 2016, our gearing ratio was 14.2% of our net equity versus 12.5% as of December 31, 2015 and 12.7% as of December 31, 2014.

**B.1. CONSOLIDATED STATEMENT OF CASH FLOWS**

**Summarized consolidated statements of cash flows**

( million)	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
Net cash provided by/(used in) operating activities excluding the held-for-exchange Animal Health business	7,838	8,290	7,165
Net cash provided by/(used in) investing activities excluding the held-for-exchange Animal Health business	(2,511)	(3,011)	(3,357)
Net cash provided by/(used in) financing activities excluding the held-for-exchange Animal Health business	(4,101)	(3,578)	(5,194)
Impact of exchange rates on cash and cash equivalents	(101)	(232)	34
<b>Net change in cash and cash equivalents</b>	<b>1,125</b>	<b>1,469</b>	<b>(1,352)</b>

(a) Cash flows of the Animal Health business are presented separately in accordance with IFRS 5.

Generally, factors that affect our earnings – for example, pricing, volume, costs and exchange rates – flow through to cash from operations. The most significant source of cash from operations is sales of our branded pharmaceutical products and human vaccines. Receipts of royalty payments also contribute to cash from operations.

#### **B.1.1. Year Ended December 31, 2016 Compared with Year Ended December 31, 2015**

**Net cash provided by operating activities excluding the held-for-exchange Animal Health business** amounted to 7,838 million in 2016, versus 8,290 million in 2015.

Operating cash flow before changes in working capital (excluding the net income or loss of the held-for-exchange Animal Health business) for 2016 was 7,010 million, versus 7,235 million in 2015. Working capital requirements fell by 828 million in 2016, compared with a reduction of 1,055 million in 2015, mainly reflecting a 447 million increase in accounts payable and a 168 million reduction in accounts receivable.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect *Operating income*, which is discussed in detail above under Results of Operations – Year Ended December 31, 2016 Compared

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

with Year Ended December 31, 2015 . The principal difference is that operating cash flow before changes in working capital includes our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

**Net cash used in investing activities excluding the held-for-exchange Animal Health business** amounted to 2,511 million in 2016, compared with 3,011 million in 2015.

Acquisitions of property, plant and equipment and intangible assets totaled 2,083 million, compared with 2,772 million in 2015. The main items were investments in industrial and research facilities ( 1,267 million, versus 1,163 million in 2015) and contractual payments for intangible rights, primarily under license and collaboration agreements ( 668 million, versus 1,465 million in 2015).

Acquisitions of investments during 2016 amounted to 634 million, net of cash acquired and after including assumed liabilities and commitments, versus 362 million in 2015. In 2016, these acquisitions included our contribution to the Onduo joint venture, and purchase of additional shares in Regeneron.

After-tax proceeds from disposals amounted to 209 million, and arose mainly from the sale of the equity interest in Nichi-Iko Pharmaceutical Co., Inc. and of product rights relating to Oenobiol®. In 2015, after-tax proceeds from disposals totaled 211 million, and related mainly to the divestment of our equity interest in Merrimack Pharmaceuticals and the sale of rights to Sklice® to Arbor Pharmaceuticals LLC in the United States.

**Net cash used in financing activities excluding the held-for-exchange Animal Health business** amounted to 4,101 million in 2016, compared with 3,578 million in 2015. The 2016 figure includes net external debt finance raised of 2,293 million ( 1,346 million in 2015); the effect of changes in our share capital (repurchases of own shares, net of capital increases), amounting to 2,603 million ( 1,211 million in 2015); and the dividend payout to our shareholders of 3,759 million ( 3,694 million in 2015).

**The net change in cash and cash equivalents excluding the held-for-exchange Animal Health business** was an increase of 1,125 million in 2016, compared with an increase of 1,469 million in 2015.

**Net cash flows for the held-for-exchange Animal Health business** represented net cash inflows of 339 million in 2016 and 361 million in 2015. This comprised a net cash inflow from operating activities of 346 million in 2016 ( 630 million in 2015); a net cash outflow from investing activities of 126 million ( 246 million in 2015); and a net cash outflow from financing activities of 11 million ( 23 million in 2015).

**B.1.2. Year Ended December 31, 2015 Compared with Year Ended December 31, 2014**

**Net cash provided by operating activities excluding the held-for-exchange Animal Health business** amounted to 8,290 million in 2015, versus 7,165 million in 2014.

Operating cash flow before changes in working capital (excluding the net income or loss of the held-for-exchange Animal Health business) for 2015 was 7,235 million, versus 6,257 million in 2014. Working capital requirements fell by 1,055 million in 2015, compared with a reduction of 908 million in 2014, due mainly to an increase in non-current liabilities related to commercial terms of business.

Our operating cash flow before changes in working capital is generally affected by the same factors that affect *Operating income*, which is discussed in detail above under Results of Operations Year Ended December 31, 2015 Compared with Year Ended December 31, 2014 . The principal difference is that operating cash flow before changes in working capital includes our share of the profits and losses of associates and joint ventures, net of dividend and similar income received.

## Edgar Filing: Sanofi - Form 20-F

**Net cash used in investing activities excluding the held-for-exchange Animal Health business** amounted to 3,011 million in 2015, compared with 3,357 million in 2014.

Acquisitions of property, plant and equipment and intangible assets totaled 2,772 million, versus 1,453 million in 2014. The main items were investments in industrial and research facilities ( 1,163 million in 2015, versus 970 million in 2014) and contractual payments for intangible rights, mainly under license and collaboration agreements ( 1,465 million in 2015, versus 354 million in 2014).

Acquisitions of investments during 2015 amounted to 362 million, net of cash acquired and after including assumed liabilities and commitments, compared with 2,294 million in 2014. The main items were our acquisitions of shares in Regeneron ( 117 million in 2015, 1,629 million in 2014) and Alnylam ( 79 million in 2015, 535 million in 2014).

After-tax proceeds from disposals ( 211 million) related mainly to the divestment of our equity interest in Merrimack Pharmaceuticals and the sale of rights in Sklice® to Arbor Pharmaceuticals LLC in the United States. In 2014, after-tax proceeds from disposals ( 262 million) related mainly to the divestment of Genzyme's equity interest in Ionis Pharmaceuticals (formerly Isis Pharmaceuticals) and to a payment received from Tolmar in exchange for the transfer of rights to Eligard and Aplenzin® in the United States.

**Net cash used in financing activities excluding the held-for-exchange Animal Health business** amounted to 3,578 million in 2015, compared with 5,194 million in 2014. The 2015 figure includes net external debt finance raised of 1,346 million; this compares with net external debt finance repaid (i.e., net change in short-term and long-term debt) of 390 million in 2014. It also includes the effect of changes in share capital (repurchases of own shares, net of capital increases), amounting to 1,211 million (versus 1,121 million in 2014), and the dividend payout to our shareholders of 3,694 million (versus 3,676 million in 2014).

**The net change in cash and cash equivalents excluding the held-for-exchange Animal Health business** was an

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

increase of 1,469 million in 2015, compared with a decrease of 1,352 million in 2014.

**Net cash flows for the held-for-exchange Animal Health business** represented net cash inflows of 361 million in 2015 and 436 million in 2014. This comprised a net cash inflow from operating activities of 630 million in 2015 ( 525 million in 2014); a net cash outflow from investing

activities of 246 million ( 103 million in 2014); and a net cash outflow from financing activities of 23 million (versus a net cash inflow of 14 million in 2014). The net change in cash and cash equivalents during 2015 (after the 23 million impact on cash and cash equivalents of the reclassification of the Animal Health business to Assets held for sale or exchange ), was an increase of 1,807 million; this compares with a reduction of 916 million in 2014.

**B.2. CONSOLIDATED BALANCE SHEET AND DEBT**

Total assets were 104,672 million as of December 31, 2016, versus 102,321 million as of December 31, 2015, an increase of 2,351 million.

Our debt, net of cash and cash equivalents was 8,206 million as of December 31, 2016, compared with 7,254 million as of December 31, 2015. The table below shows our financial position for the years ended December 31, 2016, 2015 and 2014:

( million)	2016	2015	2014
Long-term debt	16,815	13,118	13,276
Short-term debt and current portion of long-term debt	1,764	3,436	1,538
Cash and cash equivalents	(10,273)	(9,148)	(7,341)
Related interest rate and currency derivatives	(100)	(152)	(302)
<b>Debt, net of cash and cash equivalents</b>	<b>8,206</b>	<b>7,254</b>	<b>7,171</b>
Total equity	57,724	58,210	56,268
<b>Gearing ratio</b>	<b>14.2%</b>	<b>12.5%</b>	<b>12.7%</b>

Our gearing ratio (debt, net of cash and cash equivalents as a proportion of total equity) rose from 12.5% in 2015 to 14.2% in 2016. Analyses of debt as of December 31, 2016 and December 31, 2015, by type, maturity, interest rate and currency, are provided in Note D.17. to our consolidated financial statements.

We expect that the future cash flows generated by our operating activities will be sufficient to repay our debt. The financing arrangements in place as of December 31, 2016 at Sanofi parent company level are not subject to covenants regarding financial ratios and do not contain any clauses linking credit spreads or fees to our credit rating.

Other key movements in the balance sheet are described below.

**Total equity** amounted to 57,724 million as of December 31, 2016, versus 58,210 million as of December 31, 2015. The year-on-year decrease in equity was attributable primarily to:

· increases: our net income for the year ended December 31, 2016 ( 4,800 million), and the change in currency translation differences ( 1,090 million, mainly on the US dollar);

· decreases: the dividend payout to our shareholders in respect of the 2015 financial year ( 3,759 million), repurchases of our own shares ( 2,905 million), and actuarial losses ( 128 million).

As of December 31, 2016, we held 20.0 million of our own shares, recorded as a deduction from equity and representing 1.55% of our share capital.

**Goodwill and Other intangible assets** ( 51,166 million in total) decreased by 417 million year-on-year, mainly reflecting:

· decreases: amortization and impairment losses recognized during the period ( 2,012 million);

· increases: the transfer to Sanofi of the vaccines portfolio previously held by the SPMSD joint venture ( 465 million), and currency translation differences on assets denominated in foreign currencies ( 938 million, mainly on the US dollar).

**Investments in associates and joint ventures** increased by 214 million to 2,890 million, due primarily to our share of profits from Regeneron.

**Other non-current assets** were 95 million higher at 2,820 million. The main movements during the year were the impairment loss taken against the investment in Alnylam ( 457 million), and the deferred consideration recognized on the divestment of the SPMSD joint venture ( 458 million).

**Provisions and other non-current liabilities** were 335 million lower at 8,834 million, mainly as a result of reversals of tax-related provisions.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

**Deferred taxes** represented a net asset of 2,377 million, a year-on-year increase of 558 million, mainly due to reversals of deferred tax liabilities on the remeasurement of acquired intangible assets ( 573 million).

**Liabilities related to business combinations and to non-controlling interests** were 325 million higher at 1,576 million. As of December 31, 2016, this line item included contingent consideration liabilities of 354 million based on a percentage of future sales made by Sanofi Pasteur of products formerly held by the SPMSD joint venture.

**Assets held for sale or exchange** ( 6,421 million) and **Liabilities related to assets held for sale or exchange** ( 1,195 million) mainly comprise the assets and liabilities of the held-for-exchange Animal Health business (see Note D.8. to our consolidated financial statements).

**B.3. LIQUIDITY**

We expect that our existing cash resources and cash from operations will be sufficient to finance our foreseeable working capital requirements. At year-end 2016, we held cash and cash equivalents amounting to 10,273 million, substantially all of which were held in euros (see Note D.13. to our consolidated financial statements included at Item 18 of this annual report). As at December 31, 2016, our subsidiaries based in Venezuela held cash and cash equivalents in bolivars representing 6 million, which are subject to foreign exchange controls (see Note A.4. to our consolidated financial statements included at Item 18 of this annual report). As at December 31, 2016, 553 million of our cash and cash equivalents were held by our captive insurance and reinsurance companies in accordance with insurance regulations.

We run the risk of delayed payments or even non-payment by our customers, who consist principally of wholesalers, distributors, pharmacies, hospitals, clinics and government agencies (see Item 3.D. Risk Factors 2. Risks Relating to Our Business). We are subject to the risk of non-payment by our customers. Deteriorating credit and economic conditions and other factors in some countries have resulted in, and may continue to result in an increase in the average length of time taken to collect our accounts receivable in these countries. Should these factors continue, it may require us to re-evaluate the collectability of these receivables in future periods. We carefully monitor sovereign debt issues and economic conditions and evaluate accounts receivable in these countries for potential collection risks. We have been conducting an active recovery policy, adapted

to each country and including intense communication with customers, negotiations of payment plans, charging of interest for late payments, and legal action. Over our business as a whole, the amount of trade receivables overdue by more than 12 months (which primarily consists of amounts due from public sector bodies) rose from 159 million as of December 31, 2015 to 198 million as of December 31, 2016 (see Note D.10. to our consolidated financial statements).

In November 2011, Sanofi obtained the necessary corporate authorizations to purchase any or all of the outstanding Contingent Value Rights ( CVR ) and subsequently purchased CVRs in 2011. In 2012 following a tender offer initiated in September 2012 on the basis of the same corporate authorization, Sanofi purchased an additional 40,025,805 CVRs (for a total consideration of approximately \$70 million), followed by a further 10,928,075 CVRs (for approximately \$9 million) in 2013, 1,879,774 CVRs (for approximately \$1 million) in 2014, and none in 2015. As of December 31, 2016, a total of 236,457,284 CVRs were outstanding out of the 291,313,510 issued at the time of the Genzyme acquisition.

At year-end 2016, we had no commitments for capital expenditures that we consider to be material to our consolidated financial position. Undrawn confirmed credit facilities amounted to a total of 8.0 billion at December 31, 2016. For a discussion of our treasury policies, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

We expect that cash from our operations will be sufficient to repay our debt. For a discussion of our liquidity risks, see Item 11. Quantitative and Qualitative Disclosures about Market Risk.

**C. Off-Balance Sheet Arrangements / Contractual Obligations and Other Commercial Commitments**

## Edgar Filing: Sanofi - Form 20-F

We have various contractual obligations and other commercial commitments arising from our operations. Our contractual obligations and our other commercial commitments as of December 31, 2016 are shown in Notes D.3., D.17., D.18., D.21. and D.36. to our consolidated financial statements included at Item 18 of this annual report. Note D.21. to our consolidated financial statements discloses details of commitments under our principal research and development collaboration agreements. For a description of the principal contingencies arising from certain business divestitures, refer to Note D.22.e) to our 2016 consolidated financial statements.

**Table of Contents****ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

Sanofi's contractual obligations and other commercial commitments are set forth in the table below:

December 31, 2016 ( million)	Total	Payments due by period <sup>(a)</sup>			
		Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Future contractual cash-flows relating to debt and debt hedging instruments <sup>(b)</sup>	19,986	2,056	4,720	5,245	7,965
Operating lease obligations	1,543	273	419	290	561
Finance lease obligations <sup>(c)</sup>	75	24	20	9	22
Irrevocable purchase commitments <sup>(d)</sup> given	4,444	2,945	1,008	188	303
received	(231)	(125)	(68)	(14)	(24)
Research & development license agreements					
Commitments related to R&D and other commitments	1,594	699	539	294	62
Potential milestone payment <sup>(e)</sup>	2,082	85	788	211	998
Obligations related to R&D license agreements reflected in the balance sheet	308	219	54	35	-
Obligations relating to business combinations <sup>(f)</sup>	4,832	186	602	3,732	312
Firm commitment related to the BMS agreement <sup>(g)</sup>	120	120	-	-	-
Estimated benefit payments on unfunded pensions and post-employment benefits <sup>(h)</sup>	1,420	75	148	160	1,037
<b>Total contractual obligations and other commitments</b>	<b>36,173</b>	<b>6,557</b>	<b>8,230</b>	<b>10,150</b>	<b>11,236</b>
<b>Undrawn general-purpose credit facilities</b>	<b>8,004</b>	<b>-</b>	<b>-</b>	<b>8,004</b>	<b>-</b>

(a) Including payments related to contractual obligations and other commercial commitments of the Animal Health business, reclassified as held for sale exchange as of December 31, 2016 in accordance with IFRS 5 (see Note D.2.1 and D.36 to our consolidated financial statements included at Item 18 of this annual report).

(b) Of which 19,833 million related to payments excluding the Animal Health business (see Note D.17. to our consolidated financial statements included at Item 18 of this annual report) and 153 million related to the Animal Health business.

(c) Of which 66 million related to payments excluding the Animal Health business (see Note D.3. to our consolidated financial statements included at Item 18 of this annual report) and 9 million related to the Animal Health business.

(d) These comprise irrevocable commitments to third parties for (i) property, plant and equipment, net of down payments (of which 545 million related to payments excluding the Animal Health business see Note D.3. to our consolidated financial statements included at Item 18 of this annual report and 60 million related to the Animal Health business) and (ii) goods and services.

(e) This line includes all potential milestone payments on projects regarded as reasonably possible, i.e., on projects in the development phase.

(f) See Note D.18. to our consolidated financial statements included at Item 18 of this annual report.

## Edgar Filing: Sanofi - Form 20-F

(g) See Note C.2. to our consolidated financial statements included at Item 18 of this annual report.

(h) Of which 1,374 million related to payments excluding the Animal Health business (See Note D.19.1. to our consolidated financial statements included at Item 18 of this annual report) and 46 million related to the Animal Health business. The table above does not include the ongoing annual employer's contributions to plan assets, estimated at 147 million in 2016 (of which 143 million excluding the Animal Health business and 4 million related to the Animal Health business).

We may have payments due to our current or former research and development partners under collaborative agreements. These agreements typically cover multiple products, and give us the option to participate in development on a product-by-product basis. When we exercise our option with respect to a product, we pay our collaboration partner a fee and receive intellectual property rights to the product in exchange. We are also generally required to fund some or all of the development costs for the products that we select, and to make payments to our partners when those products reach development milestones.

We have entered into collaboration agreements under which we have rights to acquire products or technology from third parties through the acquisition of shares, loans, license agreements, joint development, co-marketing and other contractual arrangements. In addition to upfront payments on signature of the agreement, our contracts frequently require us to make payments contingent upon the completion of development milestones by our alliance partner or upon the granting of approvals or licenses.

Because of the uncertain nature of development work, it is impossible to predict (i) whether Sanofi will exercise further

**Table of Contents**

**ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

options for products, or (ii) whether the expected milestones will be achieved, or (iii) the number of compounds that will reach the relevant milestones. It is therefore impossible to estimate the maximum aggregate amount that Sanofi will actually pay in the future under existing collaboration agreements.

Given the nature of its business, it is highly unlikely that Sanofi will exercise all options for all products or that all milestones will be achieved.

The main collaboration agreements relating to development projects are described in Note D.21.1. to our consolidated financial statements included at Item 18 of this annual report. Milestone payments relating to development projects under these agreements included in the table above exclude projects still in the research phase ( 6.2 billion in 2016, 4.7 billion in 2015) and payments contingent upon the attainment of sales targets once a product is on the market ( 8.2 billion in 2016, 8.0 billion in 2015).

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Item 6. Directors, Senior Management and Employees**

**A. Directors and Senior Management**

Since January 1, 2007, Sanofi has separated the offices of Chairman and Chief Executive Officer. The annual evaluations conducted since that date have indicated that this governance structure is appropriate to Sanofi's current configuration. This arrangement was maintained with the appointment of Serge Weinberg to the office of Chairman firstly on May 17, 2010, then on May 6, 2011 and again on May 4, 2015. The Board of Directors regards this governance structure as appropriate in our current context.

The **Chairman** organizes and directs the work of the Board, and is responsible for ensuring the proper functioning of the corporate decision-making bodies in compliance with good governance principles. The Chairman coordinates the work of the Board of Directors with that of its Committees. The Chairman is accountable to the Shareholders' General Meeting, which he chairs.

When the offices of Chairman and Chief Executive Officer are separated, the Chairman may remain in office until the Ordinary Shareholders General Meeting called to approve the financial statements held during the calendar year in which he reaches the age of 70.

The **Chief Executive Officer** is responsible for the management of the Company, and represents the Company in dealings with third parties within the limit of the corporate purpose. The Chief Executive Officer has the broadest powers to act in all circumstances in the name of the Company, subject to the powers that are attributed by law to the Board of Directors and to the Shareholders' General Meeting and within the limits set by the Board of Directors.

The Chief Executive Officer may not be more than 65 years old.

**Limitations on the powers of the Chief Executive Officer set by the Board**

The Board of Directors Meeting of July 28, 2009 set limitations on the powers of the Chief Executive Officer in a decision that supplements the Board Charter. The prior authorization of the Board of Directors is required to commit Sanofi to investments, acquisitions and divestments in the following cases:

· a 500 million cap for each undertaking pertaining to a previously approved strategy; and

· a 150 million cap for each undertaking not pertaining to a previously approved strategy.

When the consideration payable to the contracting party or parties for such undertakings includes potential installment payments contingent upon the achievement of future results or objectives, such as the registration of one or more products, the caps are calculated by aggregating the various payments due from signature of the contract until (and including) filing of the first application for marketing authorization in the United States or in Europe.

## Edgar Filing: Sanofi - Form 20-F

Following the appointment of a new Chief Executive Officer in 2015 and on the recommendation of the Appointments and Governance Committee, the Board of Directors reassessed these limitations and decided to maintain them.

### **Board of Directors**

The Company is administered by a Board of Directors, comprising twelve members as of December 31, 2016.

Subject to the powers expressly attributed to the Shareholders' General Meeting and within the scope of the Company's corporate purpose, the Board of Directors' powers cover all issues relating to the proper management of the Company, and through its decisions the Board determines all matters falling within its authority.

The term of office of directors is four years. Directors are required to seek reappointment by rotation, such that members of the Board are required to seek reappointment on a regular basis in the most equal proportions possible. Exceptionally, the Shareholders' Ordinary General Meeting may appoint a director to serve for a term of one, two or three years, in order to ensure adequate rotation of Board members.

Each year, the Board of Directors conducts a review to ensure that there is an appropriate balance in its composition and in the composition of its Committees. In particular, the Board seeks to ensure gender balance and a broad diversity of backgrounds and countries of origin, reflecting Sanofi's status as a diversified global business. The Board investigates and evaluates not only potential candidates, but also whether existing directors should seek reappointment. Above all, the Board seeks directors who show independence of mind and who are competent, dedicated and committed.

### **Independence of Board Members**

Under the terms of the AFEP-MEDEF corporate governance code (the AFEP-MEDEF Code), a director is independent when he or she has no relationship of any kind whatsoever with the Company, its Group or its senior management that

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

may interfere with his or her freedom of judgment. More specifically, a director can only be regarded as independent if he or she:

- is not (and has not been during the past five years):
    - an employee or executive officer of the Company;
    - an employee, executive officer or director of an entity consolidated by the Company; or
    - an employee, executive officer or director of the Company's parent, or of an entity consolidated by that parent (criterion 1);
  - is not an executive officer of an entity in which (i) the Company directly or indirectly holds a directorship or (ii) an employee of the Company is designated as a director or (iii) an executive officer of the company (current, or who has held office within the past five years) holds a directorship (criterion 2);
  - is not a customer, supplier, investment banker or corporate banker that is material to the Company or its group, or for whom the Company or its Group represent a significant proportion of its business (criterion 3);
  - has no close family ties with a corporate officer of the Company (criterion 4);
  - has not acted as auditor for the Company over the course of the past five years (criterion 5); or
  - does not represent a shareholder that has a significant or controlling interest in the Company (criterion 6).
- The influence of other factors such as length of service on the Board, the ability to understand challenges and risks, and the courage to express ideas and form a judgment, is also evaluated before it is decided whether a director can be regarded as independent.

In compliance with our Board Charter and pursuant to the AFEP-MEDEF Code, the Board of Directors' meeting of March 2, 2017 reviewed the independence of the current directors. Of the twelve directors, nine are regarded as independent directors by reference to the independence criteria used by the Board of Directors pursuant to the AFEP-MEDEF Code: Serge Weinberg, Robert Castaigne, Claudie Haigneré, Patrick Kron, Fabienne Lecorvaisier, Suet-Fern Lee, Carole Piwnica, Diane Souza and Thomas Südhof.

Criterion 1	Criterion 2	Criterion 3 <sup>(1)</sup>	Criterion 4	Criterion 5	Criterion 6	Less than 12 years on the Board	Status
----------------	----------------	-------------------------------	----------------	----------------	----------------	--	--------

## Edgar Filing: Sanofi - Form 20-F

<b>Serge Weinberg</b>	No <sup>(2)</sup>	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Robert Castaigne</b>	Yes	Yes	Yes	Yes	Yes	Yes	No <sup>(3)</sup>	Independent
<b>Claudie Haigneré</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Patrick Kron</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Fabienne Lecorvaisier</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Suet-Fern Lee</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Carole Piwnica</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Diane Souza</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent
<b>Thomas Südhof</b>	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Independent

Failure to meet one of the above criteria does not automatically disqualify a director from being regarded as independent.

The Board's conclusions on specific cases are set out below.

### (1) Business Relationships Review

In its examination of the independence of each director, the Board of Directors took into account the various relationships between directors and Sanofi and concluded that no relationships were of a kind that might undermine their independence. The Board of Directors noted that the Company and its subsidiaries had, in the normal course of business, over the past three years, sold products and provided services to, and/or purchased products and

received services from, companies in which certain of the Company's directors who are classified as independent (or their close family members) were senior executives or employees during 2016. In each case, the amounts paid to or received from such companies over the past three years were determined on an arm's length basis and did not represent amounts that the Board regarded as undermining the independence of the directors in question.

### (2) Serge Weinberg

In 2013, the rules governing the office of the Chairman of the Board changed such that the Board was able to classify its Chairman as an independent director, in line with the assessment consistently made by the Board prior to that change. Until 2013, Serge Weinberg had not been classified

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

as an independent director solely because of the then wording of the AFEP-MEDEF Code, which in its former article 8.4 did not distinguish the case where the functions of Chairman and Chief Executive Officer are separated from the case where the two functions are combined. With effect from June 2013, the AFEP-MEDEF Code (in its article 9.4) stipulated that if the offices of Chairman and Chief Executive Officer were separated the Chairman would not automatically be deemed non-independent, but rather that his or her independence should be assessed using the general criteria applicable in determining the independence of directors. The Board of Directors took the view that no factor other than his role as Chairman was liable to undermine his independence, especially given that prior to joining the Board he had no relationship with Sanofi. The Board assessment concerning his situation was reflected in the previous annual reports on Form 20-F. At its meeting of October 29, 2013, the Board determined that Serge Weinberg was an independent director.

When the offices of Chairman of the Board and Chief Executive Officer were temporarily combined on October 29, 2014, the Board of Directors determined that Serge Weinberg given his role as Chief Executive Officer could no longer be regarded as independent. When the two offices were separated again, the Board of Directors determined that Serge Weinberg could be regarded as independent and could therefore resume the chairmanship of the Appointments and Governance Committee.

Under Article 8.6 of the amended AFEP-MEDEF code issued in November 2016, a non-executive officer cannot be regarded as independent if he or she receives variable compensation in cash or shares, or any compensation linked to the performance of the Company or Group. This is consistent with recommendations made by the *Autorité des Marchés Financiers* (AMF), the French financial markets regulator, in its 2015 report on corporate governance and executive compensation in listed companies. Serge Weinberg complies with this criterion, in that he receives fixed compensation only, with no entitlement to variable compensation in either cash or shares.

(3) Robert Castaigne

The Board of Directors considers that the situation of Robert Castaigne has changed since his first appointment to the Board. Prior to 2012, Robert Castaigne had not been regarded as an independent director due to his past relationship with Total. Since April 2008, when the independence criteria of the AFEP-MEDEF Code were adopted, his situation has changed in two ways:

- Robert Castaigne retired from Total more than four years ago;
- Total passed below the 5% threshold of our voting rights (as per the notification of February 16, 2012). Later in 2012, Total ceased to have any equity interest in Sanofi.

Consequently, the Board of Directors took the view that Robert Castaigne's historical links with Total no longer created a presumption of non-independence.

Moreover, the Board of Directors does not believe that belonging to the Board for more than 12 years in and of itself disqualifies a director from being independent. The length of Board service criterion is intended to address the concern that the passage of time may deprive a director of his ability to challenge senior management. This is a legitimate concern, which Sanofi takes very seriously.

This is why the Board of Directors applies this criterion pragmatically in light of the specific circumstances of each case. In the case of Robert Castaigne, the Board considers that he has demonstrated great independence of mind, which is fundamentally what the AFEP-MEDEF Code criteria are seeking to check. For more information see C. Board Practices, below.

Finally, there was no other factor calling into question Robert Castaigne's independence.

## Edgar Filing: Sanofi - Form 20-F

Consequently, the Board determined on that basis, at its meeting of May 4, 2012 and upon the recommendation of its Appointments and Governance Committee, that Robert Castaigne qualified as an independent director. That position was reiterated at the Board meeting of March 2, 2017.

This decision has no effect on compliance with the independence rules of the AFEP-MEDEF Code, which is the main objective of the Code. The fact that the proportion of independent directors on the Board is 75% demonstrates that the Board in no way underestimates the importance of having a majority of independent directors in its governance.

No more than one-third of the serving members of our Board of Directors may be over 70 years of age.

### **Board evaluation**

Under the terms of the Board Charter, a discussion of the Board's operating procedures must be included in the agenda of one Board meeting every year. The Charter also requires a formal evaluation to be performed every three years.

As part of the process of renewing their terms of office, the contribution of each director concerned to the work of the Board and its committees was assessed and in each case was judged to have met Sanofi's needs and to have been in line with its expectations.

In 2015, the Board decided for the first time to retain an independent consultant to perform a formal evaluation of the work of the Board and its committees. This decision was largely motivated by a commitment to ensure that lessons were learned from recent events.

At its meeting of March 2, 2017, the Board of Directors discussed its operating procedures and those of its committees.

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

Each Board member completed a questionnaire and some of them met with the Secretary to the Board. Issues addressed by these questions included:

- governance methods and structures;
- the effectiveness of the Board;
- how the committees are perceived by the Board;
- composition of the Board;
- board competencies and working practices; and
- relations between the Board and senior management, shareholders and other stakeholders.

Directors noticed an improvement in the Board's operating procedures since the previous evaluation performed in late 2015 and early 2016. The issues most frequently mentioned were the transparency and openness of discussions; the quality of interactions between the management and the Board; the quality of teamwork within the Board; the involvement of the Board in strategic decisions; the quality of the decision-making process; and the focus on important subjects.

The Board identified the following areas for improvement and scrutiny:

- continuation of the work initiated on succession planning for the role of Chief Executive Officer;
- fuller information about the competitive environment, and deeper analysis of changes in this environment and their potential consequences for Sanofi;
- allocation of more time to discussions about the Company's strategy;
- increasing the number of executive sessions (Board meetings held without the Chief Executive Officer present);
- implementation of the external growth strategy;

- enhanced monitoring of the key risks facing the Company; and

- monitoring implementation of Company's digital strategy.

The Board reiterated the objective, expressed in its roadmap on the future composition of the Board, of bringing onto the Board more scientific expertise, as well as more current or past Chief Executive Officer experience within international groups and more non-French and female directors.

Two candidates whose profile fits these priorities will be submitted for approval by the shareholders at the Annual General Meeting on May 10, 2017.

#### **Composition of the Board of Directors as of December 31, 2016**

As of December 2016, our Board was composed as follows (the dates in parentheses indicate the year during which the term of office is due to expire):

- the Chief Executive Officer, Olivier Brandicourt (2018);

- two directors who are employees of the largest Sanofi shareholder : Laurent Attal (2020) and Christian Mulliez (2018); and

- nine independent directors: Serge Weinberg, Chairman of the Board (2019), Robert Castaigne (2018), Claudie Haigueré (2020), Patrick Kron (2018), Fabienne Lecorvaisier (2017), Suet-Fen Lee (2019), Carole Piwnica (2020), Diane Souza (2020) and Thomas Südhof (2020).

Positions held in listed companies are flagged by an asterisk. Each director's principal position is indicated in bold.

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Serge Weinberg**

Date of birth:	February 10, 1951
Nationality:	French
First elected:	December 2009
Last reappointment:	May 2015
Term expires:	2019
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Serge Weinberg  
Within the Sanofi Group**

**Current directorships  
and appointments**

**In French companies**

Chairman of the Board of Directors of Sanofi\*

Chairman of the Strategy Committee of Sanofi

Chairman of the Appointments and Governance Committee of Sanofi

**In foreign companies**

None

**Past directorships**

**In French companies**

None

**expiring within the  
last five years**

**In foreign companies**

None

**Outside the Sanofi Group**

**Chairman of Weinberg Capital Partners**

Chairman of Financière Piasa, Piasa Holding and Maremma

Manager of Alret

Chairman of the Supervisory Board of Financière

Climater SAS

Chairman of the Supervisory Board of Financière Tess SAS

Director of Madrigall

None

Director of Alliance Automotive Participations SAS (until 2014) and Schneider Electric\* (until 2014)

Member of the Supervisory Board of Financière BFSA (until 2013), and Schneider Electric\* (until 2013)

Weinberg Capital Partners permanent representative on the Board of Sasa Industrie (until 2013)

Vice Chairman and Director of Financière Sasa (until 2016)

Chairman of Corum (Switzerland, until 2013)

**Education and business experience**

Graduate in law, degree from the *Institut d Études Politiques*

Graduate of ENA (*École Nationale d Administration*)

Since 2005

**Chairman of Weinberg Capital Partners**

1976-1982

*Sous-préfet* and then Chief of Staff of the French Budget Minister (1981)

1982-1987

Deputy General Manager of FR3 (French Television Channel) and then Chief Executive Officer of Havas Tourisme

1987-1990

Chief Executive Officer of Pallas Finance

## Edgar Filing: Sanofi - Form 20-F

1990-2005	Various positions at PPR* group including Chairman of the Management Board for 10 years
2006-2008	Director of Alliance Industrie
2007-2008	Director of Road Holding
2006-2009	Chairman of the Board of Accor*
2006-2010	Member of the Board of Pharma Omnium International
2005-2010	Vice Chairman of the Supervisory Board of Schneider Electric*
2007- 2011	Director of Team Partners Group
2006- 2011	Member of the Supervisory Board of Amplitude Group and Alfina
2006- 2011	Weinberg Capital Partners permanent representative on the Board of Alliance Industrie
2007- 2011	Vice Chairman and Director of Financière Poinsétia

### Number of shares held

1,636 shares

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Olivier Brandicourt**

Date of birth:	February 13, 1956
Nationality:	French
First elected:	April 2015
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Olivier Brandicourt**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

**In French companies**

**Chief Executive Officer of Sanofi\***

None

Chairman of the Executive Committee of Sanofi

Member of the Strategy Committee of Sanofi

**In foreign companies**

None

Member of the Board of Management of the Pharmaceutical Research and Manufacturers of America (PhRMA, United States) and the Board of Directors of the National Committee on US-China Relations (United States)

Member of the Council of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA, Switzerland)

Member and Vice-Chair of the Board of Trustees of the Children's Aid Society of New York (United States)

Honorary Member of the Royal College of Physicians (United Kingdom)

**Past directorships expiring within the last five years**

**In French companies**

None

**In foreign companies**

None

None

Bayer Group (Germany):

Chief Executive Officer and Chairman of the Executive Committee of Bayer HealthCare AG (until 2015)

Member of the Executive Council of Bayer AG\* (until 2015)

**Education and business experience**

Degree in Medical Mycology, Pasteur Institute, France

Masters in Human Biology, Paris XII University, France

Medical Degree with subspecialty in Infectious Diseases and Tropical Medicine, Paris V University, France

1979-1981

## Edgar Filing: Sanofi - Form 20-F

	National Service with the <i>Office de la recherche scientifique et technique outre-mer</i> (ORSTOM) (Republic of Congo)
1981-1987	Research Fellow and Hospital & University Assistant in the Department of Parasitology, Tropical Medicine and Public Health at the Pitié-Salpêtrière Hospital (France)
1987-2000	Various operational and commercial positions at Warner-Lambert/Parke-Davis, including Vice-President and General Manager (1998-2000)
2000-2013	Various operational and managerial positions at Pfizer Inc.*, including member of the Executive Leadership Team (2010-2013) and President & General Manager Emerging Markets & Established Business Unit (2012-2013)
2013-2015	Chief Executive Officer and Chairman of the Executive Committee of Bayer HealthCare AG and Member of the Executive Council of Bayer AG*

### Number of shares held

1,000 shares

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Laurent Attal**

Date of birth:	February 11, 1958
Nationality:	French
First elected:	May 2012
Last reappointment:	May 2016
Term expires:	2020
	Sanofi 54, rue La Boétie 75008 Paris France

Business address:

**Directorships and appointments of Laurent Attal**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

**In French companies**

Director of Sanofi\*

Director of *Fondation d'Entreprise L'Oréal*

Member of the Strategy Committee of Sanofi

**In foreign companies**

None

None

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None

None

**Education and business experience**

Doctor of Medicine, dermatologist

MBA from INSEAD (*Institut Européen d'Administration des Affaires*)

Since 1986

Various positions within the L'Oréal\* Group, including posts within the active cosmetics division and as President and Chief Executive Officer of L'Oréal USA (United States)

Since 2002

Member of the Executive Committee of L'Oréal\*

Since 2010

**Vice-President General Manager Research and Innovation at L'Oréal\***

**Number of shares held**

1,000 shares

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Robert Castaigne**

Date of birth:	April 27, 1946
Nationality:	French
First elected:	February 2000
Last reappointment:	May 2014
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Robert Castaigne**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

**In French companies**

Independent director of Sanofi\*

Chairman of the Audit Committee of Sanofi

Société Générale\*:

Director  
Member of the Audit and Internal Control Committee  
Member of the Nomination Committee  
Vinci\*:

Director  
Member of the Audit Committee  
Chairman of the Remuneration Committee

**In foreign companies**

Novatek\* (Russia):

Director  
Member of the Audit Committee  
Member of the Remuneration and Nomination Committee

None

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None

None

**Education and business experience**

Degree from *École Centrale de Lille* and *École Nationale Supérieure du Pétrole et des Moteurs*

Doctorate in economics

1972-2008 Various positions at the Total\* group, including Chief Financial Officer and member of the Executive Committee (1994-2008)

2007-2011 Director and member of the Audit Committee of Compagnie Nationale à Portefeuille (Belgium)

**Number of shares held**

1,000 shares



**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Claudie Haigneré**

Date of birth:	May 13, 1957
Nationality:	French
First elected:	May 2008
Last reappointment:	May 2016
Term expires:	2020
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Claudie Haigneré**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

**In French companies**

Independent director of Sanofi\*

Member of the Appointments and Governance Committee of Sanofi

Member of the Compensation Committee of Sanofi

**In foreign companies**

None

Director of *Fondation de l'Université de Lyon*, *Fondation C-Génial* and *Fondation d'Entreprise L'Oréal*

Member of *Académie des Technologies*, *Académie des Sports*, *Académie Nationale de l'Air et de l'Espace* and *Académie des Sciences de l'Outre-Mer*

None

**Past directorships expiring within the last five years**

**In French companies**

None

**In foreign companies**

None

Director and member of the Innovation and Technology Committee of Orange\* (until 2016)

Chairwoman of Universcience (*Cité des Sciences et de l'Industrie et Palais de la Découverte*) (until 2015)

Director of *Fondation de France* (until 2015), *École Normale Supérieure* (until 2015), *Campus Condorcet* (until 2015), *Pôle de Recherche et d'Enseignement Supérieur Hautes-Études-Sorbonne-Arts-et-Métiers* (until 2015) and *Fondation Lacoste* (until 2016)

Chairwoman of the Board of Directors of *La Géode* (until 2015)

None

**Education and business experience**

Rheumatologist, doctorate in sciences majoring in neurosciences

Selected in 1985 by the CNES (French National Space Center) as an astronaut candidate

1984-1992

Rheumatologist, Cochin Hospital (Paris)

1996

Scientific space mission to the MIR space station (Cassiopee, Franco-Russian mission)

2001

Scientific and technical space mission to the International Space Station (Andromède mission)

2002-2004

Deputy Minister for Research and New Technologies in the French government

2004-2005

Deputy Minister for European Affairs in the French government

2005-2009

Adviser to the Director General of the European Space Agency

## Edgar Filing: Sanofi - Form 20-F

2007-2011	Vice-Chairwoman (Finance) of the IAA (International Academy of Astronautics)
2010-2011	Director of <i>Aéro Club de France</i>
2010-2015	Chairwoman of Universcience (French public-sector body)
2015	Special Adviser to the Director General of the European Space Agency

### **Number of shares held**

1,000 shares

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Patrick Kron**

Date of birth:	September 26, 1953
Nationality:	French
First elected:	May 2014
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Patrick Kron  
Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships  
and appointments**

**In French companies**

Independent director of Sanofi\*

Director of Bouygues\*

Chairman of the Compensation Committee of Sanofi

**Chairman of Truffle Capital SAS**

Member of the Appointments and Governance Committee of Sanofi

Vice-President of the *Les Arts Florissants* choral group association

Member of the Strategy Committee of Sanofi

Chairman of PKC&I SAS

Permanent representative of PKC&I to the Supervisory Board of Segula Technologies

**In foreign companies**

None

None

**Past directorships  
expiring within the  
last five years**

**In French companies**

None

Alstom:

Chairman and Chief Executive Officer (until 2016)

Chairman of Alstom Resources Management (until 2015)

Director of *Association Française des Entreprises Privées* (AFEP, until 2015)

**In foreign companies**

None

Alstom\*:

Director of Alstom UK Holdings Ltd. (United Kingdom, until 2012)

Director and Managing Director of Alstom Asia Pte. Ltd. (Singapore, until 2014)

**Education and business experience**

Degree from *École Polytechnique* and *École Nationale Supérieure des Mines de Paris*

## Edgar Filing: Sanofi - Form 20-F

Since 2016	<b>Chairman of Truffle Capital SAS</b>
1979-1984	Various positions at the French Ministry of Industry, including as project officer at the <i>Direction régionale de l'Industrie, de la Recherche et de l'Environnement</i> (DRIRE) and in the Ministry's general directorate
1984-1988	Operational responsibilities in one of the Pechiney Group's biggest factories in Greece, then manager of the Greek subsidiary
1988-1993	Various senior operational and financial positions within the Pechiney Group
1993	Member of the Executive Committee of the Pechiney Group
1993-1997	Chairman and Chief Executive Officer of Carbone Lorraine
1995-1997	Manager of the Food and Health Care Packaging Sector at Pechiney, and Chief Operating Officer of American National Can Company in Chicago (United States)
1998-2002	Chief Executive Officer of Imerys
2003-2016	Chief Executive Officer, then Chairman and Chief Executive Officer, of Alstom*

### Number of shares held

1,000 shares

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Fabienne Lecorvaisier**

Date of birth:	August 27, 1962
Nationality:	French
First elected:	May 2013
Term expires:	2017
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Fabienne Lecorvaisier  
Within the Sanofi Group**

**Current directorships and appointments** **In French companies**  
Independent director of Sanofi\*  
  
Member of the Audit Committee

**In foreign companies**  
None

**Outside the Sanofi Group**

Air Liquide Group\*:  
  
Director of Air Liquide International  
  
Chairwoman and Chief Executive Officer of Air Liquide Finance  
  
Director of Air Liquide France Industries, Air Liquide Eastern Europe, Aqualung International and Air Liquide Welding SA  
  
Air Liquide Group\*:  
  
Executive Vice President of Air Liquide International Corporation  
  
Director of American Air Liquide Holdings, Inc. and SOAEO  
  
Manager of Air Liquide US LLC

**Past directorships expiring within the last five years** **In French companies**  
None  
  
**In foreign companies**  
None

None  
  
Air Liquide Group\*:  
  
Director of Air Liquide Japon (Japan, until 2013)

**Education and business experience**

Civil engineer, graduate of <i>École Nationale des Ponts et Chaussées</i>	
Since 2008	<b>Chief Financial Officer and Executive Committee member of Air Liquide*</b>
Since 2013	In charge of the diving activities of Air Liquide* (Aqualung)

## Edgar Filing: Sanofi - Form 20-F

1985-1989	Member of the Corporate Finance Department, then Mergers and Acquisitions Department of Société Générale*
1989-1990	Senior Banking Executive in charge of the LBO Department (Paris)/Corporate Finance Department (Paris and London) at Barclays
1990-1993	Assistant General Manager of Banque du Louvre, Taittinger Group
1993-2007	Various positions within Essilor* including Group Chief Financial Officer (2001-2007) and Chief Strategy and Acquisitions Officer (2007-2008)

### **Number of shares held**

1,000 shares

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****Suet-Fern Lee**

Date of birth:	May 16, 1958
Nationality:	Singaporean
First elected:	May 2011
Last reappointment:	May 2015
Term expires:	2019
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Suet-Fern Lee  
Within the Sanofi Group**

**Current directorships and appointments**    **In French companies**  
Independent director of Sanofi\*

**In foreign companies**  
None

**Past directorships expiring within the last five years**

**In French companies**  
None  
**In foreign companies**  
None

**Outside the Sanofi Group**

Axa\*:  
Director  
Member of the Finance Committee

Director of Rickmers Trust Management Pte Ltd\* (Singapore), Stamford Corporate Services Pte Ltd (Singapore), the World Justice Project (United States), Caldecott Inc. (Bermuda), and Morgan Lewis & Bockius (United States)

None

Director of Macquarie International Infrastructure Fund Ltd\* (Bermuda, until 2015) and of the National Heritage Board (Singapore, until 2015)  
Chairwoman of the Board of Directors of the Asian Civilisations Museum (Singapore, until 2015)

**Education and business experience**

Law degree from Cambridge University (1980)  
Admitted to the Bar in London (1981) and Singapore (1982)  
**Managing Partner of Morgan Lewis & Bockius LLP (previously Morgan Lewis Stamford LLC, Singapore)**  
Member of the Board of Morgan Lewis & Bockius (United States)  
Chairwoman of the International Leadership Team of Morgan Lewis & Bockius

Since 2006	Member of the Board of Trustees of Nanyang Technological University (Singapore) Member of the Accounting Advisory Board of National University of Singapore Business School (Singapore)
Since 2007	Member of the Advisory Committee of Singapore Management University School of Law (Singapore)
Since 2014	Member of the Senate of the Singapore Academy of Law where she also chairs the Committee on Legal Education and Studies (Singapore) Chairwoman of the Expert Panel of the Centre of the Cross-Border Commercial Law in Asia of the Singapore Management University School of Law (Singapore)
2000-2007	Director of ECS Holdings Limited* (Singapore)

## Edgar Filing: Sanofi - Form 20-F

2004-2007	Director of International Capital Investment Limited (Singapore) Director of Media Asia Entertainment Group Limited (Hong Kong) Director of Transpac Industrial Holdings Limited* (Singapore)
2005-2008	Director of China Aviation Oil* (Singapore)
2006-2008	Director of Sincere Watch* (Hong Kong)
2005-2009	Director of Richina Pacific Limited* (Bermuda)
2008-2010	Director of Transcu Group Limited* (Singapore)
2005-2011	Director of SembCorp Industries Ltd* (Singapore)
2010-2011	President of the Inter-Pacific Bar Association

### **Number of shares held**

1,000 shares

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Christian Mulliez**

Date of birth:	November 10, 1960
Nationality:	French
First elected:	June 2004
Last reappointment:	May 2014
Term expires:	2018
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Christian Mulliez  
Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships  
and appointments**

**In French companies**

Director of Sanofi\*

Member of the Audit Committee of Sanofi

Member of the Compensation Committee  
of Sanofi

**In foreign companies**

None

Chairman of the Board of Directors of Regefi  
Director of DG 17 Invest

Director of L. Oréal USA Inc. (United States) and The  
Body Shop International (United Kingdom)

**Past directorships  
expiring within the  
last five years**

**In French companies**

None

**In foreign companies**

None

None

Director of Galderma Pharma (Switzerland, until 2014)

**Education and business experience**

Degree from ESSEC (*École Supérieure des Sciences Économiques et Commerciales*)

Since 2003 **Executive Vice President, Chief Financial Officer of L. Oréal\***

1984-2002 Various positions at Synthélabo and then Sanofi-Synthélabo, including Vice President Finance

**Number of shares held**

1,525 shares

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****Carole Piwnica**

Date of birth:	February 12, 1958
Nationality:	Belgian
First elected:	December 2010
Last reappointment:	May 2016
Term expires:	2020
Business address:	Sanofi 54, rue La Boétie 75008 Paris France

**Directorships and appointments of Carole Piwnica****Within the Sanofi Group****Current directorships and appointments****In French companies**

Independent director of Sanofi\*

Member of the Audit Committee of Sanofi

**In foreign companies**

None

**Outside the Sanofi Group**

Eutelsat Communications\*:

Independent director

Chairwoman of the Governance, Selection and Remuneration Committee

Rothschild &amp; Co\* (formerly Paris Orléans):

Independent member of the Supervisory Board

Member of the Audit Committee and the Strategy Committee

**Director of Naxos UK Ltd** (United Kingdom)

Director of Big Red (United States), Elelevance (United States) and i2O (United Kingdom)

Director of Amyris Inc.\* (United States)

**Past directorships expiring within the last five years****In French companies**

None

**In foreign companies**

None

None

Director of Louis Delhaize\* (Belgium, until 2013) and RecyCoal Ltd. (United Kingdom, until 2015)

**Education and business experience**Degree in Law, *Université Libre de Bruxelles*

Masters in Law, New York University

Admitted to the Bar in Paris and New York

Since 2006

**Founder Director of Naxos UK Ltd** (United Kingdom)

1985-1991

Attorney at Proskauer, Rose (New York) and Shearman &amp; Sterling (Paris) with practice in mergers and acquisitions

1991-1994

General Counsel of Gardini &amp; Associés

1994-2000

Chief Executive Officer of Amylum France, then Chairwoman of Amylum Group

1998-2004

Director of Spadel (Belgium)

1996-2006

Director of Tate &amp; Lyle Plc. (United Kingdom)

2000-2006

Director and Vice-Chairwoman of Tate &amp; Lyle Plc for Governmental Affairs (United Kingdom)

1996-2006

Chairwoman of the Liaison Committee and director of the *Confédération Européenne des Industries Agro-Alimentaires* (CIAA)

## Edgar Filing: Sanofi - Form 20-F

2000-2006	Chairwoman of the Export Commission and director of the <i>Association Nationale des Industries Alimentaires</i> (ANIA)
2006-2009	Member of the Ethical Committee of Monsanto* (United States)
1996-2010	Director of Toepfer GmbH (Germany)
2007-2010	Director of Dairy Crest Plc* (United Kingdom)
2003-2011	Director, Chairwoman of the Corporate Responsibility Committee and member of the Compensation Committee of Aviva Plc* (United Kingdom)

### **Number of shares held**

1,000 shares

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Diane Souza**

Date of birth:	July 3, 1952
Nationality:	American
First elected:	May 2016
Term expires:	May 2020

**Directorships and appointments of Diane Souza**

**Within the Sanofi Group**

**Outside the Sanofi Group**

**Current directorships and appointments**

**In French companies**

Independent director of Sanofi\*  
Member of the Compensation Committee of Sanofi

None

**In foreign companies**

None

Member of the Board of Directors of Farm Credit East (United States)

**Past directorships expiring within the last five years**

**In French companies**

None

None

**In foreign companies**

None

UnitedHealth Group:

Member of the Board of Directors of Unimerica Insurance Company, Unimerica Life Insurance Company of New York, National Pacific Dental, Inc., Nevada Pacific Dental, DBP Services of New York, IPA, Dental Benefits Providers of California, Inc., Dental Benefit Providers of Illinois, Inc., Dental Benefit Providers, Inc., Spectera, Inc. and Spectera of New York, IPA, Inc. (United States)

**Education and business experience**

Degree in Accounting from University of Massachusetts  
Honorary doctorate in Business Studies from University of Massachusetts Dartmouth  
Certified Public Accountant  
Diploma in Dental Hygiene from Northeastern University, Forsyth School for Dental Hygienists

1979	Audit Staff Accountant at Price Waterhouse (United States)
1980-1988	Various positions at Deloitte Haskins & Sells, from Audit Staff Accountant to Senior Tax Manager-in-Charge (United States)
1988-1994	Various positions at Price Waterhouse from Audit Staff Accountant to Head of the Northeast Insurance Tax Region (United States)
1994-2006	Various positions at Aetna Inc. including Deputy Vice President Federal and State Taxes; Vice President and Chief Financial Officer, Large Case Pensions; Vice President and Head of Global Internal Audit Services; Vice President, National Customer Operations; and finally Vice President, Strategic Systems & Processes (United States)
2007-2008	Principal consultant at Strategic Business Solutions, LLC (United States)
2008-2014	Chief Operating Officer of OptumHealth Specialty Benefits (2008), then Chief Executive Officer of UnitedHealthcare Specialty Benefits (United States)

**Number of shares held**

2,000 American Depositary Receipts,  
equivalent to 1,000 shares

**146**

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****Thomas Südhof**

Date of birth:	December 22, 1955
Nationality:	German and American
First elected:	May 2016
Term expires:	May 2020

**Directorships and appointments of Thomas Südhof****Within the Sanofi Group****Outside the Sanofi Group**

<b>Current directorships and appointments</b>	<b>In French companies</b>	
	Independent director of Sanofi*	None
	<b>In foreign companies</b>	
	None	None

<b>Past directorships expiring within the last five years</b>	<b>In French companies</b>	
	None	None
	<b>In foreign companies</b>	
	None	None

**Education and business experience**

	Degree in medicine from the Faculty of Medicine of the University of Göttingen (Germany)
Since 2008	<b>Avram Goldstein Professor of Molecular &amp; Cellular Physiology in the School of Medicine at Stanford University</b> (United States)
Since 1991	Investigator at the Howard Hughes Medical Institute (United States)
Since 2002	Co-founder and member of the Scientific Advisory Board of REATA Pharmaceuticals (United States)
Since 2011	Co-founder and member of the Scientific Advisory Board of Circuit Therapeutics, Inc. (United States)
Since 2012	Member of the Scientific Advisory Board of the Picower Institute at MIT (Massachusetts Institute of Technology) (United States)
Since 2013	Member of the Review Board of Genentech Neuroscience (United States)
Since 2013	Member of the Scientific Advisory Board of the Shemyakin-Ovchinnikov Institute of Bio-Organic Chemistry (Russia)
Since 2014	Co-founder and member of the Scientific Advisory Board of Bluenobel, Inc. (China)
Since 2014	Member of the Scientific Advisory Board of Elysium, Inc. (United States)
Since 2014	Member of the Scientific Advisory Board of the Singapore National Research Foundation (Singapore)
Since 2014	Member of the Scientific Advisory Board of the Chinese Academy Institute of Biophysics (China)
Since 2014	Member of the Scientific Advisory Committee of the Institute of Cellular and Molecular Biology of A*Star (China)
Since 2015	Member of the Scientific Advisory Board of Fulcrum Therapeutics (United States)
1978-1981	Research assistant at the Max Planck Institute for Biophysical Chemistry (Germany)
1979	Student on exchange clerkship program at Harvard Medical School (United States)
1981-1982	Intern at the University Hospital of Göttingen (Germany)
1983-2008	Assistant Professor and subsequently Chair of the Neuroscience Department at the University of Texas Southwestern Medical School (United States)
2008	Bernard Katz Prize of the Biophysical Society, jointly with Reinhard Jahm
2013	Nobel Prize for Physiology or Medicine, jointly with James Rothman and Randy Shekman
2013	Albert Lasker Prize for Basic Medical Research, jointly with Richard Sheller

**Number of shares held**

997.38 American Depositary  
Receipts, equivalent to  
498 shares

147

## **Table of Contents**

### **ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

#### **Changes in the composition of the Board of Directors in 2016**

The composition of our Board of Directors changed during 2016.

Diane Souza and Thomas Südhof were appointed as directors at our Annual General Meeting on May 4, 2016. Those appointments brought extra scientific and pharmaceutical expertise to the Board, improved its gender balance and international diversity, and reduced the average age of Board members.

Three directors (Laurent Attal, Claudie Haigneré and Carole Piwnica) were reappointed in 2016.

Uwe Bicker, Jean-René Fourtou and Klaus Pohle, whose terms of office also expired at the conclusion of the 2016 Annual General Meeting, did not seek reappointment.

Consequently, the number of seats on the Board was reduced by one, in line with the Board's medium-term objective.

On September 6, 2016, Bonnie Bassler resigned as a director of Sanofi due to a potential conflict of interest following her appointment to the Regeneron Board of Directors.

As of December 31, 2016, the members of our Board of Directors collectively held (directly, or via the employee share ownership fund associated with the Group savings scheme) 12,659 of our shares, representing 0.0009% of our share capital.

As of December 31, 2016, no corporate officer has been the subject of any conviction or court order, or been associated with any bankruptcy or winding-up order. As of this day, there is no potential conflict of interest between any corporate officer and Sanofi.

Following the enactment of the French Employment Protection Act of June 14, 2013, the Appointments and Governance Committee assessed its impact on Sanofi. On the basis of that assessment, our Board concluded that Sanofi could not apply the Act because the parent company has a workforce of less than 50 people and therefore does not have a works council.

Under current French legislation, and given that employees own less than 3% of our share capital, the Board does not include a director representing employee shareholders.

Nevertheless, five employee representatives attend Board meetings without voting rights, pursuant to the agreement of February 24, 2005 to establish a European Works Council.

One of our French subsidiaries that falls within the scope of the French Employment Protection Act appointed an employee representative to its Board in 2015.

Following the enactment of the French Social Dialogue and Employment Act of August 17, 2015, an assessment has

been carried out to determine the most appropriate level for achieving employee representation within Sanofi, and the most suitable methods for appointing employee representatives.

At our Annual General Meeting to be held on May 10, 2017, a resolution aiming to amend our articles of association will be submitted for the approval of our shareholders. It provides (i) that one employee representative director would be designated by the trade union body which is the most representative (within the meaning of the applicable legislation) in our Company and those of its direct or indirect subsidiaries that have their registered office in French territory, and (ii) that one employee representative director would be designated by the European Works

Council.

An employee representative director would hold office for a term of four years. His or her term of office would end at the close of the Annual General Meeting held during the calendar year in which his or her term of office expires to approve the financial statements for the previous financial year.

#### **Executive Committee**

The Executive Committee is chaired by the Chief Executive Officer.

The Committee meets at least twice a month, and as of the date of this annual report on Form 20-F, has the following permanent members:

- **Olivier Brandicourt**, Chief Executive Officer;
- **Olivier Charmeil**, Executive Vice President and General Manager, General Medicines and Emerging Markets;
- **Jérôme Contamine**, Executive Vice President, Chief Financial Officer;
- **Peter Guenter**, Executive Vice President, Diabetes & Cardiovascular;
- **Karen Linehan**, Executive Vice President, Legal Affairs and General Counsel;
- **David Loew**, Executive Vice President, Sanofi Pasteur;
- **Philippe Luscan**, Executive Vice President, Global Industrial Affairs;
- **Alan Main**, Executive Vice President, Consumer HealthCare;
- **Muzammil Mansuri**, Executive Vice President, Strategy and Business Development;
- **David P. Meeker**, Executive Vice President, Sanofi Genzyme;
- **Ameet Nathwani**, Executive Vice President, Medical Affairs;
- **Roberto Pucci**, Executive Vice President, Human Resources;

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Kathleen Tregoning**, Executive Vice President, External Affairs;

**Elias Zerhouni**, President, Global Research and Development.

The name, business address, present principal occupation or employment and material occupations, positions, offices or employment for the past five years of each of the executive officers of Sanofi are set forth below. The business address and phone number of each such executive officer is c/o Sanofi, 54 rue La Boétie, 75008 Paris, France, +33 1 53 77 40 00.

***Olivier Brandicourt***

**Chief Executive Officer**

**Chairman of the Executive Committee**

*Date of birth: February 13, 1956*

Olivier Brandicourt was appointed Chief Executive Officer on April 2, 2015, and is also a member of the Strategy Committee of Sanofi.

For additional information regarding his professional education and business experience see Composition of the Board of Directors as of December 31, 2016 in A. Directors and Senior Management of this Item 6.

Olivier Brandicourt is a citizen of France.

***Olivier Charmeil***

**Executive Vice President and General Manager, General Medicines and Emerging Markets**

*Date of birth: February 19, 1963*

Olivier Charmeil is a graduate of HEC (*École des Hautes Études Commerciales*) and of the *Institut d'Études Politiques* in Paris. From 1989 to 1994, he worked in the Mergers & Acquisitions department of Banque de l'Union Européenne. He joined Sanofi Pharma in 1994 as head of Business Development. Subsequently, he held various positions within Sanofi, including Chief Financial Officer (Asia) of Sanofi-Synthélabo in 1999 and Attaché to the Chairman, Jean-François Dehecq, in 2000, before being appointed as Vice President, Development within the Sanofi-Synthélabo International Operations Directorate, where he was responsible for China and support functions. In 2003, Olivier Charmeil was appointed Chairman and Chief Executive Officer of Sanofi-Synthélabo France, before taking the position of Senior Vice President, Business Management and Support within the Pharmaceutical Operations Directorate. In this role, he piloted the operational integration of Sanofi-Synthélabo and Aventis. He was appointed Senior Vice President Asia/Pacific, Pharmaceutical Operations in February 2006; Operations Japan reported to him from January 1, 2008, as did Asia/Pacific and Japan Vaccines from February 2009. On January 1, 2011, Olivier Charmeil was appointed Executive Vice President Vaccines, and joined our Executive Committee.

In May 2015, Olivier Charmeil and André Syrota were appointed as Co-Leaders of *Medicine of the Future*, an initiative developed by the French Minister for Economy, Industry and Digital Affairs, the French Minister for Social Affairs, Health and Women's Rights and the French Minister for National and Higher Education and Research. They have been tasked with assembling a group of industrialists and academics, with the objective of imagining how French industry can accelerate the launch and export of innovative industrial products, with an emphasis on new biotechnologies.

## Edgar Filing: Sanofi - Form 20-F

On June 1, 2016, Olivier Charmeil was appointed Executive Vice President and General Manager of our General Medicines and Emerging Markets Global Business Unit.

Olivier Charmeil is a citizen of France.

### ***Jérôme Contamine***

#### **Executive Vice President, Chief Financial Officer**

*Date of birth: November 23, 1957*

Jérôme Contamine is a Graduate of *École Polytechnique (X)*, ENSAE (*École Nationale de la Statistique et de l'Administration Économique*), and ENA (*École Nationale d'Administration*). After four years at the *Cour des Comptes* as a Senior State General Auditor, he joined Elf Aquitaine in 1988 as advisor to the Chief Financial Officer, and became Group Finance and Treasury Director in 1991. He became the General Manager of Elf Petroleum Norway in 1995, after being named Deputy Vice President of Elf Upstream Division for Europe and the US. In 1999, he was appointed as a member of the taskforce for integration with Total, in charge of the reorganization of the merged entity, TotalFinaElf, and in 2000 became Vice President Europe and Central Asia, Upstream Division of Total. The same year, he joined Veolia Environnement as CFO and Deputy General Manager. In 2003, he was appointed Senior Executive Vice President, Deputy Chief Executive Officer, Financial Director of Veolia Environnement. Since 2006 he has been a director of Valeo. Jérôme Contamine joined Sanofi as Executive Vice President, Chief Financial Officer (CFO) in March 2009.

Jérôme Contamine is a citizen of France.

### ***Peter Guenter***

#### **Executive Vice President, Diabetes & Cardiovascular**

*Date of birth: September 2, 1962*

Peter Guenter holds a Master's Degree in Physical Education from the Faculty of Medicine and Health Sciences, University of Ghent, Belgium. Peter started his career in sales at SmithKline in 1986. He joined Sanofi in 1995 and held various positions in France, Europe and Global Marketing. In 2000, he was appointed General Manager Belgium and then Vice President for Eastern Europe and subsequently Northern Europe. In 2008, he took up the position of General Manager, Commercial Operations

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

for Germany and in 2011, Peter became General Manager for the Multi-Country-Organization for Germany, Switzerland and Austria. He was appointed Senior Vice President, Europe Global Operations in July 2011. He became a member of the Executive Committee and was appointed as Executive Vice President, Global Commercial Operations in July 2013.

From January 2016, he headed up our General Medicines & Emerging Markets Global Business Unit.

On June 1, 2016 he was appointed Executive Vice President and General Manager of our Diabetes and Cardiovascular Global Business Unit.

Peter Guenter is a citizen of Belgium.

***Karen Linehan***

**Executive Vice President, Legal Affairs and General Counsel**

*Date of birth: January 21, 1959*

Karen Linehan graduated from Georgetown University with Bachelor of Arts and Juris Doctorate degrees. Prior to practicing law, she served on the congressional staff of the Speaker of the US House of Representatives from September 1977 to August 1986. Until December 1990, she was an Associate in a mid-size law firm in New York. In January 1991, she joined Sanofi as Assistant General Counsel of its US subsidiary. In July 1996, Karen moved to Paris to work on international legal matters within Sanofi and she has held a number of positions within the Legal Department, most recently as Vice President Deputy Head of Legal Operations. She was appointed to her current position in March 2007.

Karen Linehan is a citizen of the United States of America and Ireland.

***David Loew***

**Executive Vice President, Sanofi Pasteur**

*Date of birth: March 20, 1967*

David Loew has a degree in Finance and Marketing and an MBA from the University of St. Gallen in Switzerland.

He started his career in the United States at Coopers & Lybrand and Hewlett Packard in 1990, before joining Roche in 1992. Over the next 21 years, David held a variety of positions with Roche including Global Oncology Head, General Manager Switzerland, Global Chief Marketing Officer & Head of Global Product Strategy, Region Head Eastern Europe, Middle East and Africa for the Pharma Division of Roche. He is the International Federation Pharmaceutical Manufacturers & Associations (IFPMA) representative on the Board of the Global Alliance for Vaccines and Immunization (GAVI). He also chairs the Steering Committee of IFPMA, comprising the CEOs of the

member companies (GSK, Merck, Johnson & Johnson, Pfizer, Takeda, Novartis and Daiichi Sankyo).

David joined Sanofi in July 2013 as Senior Vice President Commercial Operations Europe and became Head of Global Commercial Operations at Sanofi Pasteur in January 2016. On June 1, 2016 he was appointed Executive Vice President of Sanofi Pasteur.

David Loew is a citizen of Switzerland.

*Philippe Luscan*

**Executive Vice President, Global Industrial Affairs**

*Date of birth: April 3, 1962*

Philippe Luscan is a graduate of the *École Polytechnique (X)* and the *École Nationale Supérieure des Mines de Paris* in Biotechnology. He began his career in 1987 as a Production Manager at Danone. In 1990, he joined Sanofi as Director of the Sanofi Chimie plant at Sisteron, France, and subsequently served as Industrial Director of Sanofi in the United States, as Vice President Supply Chain and as Vice President Chemistry from September 2006. He was appointed to his present position in September 2008. Since January 1, 2015, Philippe Luscan has also been Chairman of Sanofi in France.

Philippe Luscan is a citizen of France.

*Alan Main*

**Executive Vice President, Consumer HealthCare**

*Date of birth: December 5, 1967*

Alan Main has a BA (Hons) in International Marketing from Thames Polytechnic in London, and has completed various executive and leadership development programs at London, Harvard and Columbia Business Schools, as well as INSEAD (Asia).

Alan has more than 30 years of marketing and general management experience in the Consumer Health and Medical Device fields, initially with Stafford Miller/Block Drug (now part of GSK). He then moved to Merrell Dow (now part of Sanofi) and London Rubber Company. In 1992, he joined Roche Consumer Health where he took on positions of increasing responsibility in the United Kingdom, South Africa and the Asia-Pacific region. Following the acquisition of Roche Consumer Health by Bayer in 2004, Alan continued to occupy key management roles, including Region Head for Asia Pacific and Europe. In 2010 Alan transferred to the medical device business of Bayer as Global President for Bayer Medical Care.

He was appointed to his present position in October 2016.

Alan Main is a citizen of the United Kingdom.

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

***Muzammil Mansuri***

**Executive Vice President, Strategy and Business Development**

*Date of birth: January 20, 1954*

Muzammil Mansuri holds a Bachelor of Science degree in Chemistry and a Ph.D. in Organic Chemistry from University College London. He held post-doctoral positions at the University of California, Los Angeles (UCLA) and Columbia University. He started his career in 1981 with Shell Research Limited where he began as a research scientist. After Shell, he spent several years with Bristol-Myers Company in various R&D roles with increasing responsibility. From 2007 to 2010, he was Chairman and CEO at CGI Pharmaceuticals. Before joining Sanofi, Muzammil's most recent position was Senior Vice President, Research & Development Strategy and Corporate Development at Gilead Sciences. He was appointed to his current position in February 2016.

Muzammil Mansuri is a citizen of the United States of America and the United Kingdom.

***David P. Meeker***

**Executive Vice President Sanofi Genzyme**

*Date of birth: October 4, 1954*

Dr. Meeker received his M.D. from the University of Vermont Medical School. He completed an Internal Medicine residency at Beth Israel Hospital in Boston and a Pulmonary/Critical Care fellowship at Boston University. He completed the Advanced Management Program at Harvard Business School in 2000. Prior to joining Genzyme, Dr. Meeker was the Director of the Pulmonary Critical Care Fellowship at the Cleveland Clinic and an assistant professor of medicine at Ohio State University. He is the author of more than 40 scientific articles and multiple book chapters. Dr. Meeker joined Genzyme in 1994 as Medical Director to work on the Gene Therapy and Cystic Fibrosis program. Subsequently, as Vice President, Medical Affairs, he was responsible for the development of therapeutic products, including treatments in the current rare genetic diseases portfolio. He was promoted to Senior Vice President in 1998, and in 2000 became the Business Unit Leader for the Lysosomal Storage Disease and Thyrogen<sup>®</sup> programs in Europe. Dr. Meeker was promoted to President of the Global LSD business unit in 2003. In this role, he oversaw the global launches of Aldurazyme<sup>®</sup>, Fabrazyme<sup>®</sup> and Myozyme<sup>®</sup>. In 2008, he was promoted to Executive Vice President of Therapeutics, Biosurgery and Transplant. In 2009, he became Chief Operating Officer. In this role, he was responsible for Genzyme's commercial organization, overseeing the business units, country management organization and global market access functions. He became Chief Executive Officer of Genzyme in November 2011, and a member of Sanofi's Executive Committee in September 2013.

Since January 2016, Dr. Meeker has been Director of the Specialty Care Global Business Unit, Sanofi Genzyme.

David P. Meeker is a citizen of the United States of America.

***Ameet Nathwani***

**Executive Vice President, Medical Affairs**

*Date of birth: October 5, 1967*

Dr. Nathwani was born in Uganda and studied in the United Kingdom. He qualified in medicine in 1987 in London, and acquired his specialization in Cardiology at a number of University Hospitals in London. He also has a diploma in Pharmaceutical Medicine and an executive

Masters in Business Administration.

Dr. Nathwani has more than twenty years' experience in the pharmaceutical industry, beginning in 1994 when he joined Glaxo Group Research. Between 1994 and 2004 he held increasingly senior functional and franchise leadership roles in research and development at Glaxo, SmithKline Beecham and GlaxoSmithKline, in Europe and the US. He joined Novartis in 2004 as Senior Vice President and Global Development Head of the Cardiovascular and Metabolic Franchise, and over an 11-year period held a number of senior development and commercial positions including Global Head of the Critical Care Franchise. In June 2014 he was appointed Global Head of Medical Affairs at Novartis Pharma AG and became a member of the Pharma Executive Committee, where he led the establishment of a Real World Evidence Center of Excellence and piloted the Digital Medicine strategy.

He was appointed to his present position in May 2016.

Ameet Nathwani is a citizen of the United Kingdom.

***Roberto Pucci***

**Executive Vice President, Human Resources**

*Date of birth: December 19, 1963*

Roberto Pucci has a law degree from the University of Lausanne, Switzerland. He started his career in 1985 at Coopers & Lybrand in Geneva, Switzerland as an external auditor. He then joined Hewlett-Packard (HP) in 1987, where he held various positions in Human Resources in Switzerland and Italy including HR Manager for the European Headquarters and Human Resources Director in Italy. In 1999, he became Director, Compensation & Benefits for Agilent Technologies, a spin off from HP, and was appointed Vice President Human Resources Europe in 2003. In 2005 he moved to the United States to join Case New Holland, a subsidiary of the Fiat Group, as Senior Vice President, Human Resources, and in 2007 was appointed Executive Vice President, Human Resources for the Fiat Group in Turin, Italy. Roberto Pucci joined Sanofi as Executive Vice President Human Resources in October 2009.

Roberto Pucci is a citizen of Italy and Switzerland.

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

***Kathleen Tregoning***

**Executive Vice President, External Affairs**

*Date of birth: January 20, 1971*

Kathleen Tregoning received her Bachelor's degree in International Relations from Stanford University and her master's degree in Public Policy from the Kennedy School of Government at Harvard University.

Kathleen has more than 20 years of experience in policy development and advocacy, stakeholder outreach, and external engagement. She began her career in 1993 with Andersen Consulting in San Francisco and later served as a Policy Advisory and then Assistant Deputy Mayor in the Office of the Mayor for the City of Los Angeles.

In 2001, Kathleen moved to Washington, D.C. where she served as a professional staff member in the U.S. Congress, working for the chairmen of the House of Representatives Ways & Means Committee, the House Energy & Commerce Committee, and the Senate Budget Committee. In these positions she was a key resource for members of Congress on a wide range of health care issues, including Medicare, Medicaid, prescription drugs, disease management, health care information technology, and post-acute care.

Kathleen joined Biogen in 2006 as Vice President, Public Policy & Government Affairs. Over the course of nine years, she built the company's first global government affairs team to advance policies that enable the delivery of innovative biopharmaceutical products to patients. In 2015, Kathleen was appointed Senior Vice President, Corporate Affairs at Biogen, overseeing the company's policy and advocacy engagement, corporate and employee communications, media relations, product communications and philanthropy/community outreach on a global basis.

She was appointed to her present position in February 2017.

Kathleen Tregoning is a citizen of the United States of America.

***Elias Zerhouni***

**President, Global Research and Development**

*Date of birth: April 12, 1951*

Born in Algeria where he completed his initial medical training, Dr. Zerhouni continued his academic career at the Johns Hopkins University and Hospital (United States) in 1975 where he rose to the rank of professor of Radiology and Biomedical Engineering. He served as Chair of the Russell H. Morgan Department of Radiology and Radiological Sciences, Vice Dean for Research and Executive Vice Dean of the School of Medicine from 1996 to 2002 before his appointment as Director of the National Institutes of Health of the United States of America from 2002 to 2008. Dr. Zerhouni was received as member of the US National Academy of Sciences - Institute of Medicine in 2000. He was appointed as Chair of Innovation at the *Collège de France* and elected a member of the French

Academy of Medicine in 2010, and received the Transatlantic Innovation Leadership award in December 2011. He is the author of over 200 scientific publications and has filed eight patents. In February 2009, Sanofi named Dr. Zerhouni Scientific Advisor to the Chief Executive Officer and to the Senior Vice-President Research & Development. He was appointed President Global Research & Development Medicines and Vaccines and became a member of our Executive Committee in January 2011. In 2013, he was appointed as a member of the US National Academy of Engineering.

Dr. Zerhouni is a citizen of the United States of America.

As of December 31, 2016, none of the members of the Executive Committee, aside from Kathleen Tregoning, had their principal business activities outside of Sanofi.

## **B. Compensation**

### **Compensation and arrangements for corporate officers**

#### **Compensation policy for executive officers**

This section describes the compensation policy for executive officers, as established pursuant to Article L. 225-37-2 of the French Commercial Code. It sets forth the principles and the criteria used in determining, allocating and awarding the fixed, variable and exceptional components that collectively comprise the total compensation and benefits of whatever kind awarded to our executive officers.

Payment in 2018 of the variable and exceptional components included in the compensation for 2017 described below is subject to approval by the shareholders in an Ordinary General Meeting of the compensation package of the executive officer in question, on the terms stipulated in Article L. 225-100 of the French Commercial Code.

The compensation policy for executive officers is established by the Board of Directors, acting on the recommendation of the Compensation Committee.

The Board of Directors applies the AFEP-MEDEF Code when determining the compensation and benefits awarded to our corporate officers and executive officers.

Article L. 225-37 subsection 7 of the French Commercial Code, the AFEP-MEDEF Code and the *Autorité des marchés financiers* (AMF), the French market regulator, require specific disclosures about the implementation by our Company of the recommendations contained in the AFEP-MEDEF Code, and explanations of the reasons why any of them have not been implemented by our Company.

The AFEP-MEDEF Code recommendation according to which stock options and performance shares awards should be made at the same time of year was not applied. As an exception to our usual practice (applied since 2009) of awarding stock options and performance shares in March, in

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

2016 those awards were made in May, which we intend henceforth to be the period for making such awards. For more information see C. Board Practices , below.

**Compensation policy for the Chairman of the Board of Directors**

The compensation of the Chairman of the Board of Directors (where the office of Chairman is separate from that of Chief Executive Officer, as is currently the case) consists solely of fixed compensation and benefits in kind and excludes any variable compensation, any awards of stock options and performance shares and any directors' attendance fees.

Where the office of Chairman is separate from that of Chief Executive Officer, as is currently the case, the Chairman of the Board is not entitled to the Sanofi top-up defined-benefit pension plan.

Nor is he entitled to a termination benefit or a non-compete indemnity.

Executive officers do not receive attendance fees in their capacity as directors. Consequently, the Chairman of the Board does not receive attendance fees in his capacity as Chairman of the Board, chairman of the Appointments and Governance Committee or chairman of the Strategy Committee.

**Compensation policy for the Chief Executive Officer**

The compensation policy of the Chief Executive Officer is based on the same structures and principles as the general Sanofi compensation policy.

**General principles**

The Sanofi compensation policy seeks to be consistent with market and industry practice in order to provide competitive levels of compensation, create a strong link with Sanofi's performance, and maintain a balance between short-term and medium/long-term performance.

The compensation of the Chief Executive Officer is set by the Board of Directors acting on the recommendation of the Compensation Committee, with reference to compensation paid to the chief executive officers of the ten leading global pharmaceutical companies. Consistency with market practice is fundamental in order to attract and retain the talents necessary to our success. We also review the practices of the principal CAC 40 companies in order to reach a fair balance and to take into account our corporate interest, market practices, the performance of the Chief Executive Officer, and our other stakeholders.

Equity-based compensation is a critical tool for our worldwide attractiveness as an employer, and aims to align employee and shareholder interests and reinforce employees' ties to Sanofi.

Acting on the recommendation of the Compensation Committee, the Board of Directors determines the performance conditions attached to equity-based compensation for all beneficiaries at Sanofi and its subsidiaries worldwide, favoring the attainment of objectives based on our consolidated results and balance sheet. Our equity-based compensation plan rules are made available to our shareholders on the governance page of our website (www.sanofi.com) in the same form as that distributed to our employees.

Since 2011 the Board of Directors has substantially reworked our equity-based compensation policy to reinforce the link with long-term performance for all beneficiaries and to reduce potential dilution. As a result of very positive and encouraging shareholder feedback collected through corporate governance roadshows, contacts with governance professionals and the results of votes at Annual General Meetings, the

## Edgar Filing: Sanofi - Form 20-F

Board decided to maintain and reinforce this policy in 2013.

The current policy can generally be characterized by reduced dilution; diversified, multi-year performance conditions; increased transparency; and specific additional requirements for the Chief Executive Officer.

The policy requires that grants be primarily based on performance shares, with only a limited number of high-level executives continuing to receive stock options.

Greater reliance on performance shares makes it possible to maintain a comparable level of employee incentivization while reducing the dilutive effect of equity-based compensation plans for existing shareholders. However, the Board of Directors continues to believe that due to their ratchet effect, options remain an appropriate component of the compensation of high level executives.

The Board of Directors makes any grant of stock options or performance shares contingent on several distinct performance criteria in order to ensure that our equity-based compensation plans incentivize overall performance and do not encourage excessive risk taking. Failure to achieve these criteria over the entire performance measurement period results in a reduction or loss of the initial grant.

Grants are also contingent on the beneficiary's continued employment in the Sanofi group during the lock-up period (4 years for options, 3 years for performance shares, followed by further stringent lock-up obligations in the case of the Chief Executive Officer).

The exercise price of stock options is set by the Board, never incorporates a discount, and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board.

The Board is not allowed to reset the terms of prior grants, for instance with easier performance conditions or a lower exercise price.

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**On taking up office**

When the Chief Executive Officer is an outside appointment the Board of Directors may decide, acting on a recommendation from the Compensation Committee, to compensate the appointee for some or all of the benefits he may have forfeited on leaving his previous employer. In that case, the terms on which the Chief Executive Officer is hired aim to replicate the diversity of what was forfeited, with a comparable level of risk (variable portion, medium-term equity-based or cash compensation).

**During the term of office**

*Compensation structure*

Our policy aims at achieving a balance in the compensation structure between fixed compensation, benefits in kind, short-term variable cash compensation, and medium-term variable equity-based compensation. The proportions of annual fixed and variable compensation are not reviewed on an annual basis. Compensation adjustments based on performance and market practice are mainly effected through equity-based compensation, which is medium-term and aims at aligning the interests of the Chief Executive Officer with those of our shareholders and stakeholders.

Our overall compensation policy is designed to motivate and reward performance by ensuring that a significant portion of compensation is contingent on the attainment of financial, operational and social criteria aligned with the corporate interest and with the creation of shareholder value. Variable cash compensation and equity-based compensation are the two principal levers for action.

*Annual variable compensation*

Annual variable compensation is in a potential range between 0% and 250% of fixed compensation, with a target of 150%. It is determined by reference to quantifiable and qualitative criteria. The percentage of variable compensation linked to the attainment of quantifiable criteria may be scaled down regardless of actual performance, in order to give greater weight to the attainment of qualitative criteria. This flexibility can only operate to reduce the amount of variable compensation, and cannot compensate for underperformance on quantifiable criteria.

*Equity-based compensation*

The Chief Executive Officer's equity-based compensation may not exceed 250% of his target short term compensation (fixed plus variable compensation). The valuation of stock options is calculated at the date of grant using the Black & Scholes method. The valuation of performance shares is calculated at the date of grant and it represents the difference between the quoted market price of the share on the date of grant and the current value of the dividends to be

paid over the next three years. The parameters used to calculate the valuations are market parameters available in the financial press. The Chief Executive Officer's equity-based compensation is contingent upon fulfillment of the performance conditions.

In 2016 the median fixed compensation of the chief executive officers of the ten leading global pharmaceutical companies was in the range of 1,500,000, and the median of the long-term compensation granted (whether in shares or in cash) represented around 800% of this fixed compensation.

Each grant to the Chief Executive Officer takes into account previous grants and his overall compensation.

*Attendance fees*

## Edgar Filing: Sanofi - Form 20-F

Executive officers do not receive attendance fees in their capacity as directors. Consequently, the Chief Executive Officer does not receive attendance fees in his capacity as a director or as a member of the Strategy Committee.

### On leaving office

The Chief Executive Officer is entitled to a top-up defined-benefit pension plan, a termination benefit, and a non-compete indemnity. Each of those benefits is taken into account by the Board of Directors when fixing the overall compensation of the Chief Executive Officer.

### *Pension arrangements*

The Chief Executive Officer is covered by a top-up defined-benefit pension plan. This plan, which falls within the scope of Article L. 137-11 of the French Social Security Code, is offered to all employees of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules. The plan, which remains open, was set up on October 1, 2008 as the final stage in the process of harmonizing the status of personnel across the French subsidiaries.

This top-up defined-benefit pension plan is offered to executives (as defined by AGIRC, a confederation of executive pension funds) of Sanofi and its French subsidiaries who meet the eligibility criteria specified in the plan rules; the benefit is contingent upon the plan member ending his or her career within the Sanofi group. The plan is reserved for executives with at least ten years of service whose annual base compensation has for ten calendar years (not necessarily consecutive) exceeded four times the French social security ceiling, and is wholly funded by the Company and outsourced to an insurance company.

The top-up pension, which may not exceed 37.50% (1.5% per year of service, capped at 25 years) of the reference compensation, is in the form of a life annuity, and is

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

transferable as a survivor's pension. The annuity is based on the arithmetical average of the three highest years' annual gross compensation paid during any three of the five years preceding final cessation of employment. This reference compensation is capped at 60 times the French social security ceiling applicable in the year in which the pension is taken. In addition, the Board of Directors decided that vesting of new rights for the Chief Executive Officer would be subject to a performance condition with effect from January 1, 2017.

The annuity supplements any other schemes for which the plan member may be eligible in France or abroad, subject to a cap on the total pension from all sources set at 52% of the reference compensation. If the total amount of the annuities paid under all such schemes were to exceed the 52% cap, the amount of the Sanofi top-up defined-benefit pension annuity would be reduced accordingly in order to respect this cap.

This retirement plan is subject to various charges and contributions within France: CSG, CRDS, CSAM, CASA, contributions of 7% and 14% on the annuity, and of 24% on the external funding.

*Termination benefit*

The termination benefit only becomes payable if the departure of the Chief Executive Officer is forced, i.e. in the event of removal from office or resignation linked to a change in strategy or control of the Company. Compensation for non-renewal of the term of office is irrelevant in the case of the Chief Executive Officer, because this office is held for an indefinite term.

In addition, no termination benefit is payable in the following circumstances:

- in the event of removal from office for gross or serious misconduct (*faute grave ou lourde*);
- if the Chief Executive Officer elects to leave the Company to take up another position;
- if he is assigned to another position within Sanofi;
- if he is able to take his pension.

The amount of the termination benefit is capped at 24 months of the Chief Executive Officer's most recent total compensation on the basis of (i) the fixed compensation effective on the date of leaving office and (ii) the last variable compensation received prior to that date, subject to fulfilment of the performance criteria for the three financial years preceding the date of leaving office.

The amount of the termination benefit is reduced by any benefit received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed plus variable compensation.

*Non-compete undertaking*

In the event of his departure from the Company, the Chief Executive Officer undertakes not to join a competitor of the Company as an employee or corporate officer, or to provide services to or cooperate with such a competitor.

## Edgar Filing: Sanofi - Form 20-F

The Board of Directors determines the period for which the non-compete undertaking will apply, and the amount and terms of the indemnity payable to the Chief Executive Officer in return.

However, when the Chief Executive Officer leaves, the Board of Directors reserves the right to release the Chief Executive Officer from the undertaking for some or all of the period covered by the undertaking. In that case, the non-compete indemnity would not be due for the period of time waived by the Company.

### Consequences of the Chief Executive Officer's departure for equity-based compensation

In the event that the Chief Executive Officer leaves the Company for reasons other than resignation or removal from office for gross or serious misconduct (in which case any award of equity-based compensation is forfeited), the overall allocation percentage will be prorated to reflect the amount of time the Chief Executive Officer remained with Sanofi during the vesting period.

If at any time prior to the expiration of (i) the period of validity of the options or (ii) the vesting period of the performance shares the Chief Executive Officer joins a competitor of Sanofi as an employee or corporate officer, or provides services to or cooperates with such a competitor, he irrevocably loses those options and performance shares regardless of any full or partial waiver by the Board of Directors of the non-compete undertaking relating to his office as Chief Executive Officer.

If the Chief Executive Officer retires at statutory retirement age prior to the expiration of (i) the period of validity of the options or (ii) the vesting period of the performance shares, he will retain entitlement to the options and performance shares initially awarded but will continue to be bound by the other terms of the plan, including the performance conditions.

There is no acceleration clause in the event of a change of control.

### **Compensation of the Chairman of the Board, Serge Weinberg**

Serge Weinberg has held the office of Chairman of the Board of Directors since May 17, 2010. He has never had, and does not currently have, a contract of employment with Sanofi.

The Chairman of the Board also chairs the Appointments and Governance Committee and the Strategy Committee.

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

In accordance with our Board Charter and in close collaboration with Senior Management, the Chairman represents the Company in high-level dealings with governmental bodies and with our key partners, both nationally and internationally, and participates in defining

Sanofi's major strategic choices especially as regards mergers, acquisitions and alliances. The Chairman and the Chief Executive Officer, when the two offices are separated, keep each other fully informed of one another's actions.

**Compensation, options and shares awarded to Serge Weinberg (table no. 1 of the AFEP-MEDEF Code)**

( )	2016	2015	2014
Compensation due for the year (details provided in the table below)	708,353	708,218	708,174
Value of stock options awarded during the year	N/A	N/A	N/A
Value of performance shares awarded during the year	N/A	N/A	N/A
Value of other long-term compensation plans	N/A	N/A	N/A
<b>Total</b>	<b>708,353</b>	<b>708,218</b>	<b>708,174</b>

**Compensation awarded to Serge Weinberg (table no. 2 of the AFEP-MEDEF Code)**

( )	2016		2015		2014	
	Payable	Paid	Payable	Paid	Payable	Paid
Fixed compensation <sup>(a)</sup>	700,000	700,000	700,000	700,000	700,000	700,000
Annual variable compensation	N/A	N/A	N/A	N/A	N/A	N/A
Exceptional compensation	N/A	N/A	N/A	N/A	N/A	N/A
Attendance fees	N/A	N/A	N/A	N/A	N/A	N/A
Benefits in kind	8,353	8,353	8,218	8,218	8,174	8,174
<b>Total</b>	<b>708,353</b>	<b>708,353</b>	<b>708,218</b>	<b>708,218</b>	<b>708,174</b>	<b>708,174</b>

The amounts reported are gross amounts before taxes.

(a) Fixed compensation due in respect of a given year is paid during that year.

**Compensation for 2016**

On March 3, 2016, acting on a recommendation from the Compensation Committee, the Board of Directors set the terms of Serge Weinberg's compensation for 2016.

For 2016, his annual fixed compensation was maintained at 700,000.

## Edgar Filing: Sanofi - Form 20-F

In line with our compensation policy he did not receive any variable compensation and was not awarded any stock options or performance shares. Nor did he receive any attendance fees in his capacity as a Director.

The amount reported for benefits in kind relates mainly to a company car with a chauffeur.

Serge Weinberg is not covered by the Sanofi top-up defined-benefit pension plan.

### **Compensation for 2017**

On March 2, 2017, acting on a recommendation from the Compensation Committee, the Board of Directors set the terms of Serge Weinberg's compensation. For 2017, his annual fixed compensation was maintained at 700,000. Consequently, Serge Weinberg's compensation has remained unchanged since his arrival in 2010. In line with AMF recommendations, he will not receive any variable compensation, stock options or performance shares. Nor will he receive any attendance fees.

### **Compensation of the Chief Executive Officer, Olivier Brandicourt**

Olivier Brandicourt has served as Chief Executive Officer since April 2, 2015. He has never had, and does not currently have, a contract of employment with Sanofi.

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****Compensation, options and shares awarded to Olivier Brandicourt (table no. 1 of the AFEP-MEDEF Code)**

	2016	2015
( ) Compensation due for the year (details provided in the table below)	5,155,113	4,386,888
Valuation of stock options awarded during the year <sup>(a)</sup>	1,452,000	3,546,400
Valuation of performance shares awarded during the year <sup>(b)</sup>	3,053,000	3,578,400
Valuation of performance shares awarded in lieu of benefits forfeited <sup>(c)</sup>	0	5,248,320
Valuation of other long-term compensation plans	N/A	N/A
<b>Total</b>	<b>9,660,113</b>	<b>16,760,008</b>

(a) Valuation at the date of grant using the Black & Scholes method assuming fulfillment of the performance conditions.

(b) Valuation at the date of grant assuming fulfillment of the performance conditions, representing the difference between the quoted market price of the share on the date of grant and the current value of the dividends to be paid over the next three years.

(c) Valuation at the date of grant assuming fulfillment of the performance conditions of the 66,000 performance shares awarded on May 4, 2016 upon his taking up office. It represents the difference between the quoted market price of the share on the date of grant and the current value of the dividends to be paid over the next three years.

The parameters used to calculate the valuations are market parameters available in the financial press.

**Compensation awarded to Olivier Brandicourt (table no. 2 of the AFEP-MEDEF Code)**

	2016		2015	
	Payable	Paid	Payable	Paid
( ) Exceptional compensation in lieu of benefits forfeited <sup>(a)</sup>	2,000,000	2,000,000	2,000,000	2,000,000
Exceptional compensation sub-total	2,000,000	2,000,000	2,000,000	2,000,000
Fixed compensation <sup>(b)</sup>	1,200,000	1,200,000	895,455	895,455
Annual variable compensation <sup>(c)</sup>	1,954,800	1,491,300	1,491,300	0
Attendance fees	NA	NA	NA	NA
Benefits in kind	313	313	133	133
Annual compensation sub-total	3,155,113	2,691,613	2,386,888	895,588
<b>Total</b>	<b>5,155,113</b>	<b>4,691,613</b>	<b>4,386,888</b>	<b>2,895,588</b>

The amounts reported are gross amounts before taxes.

(a) Amounts due on taking office, as described below. They only relate to 2015 and 2016.

(b) Fixed compensation due in respect of a given year is paid during that year and (in 2015) was prorated to reflect the period during which he held office.

(c) Variable compensation in respect of a given year is determined and paid at the start of the following year. It is calculated on the basis of annual fixed compensation, to which a monthly pro rata was applied for 2015.

### **Compensation for 2016**

On March 3, 2016, acting on a recommendation from the Compensation Committee, the Board of Directors set the terms of Olivier Brandicourt's compensation for 2016.

His annual compensation for 2016 comprised (i) fixed annual gross compensation of \$1,200,000 (unchanged since he took office) and (ii) variable annual compensation with a target of 150% of his fixed annual compensation, subject to quantifiable and qualitative criteria and capped at 250% of his fixed annual compensation.

Olivier Brandicourt also received in January 2016 the remaining \$2,000,000 lump-sum benefit payable to compensate him for the significant benefits that he forfeited upon his departure from his previous employer. Payment of this lump-sum benefit was subject to a condition of continued employment within Sanofi. This lump-sum benefit aimed at

compensating the significant benefits he forfeited because of his departure from Bayer (variable compensation, equity-based compensation).

For 2016, the variable compensation of Olivier Brandicourt was in a potential range between 0% and 250% of his fixed compensation, with a target of 150%.

His variable compensation for 2016 was established on the basis partly of quantifiable criteria, and partly of qualitative criteria. These criteria related to a series of objectives: 40% based on financial indicators (sales growth one-third, business net income two-thirds), and 60% based on specific individual objectives.

Those individual objectives comprise:

- new product launches (10%);
- research and development (15%);

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

ongoing transformation of Sanofi (25%); and

organization and staff relations (10%).

Qualitative criteria account for 35% of the overall variable compensation objectives, and hence represent a relatively limited proportion of the total.

In addition, acting on the recommendation of the Compensation Committee and in light of experience, the Board of Directors decided that the percentage of variable compensation linked to the attainment of quantifiable criteria could be scaled down regardless of actual performance, in order to give greater weight to the attainment of qualitative criteria. This flexibility can only operate to reduce the amount

of variable compensation, and cannot compensate for underperformance on quantifiable criteria.

In general, the performance criteria applied to variable compensation and to the vesting of stock options and performance shares are exacting, and consistent with our corporate objectives.

For confidentiality reasons, neither the level of attainment required for the quantifiable criteria nor the details of the qualitative criteria can be disclosed; however, they were pre-determined on a precise basis. In evaluating those criteria, the performance of major global pharmaceutical companies is always taken into account.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 2, 2017 reviewed the attainment of each criterion and sub-criterion. The Board's conclusions are summarized in the table below.

	CRITERION	TYPE	WEIGHTING	TARGET/		COMMENTS	ATTAINMENT
				CAP	OUTCOME		
FINANCIAL OBJECTIVES  (40%)	Sales	Quantifiable	13.3%	19.95% /	Slightly below target	Confidential target	194.1%
	Business net income <sup>(a)</sup>	Quantifiable	26.7%	33.25% / 40.05% / 66.75%	Substantially above target		
	New product launches	Quantifiable	10%	15% / 25%	Below target	Confidential target	
	Research and development	Quantifiable	15%	22.5% / 37.5%	Above target	Registrations and submissions in line with budget.	
INDIVIDUAL OBJECTIVES					Proofs of concept in line with budget.		

142.1%

Edgar Filing: Sanofi - Form 20-F

	Ongoing transformation of Sanofi	Qualitative	25%	37.5% / 62.5%	Below target	Promising new product pipeline and control over R&D programs. Closing of the swap with BI, definition of the digital strategy.
	Organization and staff relations	Qualitative	10%	15% / 25%	On target	No significant acquisition Simplification of the organizational structure completed. Work on succession planning ongoing. Executive Committee staffing.
<b>TOTAL</b>			<b>100%</b>	<b>150% / 250%</b>		<b>162.9%</b>

(a) For a definition, see Item 5. Operating and Financial Review and Prospects A.1.5. Segment information 3/ Business Net Income .

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 2, 2017 set Olivier Brandicourt s variable compensation for 2016 at 1,954,800, equivalent to 162.9% of his fixed compensation.

Olivier Brandicourt s 2016 variable compensation is to be paid in 2017.

Olivier Brandicourt is subject to, benefits from and contributes to the same health cover, and death and disability plans, as are applicable to other employees of Sanofi based in France.

He received a benefit in kind in 2016 representing social contribution payments of 313 made by Sanofi on his behalf.

(1) For a definition, see Item 5. Operating and Financial Review and Prospects A.1.5. Segment Information 3/ Business Net Income .

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

Sanofi policy is to make these payments (which arise on employer's pension contributions and are normally payable by the employee) on behalf of all of its employees in France, including Olivier Brandicourt.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of May 4, 2016 decided to award Olivier Brandicourt 220,000 stock subscription options and 50,000 performance shares in respect of the 2016 financial year. The valuation of these awards represents 3.75 times his fixed compensation.

In compliance with the AFEP-MEDEF Code, the entire award is contingent upon both internal criteria based upon business net income<sup>(1)</sup> and return on assets (ROA), and an external criterion based on total shareholder return (TSR) in comparison to a benchmark panel of pharmaceutical companies.

These criteria were selected because they align medium-term equity-based compensation with the strategy adopted by the Company.

The arrangements relating to these awards are as follows:

The performance criterion based on business net income accounts for 50% of the award. This criterion corresponds to the ratio, at constant exchange rates, of actual business net income to budgeted business net income. It represents the average actual-to-budget ratio attained over the entire period. Budgeted business net income is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The business net income objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the ratio is less than 95%, the corresponding options or performance shares will be forfeited.

<b>Actual-to-budget attainment ratio ( R )</b>	<b>Business net income allocation</b>
If R is less than 95%	0%
If R is 95%	50%
If R is > 95% but < 98%	$(50 + [(R - 95) \times 16])\%$
If R is <sup>3</sup> 98% but $\leq$ 105%	R%
If R is > 105% but < 110%	$(105 + [(R - 105) \times 9])\%$
If R is <sup>3</sup> 110%	150%

The ROA criterion accounts for 30% of the award. The award is based on a target ROA, below which some or all of the options or performance shares will be forfeited.

<b>Average ROA ( P )</b>	<b>ROA allocation</b>
If P is $\leq$ the minimum target (M)	0%
If P is between the minimum (M) and intermediate performance (I)	$[30 \times (P - M) / (I - M)]\%$
If P is equal to the intermediate performance (I)	30%
If P is between the intermediate performance (I) and the target ROA (T)	$[70 \times (P - T) / (T - I) + 100]\%$

If P is <sup>3</sup> the target ROA

100%

The TSR criterion accounts for 20% of the award. The overall return to shareholders is evaluated both on the value of Sanofi shares (the increase in the share price) and the value distributed to shareholders (dividends), i.e. the two sources of return on investment in Sanofi shares. Our TSR is compared with a benchmark panel comprised of 10 companies: AstraZeneca, Bayer, BMS, Eli Lilly, GSK, Johnson & Johnson, Merck, Novartis, Pfizer, and Roche. The number of options exercisable and of performance shares vested depends upon our position in comparison to the TSR for the other companies in the panel. Below the median, the corresponding options or performance shares are forfeited.

The median is the performance of the company ranked sixth. The upper bound is the arithmetical average of the

performances of the companies ranked first and second. The intermediate level is equal to:  $\text{median} + ((\text{upper bound} - \text{median}) \div 2)$ .

if Sanofi's TSR is below the median, the TSR allocation will be 0%;

if Sanofi's TSR is equal to the median, the TSR allocation will be 50%;

if Sanofi's TSR is equal to the intermediate level, the TSR allocation will be 100%;

if Sanofi's TSR is greater than or equal to the upper bound, the TSR allocation will be 150%;

if Sanofi's TSR is above the median but below the upper bound, the TSR allocation will be calculated using linear interpolation.

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

- In addition to the three criteria described above, in the case of stock options there is an implicit condition in the form of the exercise price, and a condition of continuing employment within Sanofi.
  - In order to align equity-based compensation with medium-term performance, performance is measured over three financial years.
  - Vesting is subject to a non-compete clause.
  - In the event that Olivier Brandicourt leaves the Company for reasons other than resignation or removal from office for gross or serious misconduct, the overall allocation percentage will be prorated to reflect the amount of time he remained with Sanofi during the vesting period.
  - Until he ceases to hold office, the Chief Executive Officer is required to retain, in registered form, a quantity of Sanofi shares equivalent to (i) 50% of any gain (net of taxes and social contributions) arising on the exercise of stock options and (ii) 50% of any gain (net of taxes and social contributions) arising on the vesting of performance shares, calculated as of the date on which those shares vest.
  - In accordance with the AFEP-MEDEF Code, the Chief Executive Officer is bound by insider trading rules (notably contained in the Board Charter) which stipulate periods during which he must refrain from trading in Sanofi shares.
  - In accordance with the AFEP-MEDEF Code and our Board Charter, Olivier Brandicourt has undertaken to refrain from entering into speculative or hedging transactions, and so far as the Company is aware no such instruments have been contracted.
- The Board regards these performance conditions as good indicators of the development of shareholder value in terms of: the quality of investment decisions in a period where external growth plays a greater role than in the past (ROA condition); a commitment to delivering challenging bottom-line results in a tough business environment (business net income condition); and matching or exceeding our peer group in terms of shareholder returns (TSR condition).
- For confidentiality reasons, the amount of the quantifiable measures for the internal criteria cannot be disclosed. However, they were determined on a precise basis, and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.
- In line with our commitment to transparency, we have since 2011 published in our annual report the level of attainment determined by the Board of Directors for performance conditions applicable to equity-based compensation plans awarded to the Chief Executive Officer and other members of the Executive Committee. The Board believes that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions.

The levels of attainment for equity-based compensation plans that have expired since 2011 are as follows:

## Edgar Filing: Sanofi - Form 20-F

	Business net income	ROA	TSR	Level of attainment
March 9, 2011 plan (stock options only)	2011-2012: 106%	2011-2012: 1.7 percentage points above the target	2011-2012: 100% (5 <sup>th</sup> of 12)	2011-2012: > 100%
	2013-2014: 97.7%	2013-2014: 0.2 percentage point above the target	2013-2014: 78.6% (8 <sup>th</sup> of 11)	2013-2014: 94.8%
March 5, 2012 plans	2012-2014: 84.4%	2012-2014: 0.5 of a percentage point above the target	2012-2014: 57.6% (9 <sup>th</sup> of 11)	i.e. 97.4% for 2011-2014 2012-2014: 85.3%
March 5, 2013 plans	2013-2015: 83.2%	2013-2015: 0.2 of a percentage point above the target	2013-2015: 0% (9 <sup>th</sup> of 11)	2013-2015: 73.3%
March 5, 2014 plans	2014-2016: 101.5%	2014-2016: 0.7 of a percentage point above the target	2014-2016: 0% (11 <sup>th</sup> of 11)	2014-2016: 80.6%

These levels of attainment correspond to equity-based compensation plans awarded to the previous Chief Executive Officer.

### Stock options awarded to Olivier Brandicourt in 2016 (table no. 4 of the AFEP-MEDEF Code)

Source	Date of plan	Type of option	Valuation of options ( )	Number of options granted during the period	Exercise price ( )	Exercise period
Sanofi	05/04/2016	Subscription options	1,452,000	220,000	75.90	05/05/2020 05/04/2026

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

Using the Black & Scholes model, each option awarded on May 4, 2016 was valued at 6.60, valuing the total benefit at 1,452,000.

The Board of Directors had previously decided to limit the number of options that could be awarded to executive officers to 15% of the total limit approved by the Shareholders Annual General Meeting of May 4, 2016 (0.5% of our share capital). The number of options awarded to the Chief Executive Officer in 2016 represents 3.61% of the total limit approved by that Meeting and 54.62% of the total award to all beneficiaries on May 4, 2016.

It is important to note that since 2015, stock options have been restricted to members of the Executive Committee

residing outside France and to beneficiaries in countries where performance shares cannot be granted; they are no longer awarded to all beneficiaries of equity-based compensation plans. This explains why the proportion of options granted to the Chief Executive Officer is higher than in the past.

**Stock options exercised by Olivier Brandicourt in 2016 (table no. 5 of the AFEP-MEDEF Code)**

No stock options are currently exercisable.

**Stock options held by Olivier Brandicourt**

Source	Date of plan	Type of option	Valuation of options ( )	Number of options granted	Exercise price ( )	Exercise period
Sanofi	06/24/2015	Subscription options	3,546,400	220,000	89.38	06/25/2019 06/24/2025
Sanofi	05/04/2016	Subscription options	1,452,000	220,000	75.90	05/04/2026

As of the date of publication of the present report, the total number of unexercised options held by Olivier Brandicourt represented 0.03% of the share capital as at December 31, 2016.

**Performance shares awarded to Olivier Brandicourt in 2016 (table no. 6 of the AFEP-MEDEF Code)**

Source	Date of plan	Valuation of performance shares ( )	Number of performance shares awarded in period	Vesting date	Availability date
Sanofi	05/04/2016	3,053,000	50,000	05/04/2019	05/05/2019

## Edgar Filing: Sanofi - Form 20-F

The award of an extra 5,000 performance shares to Olivier Brandicourt for 2016 as compared with his 2015 award was intended to bring his equity-based compensation more into line with that of his global pharmaceutical industry peers.

Each performance share awarded on May 4, 2016, was valued at 61.06, valuing the total benefit at 3,053,000.

The Board of Directors had previously decided to limit the number of performance shares that could be awarded to executive officers to 5% of the total limit approved by the

Shareholders' Annual General Meeting of May 4, 2016 (1.5% of our share capital). The number of shares awarded to Olivier Brandicourt in 2016 represents 0.26% of the total limit approved by that Meeting and 1.22% of the total award to all beneficiaries on May 4, 2016.

### **Performance shares awarded to Olivier Brandicourt which became available in 2016 (table no. 7 of the AFEP-MEDEF Code)**

No performance shares became available.

### **Performance shares awarded to Olivier Brandicourt**

Source	Date of plan	Valuation of performance shares ( )	Number of performance shares awarded	Vesting date	Availability date
Sanofi	06/24/2015	5,248,320	66,000	06/25/2019	06/26/2019
Sanofi	06/24/2015	3,578,400	45,000	06/25/2019	06/26/2019
Sanofi	05/04/2016	3,053,000	50,000	05/04/2019	05/05/2019

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

As of the date of publication of the present report, the total number of performance shares awarded to Olivier Brandicourt represented 0.01% of our share capital as of December 31, 2016.

**Compensation for 2017**

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 2, 2017 decided to maintain Olivier Brandicourt's fixed annual compensation at the same level as for 2016 (€1,200,000), and also to retain the same variable annual compensation structure whereby 40% is based on financial indicators (sales growth one-third, business net income two-thirds) and 60% on specific individual objectives.

Those individual objectives comprise:

- launch excellence (10%);
- mergers and acquisitions (14%);
- business transformation (12%);
- people and organization (12%); and
- pipeline of new products (12%).

For 2017, Olivier Brandicourt's variable compensation will be in a range between 0% and 250% of his fixed compensation, with a target of 150%.

Acting on a recommendation from the Compensation Committee, the Board of Directors meeting of March 2, 2017 decided to award Olivier Brandicourt 220,000 stock subscription options and 50,000 performance shares in respect of the 2017 financial year.

**Arrangements for executive officers**

**1. Pension arrangements**

Olivier Brandicourt is covered by a top-up defined-benefit pension plan falling within the scope of Article L. 137-11 of the French Social Security Code. For a fuller description of the plan, refer to "Compensation policy for executive officers" above.

Based on the assumptions used in the actuarial valuation of this plan, 541 executives were potentially eligible for this plan (29 retirees, 126 early retirees, 386 active employees) as of December 31, 2016.

Because Olivier Brandicourt has pursued his career in different countries and in different groups, he has not continuously paid into the French compulsory industry schemes. Taking into account the award of a deemed 10 years of service on taking up office, he had accumulated 11.75

## Edgar Filing: Sanofi - Form 20-F

years of service as of December 31, 2016. His reference compensation being limited to 60 times the French social security ceiling (i.e. 2,316,960 in 2016) the theoretical maximum of his top-up pension is currently 17.625% of that amount, i.e. 408,364.

On leaving Sanofi, Olivier Brandicourt may not benefit from our top-up pension plan unless he is entitled to benefit fully from compulsory industry schemes; this requires him to have reached statutory retirement age (which given his age, will not happen before 2018) and to have accumulated the required number of three-month periods of qualifying employment. We do not have sufficient information to determine whether retirement in 2018 is a realistic scenario in terms of his period of qualifying employment, since most of his career has been spent outside France.

If Olivier Brandicourt were to retire in 2018, he would have accumulated 12.75 years of service, entitling him to an annuity equal to 19.125% of his reference compensation. That annuity would supplement any other pension schemes for which he may be eligible in France or abroad, subject to a cap on the total pension from all sources set at 52% of the reference compensation. If the total amount of the annuities paid under all such schemes were to exceed the 52% cap, the amount of the Sanofi top-up defined-benefit pension annuity would be reduced accordingly in order to respect this cap.

The Shareholders' Annual General Meeting of May 4, 2015 approved the section on the pension benefit contained in the auditors' special report on related-party agreements.

Under the terms of Article 229 II of the law on Growth, the Economy and Equality of Opportunity (the Macron Law), Olivier Brandicourt's top-up pension arrangements fall outside the scope of that law in terms of the requirement for pension arrangements to be contingent on performance conditions.

The Sanofi Board of Directors, acting on a recommendation from the Compensation Committee, decided at its meeting of February 7, 2017 to apply a performance condition to the vesting of new contingent rights arising under Olivier Brandicourt's top-up pension plan with effect from January 1, 2017.

The performance condition is applied on the following basis:

- if the level of attainment for variable compensation is equal to or above the target (i.e. 150% of fixed compensation), 100% of the contingent top-up pension rights will vest, corresponding to an uplift of 1.5% in the annual reference compensation used to calculate the annuity payable under the plan;
  - if the level of attainment for variable compensation is less than 100% of fixed compensation, no top-up pension rights will vest for the year in question; and
  - between those two limits, vested rights are calculated on a prorata basis.
- Consequently, the annual uplift in contingent rights is capped at 1.5% of the annual reference compensation used to

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

calculate the annuity payable under the plan, which is below the upper limit of 3% of annual reference compensation stipulated in Article L. 225-42-1 of the French Commercial Code.

Every year, in advance of the Shareholders' Annual General Meeting, the Board of Directors will ascertain whether the performance condition has been met and determine the contingent top-up pension rights that will vest in Olivier Brandicourt.

None of the other terms of the pension plan has changed.

This alteration in pension arrangements will be submitted for approval at the Shareholders' Annual General Meeting of May 10, 2017.

**2. Termination arrangements**

The termination benefit only becomes payable if the departure of the Chief Executive Officer is forced, i.e. in the event of removal from office linked to a change in strategy or control of the Company; for a fuller description of the benefit, refer to Compensation policy for executive officers above.

The amount of the termination benefit is capped at 24 months of his most recent total compensation on the basis of (i) the fixed compensation effective on the date of leaving office and (ii) the last variable compensation received prior to that date, subject to fulfilment of the performance criteria described below.

In accordance with article L. 225-42-1 of the French Commercial Code and with the AFEP-MEDEF Code, payment of the termination benefit is contingent upon fulfillment of two performance criteria, assessed over the three financial years preceding his ceasing to hold office (or the last three completed financial years, if he ceases to hold office before the end of the 2017 financial year). The two criteria are:

- the average of the ratios of business net income<sup>(1)</sup> to net sales for each financial year must be at least 15%;
  - the average of the ratios of operating cash flow before changes in working capital to net sales for each financial year must be at least 18%.
- The amount of the termination benefit will be reduced by any benefit received as consideration for the non-compete undertaking, such that the aggregate amount of those two benefits may never exceed two years of total fixed plus variable compensation.

The Shareholders' Annual General Meeting of May 4, 2015 approved the section on the termination benefit contained in the auditors' special report on related-party agreements.

**3. Non-compete undertaking**

In the event of his departure from the Company, Olivier Brandicourt undertakes not to join a competitor of the Company as an employee or corporate officer, or to provide services to or cooperate with such a competitor, during the 12-month period following his departure.

In return for this undertaking, he will receive an indemnity corresponding to one year's total compensation on the basis of his fixed compensation effective on the day he ceases to hold office and the last individual variable compensation received prior to that date. This indemnity will be payable in 12 monthly installments.

However, the Board of Directors reserves the right to release him from this undertaking for some or all of that 12-month period. In that case, the non-compete indemnity would not be due for the period of time waived by the Company.

## Edgar Filing: Sanofi - Form 20-F

The Shareholders' General Meeting of May 4, 2015 approved the section on non-compete undertakings contained in the auditors' special report on related-party agreements.

### Arrangements in favor of executive officers in office as of December 31, 2016 (table no. 11 of the AFEP-MEDEF Code)

Executive officer	Contract of employment	Top-up pension plan	Compensation or benefits payable or potentially payable on cessation of office	Compensation payable payable under non-compete clause
Serge Weinberg	No	No	No	No
Olivier Brandicourt	No	Yes	Yes	Yes

<sup>(1)</sup> For a definition, see Item 5. Operating and Financial Review and Prospects A.1.5. Segment Information 3/Business Net Income .

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Share ownership and lock-up obligation of the Chief Executive Officer for shares obtained on exercise of stock options or performance shares**

The Chief Executive Officer is bound by the same obligations regarding share ownership specified in our Articles of Association and Board Charter as the other corporate officers.

In addition, until he ceases to hold office the Chief Executive Officer is required to retain a quantity of Sanofi shares equivalent to:

- 50% of any gain (net of taxes and social contributions) arising on the exercise of stock options;
- 50% of any gain (net of taxes and social contributions) arising on the vesting of performance shares, calculated as of the date on which those shares vest.

Those shares must be retained in registered form until he ceases to hold office.

In compliance with the AFEP-MEDEF Code and our Board Charter, Olivier Brandicourt has undertaken to refrain from entering into speculative or hedging transactions, and so far as the Company is aware no such instruments have been contracted.

**Compensation and pension payments for Directors other than the Chief Executive Officer and the Chairman of the Board of Directors**

**Attendance fees (table no. 3 of the AFEP-MEDEF Code)**

The table below shows amounts paid in respect of 2015 and 2016 to each member of the Sanofi Board of Directors, including those whose term of office ended during those years.

Attendance fees in respect of 2015, the amount of which was approved at the Board meeting of March 3, 2016, were partially paid in July 2015. The balance was paid in 2016.

Attendance fees in respect of 2016, the amount of which was approved at the Board meeting of March 2, 2017, were partially paid in July 2016. The balance will be paid in 2017.

For 2016, the basic annual attendance fee was set at 30,000, apportioned on a time basis for directors who assumed or left office during the year.

For 2017, the basic annual attendance fee was maintained at 30,000, apportioned on a time basis for directors who assumed or left office during the year.

The variable portion was determined on the basis of actual attendance by directors at meetings in accordance with the principles specified in our Board Charter, and in the proportions described below:

- Directors resident in France receive 5,000 per Board or Committee meeting, except for Audit Committee meetings for which the fee is 7,500 per meeting;

- Directors resident outside France but within Europe receive 7,000 per Board meeting, and 7,500 per Committee meeting;
- Directors resident outside Europe receive 10,000 per Board meeting, and per Compensation Committee and Strategy Committee meeting;
- the chairman of the Compensation Committee receives 7,500 per Committee meeting;
- the chairman of the Audit Committee receives 10,000 per Committee meeting.

The attendance fee payable to a director who participates by conference call or by videoconference is equivalent to half of the attendance fee received by a director resident in France who attends in person.

As an exception, two meetings held on the same day give entitlement to a single attendance fee:

- if on the day of a Shareholders' General Meeting, the Board of Directors meets both before and after the Meeting, only one attendance fee is paid for the two Board meetings;
- if a director participates in a meeting of the Compensation Committee and a meeting of the Appointments and Governance Committee on the same day, only one attendance fee is paid for both meetings.

Hence, in accordance with the AFEP-MEDEF Code, attendance fees are allocated predominantly on a variable basis.

The introduction of a separate attendance fee scale depending on whether or not the director is a European resident is intended to take into account the significantly longer travel time required to attend meetings in person.

The Shareholders' Annual General Meeting of May 6, 2011 approved a proposal to increase the maximum overall amount of annual attendance fees to 1,500,000.

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

Name	2016				Attendance fees			
	Attendance fees		Pensions paid in 2016	Total gross compensation	Attendance fees		Pensions paid in 2015	Total gross compensation
	Fixed portion	Variable portion			Fixed portion	Variable portion		
( )								
Laurent Attal	30,000	90,000		120,000	15,000	60,000		75,000
Bonnie Bassler <sup>(a)(b)</sup>	22,500	67,500		90,000	15,000	72,500		87,500
Uwe Bicker <sup>(c)(d)</sup>	12,500	43,500		56,000	15,000	82,000		97,000
Robert Castaigne Jean-René	30,000	137,500		167,500	15,000	110,000		125,000
Fourtou <sup>(c)(e)</sup>	12,500	35,000	573,610	621,110	15,000	105,000	1,720,829	1,840,829
Claudie Haigneré	30,000	92,500		122,500	15,000	80,000		95,000
Patrick Kron	30,000	122,500		152,500	15,000	77,500		92,500
Igor Landau <sup>(f)(g)</sup>	-	-	-	-	6,250	22,500	2,355,970	2,384,720
Fabienne Lecorvaisier	30,000	102,500		132,500	15,000	90,000		105,000
Suet-Fern Lee <sup>(a)</sup>	30,000	85,000		115,000	15,000	70,000		85,000
Christian Mulliez	30,000	97,500		127,500	15,000	125,000		140,000
Carole Piwnica <sup>(g)</sup>	30,000	93,750		123,750	15,000	73,750		88,750
Klaus Pohle <sup>(c)(d)</sup>	12,500	50,500		63,000	15,000	87,000		102,000
Diane Souza <sup>(a)(h)</sup>	20,000	77,500		97,500	-	-	-	-
Thomas Südhof <sup>(a)(h)</sup>	20,000	52,500		72,500	-	-	-	-
Gérard Van Kemmel <sup>(f)</sup>	-	-	-	-	6,250	70,000		76,250
<b>Total</b>	<b>340,000</b>	<b>1,147,750</b>	<b>573,610</b>	<b>2,061,360</b>	<b>192,500</b>	<b>1,125,250</b>	<b>4,076,799</b>	<b>5,394,549</b>
<b>Total attendance fees (theoretical)</b>	<b>1,487,750</b>				<b>1,317,750</b>			

The amounts reported are gross amounts before taxes.

(a) Director resident outside Europe.

(b) Left office September 6, 2016.

(c) Left office May 4, 2016.

(d) Director resident outside France but within Europe.

(e) Pension prorated to reflect the period during which he held office.

(f) *Left office May 4, 2015.*

(g) *Foreign director resident in France for tax purposes.*

(h) *Assumed office May 4, 2016.*

## **Pensions**

The amount recognized in the 2016 consolidated income statement in respect of corporate pension plans for corporate officers with current or past executive responsibilities at Sanofi (or companies whose obligations have been assumed by Sanofi) was 1.4 million.

## **Compensation of Senior Management**

The compensation of Executive Committee members other than the Chief Executive Officer is established upon the recommendation of the Compensation Committee, taking into consideration the practices of the leading global pharmaceutical companies.

In addition to fixed compensation, they receive variable compensation. Variable compensation depends on the function and may represent up to 100% of their fixed

compensation. The target amount of the individual variable compensation is determined in line with market practice. It rewards the individual contribution of each Executive Committee member both to Sanofi's performance and to the performance of the operations or functions for which he or she has responsibility.

For 2016, the variable component consisted of two elements:

attainment of quantifiable objectives (accounting for 50%) which are measured (i) at consolidated level (sales growth 30%, business net income 50%, research and development outcomes 20%, plus for this year an upward/downward adjustment mechanism of up to 5% linked to cash flow optimization and a bonus of up to 5% linked to new product launches) and (ii) at the level of the operations or functions for which the Executive Committee member has responsibility; and

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

attainment of quantifiable and qualitative objectives both individually (30%) and collectively (20%) within the Executive Committee (together accounting for 50%).

The indicators used are intended to measure growth (in terms of net sales, business net income, research and development outcomes, sales of new products, and cash flow optimization); talent and critical skills management (including hirings in critical areas for the Group); talent retention; increase in the proportion of women in senior management positions; and promotion of high potential individuals.

For 2016, the total gross compensation paid and accrued in respect of members of the Executive Committee (including Olivier Brandicourt) amounted to 25.4 million, including 9.4 million in fixed compensation.

In addition to this cash compensation, Executive Committee members may be awarded stock options and/or performance shares (see E. Share Ownership below for details of the related plans).

In 2011, the Board of Directors made significant changes to its equity compensation policy. In order to limit the dilutive effect on shareholders, the Board of Directors determined to primarily award performance shares, except for a limited group of high level executives who may continue to receive options. The members of the Executive Committee are included in this limited group. Furthermore, regardless of the identity of the beneficiary, any award of options or performance shares is now fully contingent upon the

performance targets being achieved over several financial years, and upon the beneficiary still being an employee when the option becomes exercisable or the performance share becomes deliverable.

On May 4, 2016, 385,500 stock options and 275,000 performance shares (including the 220,000 options and 50,000 performance shares awarded to Olivier Brandicourt) were awarded to members of the Executive Committee.

In compliance with the AFEP-MEDEF Code, these entire awards are contingent upon two internal criteria, based on business net income<sup>(1)</sup> and return on assets (ROA). These criteria were selected because they align medium-term equity-based compensation with the strategy adopted by Sanofi.

The arrangements relating to these awards are as follows:

The performance criterion based on business net income accounts for 60% of the award. This criterion corresponds to the ratio, at constant exchange rates, of actual business net income to budgeted business net income. It represents the average actual-to-budget ratio attained over the entire period. Budgeted business net income is derived from the budget as approved by the Board of Directors at the beginning of each financial year. The business net income objective may not be lower than the bottom end of the full-year guidance range publicly announced by Sanofi at the beginning of each year. If the ratio is less than 95%, the corresponding options or performance shares will be forfeited.

**Actual-to-budget attainment ratio ( R )**

If R is less than 95%

If R is 95%

If R is > 95% but < 98%

If R is <sup>3</sup> 98% but £ 105%

If R is > 105% but < 110%

**Business net income allocation**

0%

50%

$(50 + [(R - 95) \times 16])\%$

R%

$(105 + [(R - 105) \times 9])\%$

If R is <sup>3</sup> 110%

150%

The ROA criterion accounts for 40% of the award. The award is based on a target ROA, below which some or all of the options or performance shares will be forfeited.

Average ROA ( P )	ROA allocation
If P is £ the minimum target (M)	0%
If P is between the minimum (M) and intermediate performance (I)	$[30 \times (P-M)/(I-M)]\%$
If P is equal to the intermediate performance (I)	30%
If P is between the intermediate performance (I) and the target ROA (T)	$[70 \times (P-T)/(T-I) + 100]\%$
If P is <sup>3</sup> the target ROA	100%

<sup>(1)</sup> For a definition, see Item 5. Operating and Financial Review and Prospects A.1.5. Segment Information 3/ Business Net Income .

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

In addition to the two criteria described above, in the case of stock options there is an implicit condition in the form of the exercise price, and a condition of continuing employment within Sanofi.

In order to align equity-based compensation with medium-term performance, performance is measured over three financial years.

Vesting is subject to a non-compete clause.

In the event of departure from the Company for reasons other than resignation or dismissal for gross or serious misconduct, the overall allocation percentage will be prorated to reflect the amount of time the person remained with Sanofi during the vesting period. The Board regards these performance conditions as good indicators of the development of shareholder value in terms of the quality of investment decisions in a period where external growth plays a greater role than in the past

(ROA condition), and a commitment to delivering challenging bottom-line results in a tough business environment (business net income condition).

For confidentiality reasons, the amount of the quantifiable measures for the internal criteria cannot be disclosed. However, they were determined on a precise basis, and the level of attainment for the internal criteria will be disclosed at the end of the performance measurement period.

In line with our commitment to transparency, we have since 2011 published in our annual report the level of attainment determined by the Board of Directors for performance conditions applicable to equity-based compensation plans awarded to the Chief Executive Officer and other members of the Executive Committee. The Board believes that disclosing the level of attainment allows our shareholders to better understand the demanding nature of the performance conditions.

The levels of attainment for equity-based compensation plans that have expired since 2011 are as follows:

	<b>Business net income</b>	<b>ROA</b>	<b>Level of attainment</b>
March 9, 2011 plan (for stock options only)	2011-2012: 106%	2011-2012: 1.7 percentage points above the target	2011-2012: > 100%
	2013-2014: 97.7%	2013-2014: 0.2 of a percentage point above the target	2013-2014: 98.9%
March 5, 2012 plans	2012-2014: 84.4%	2012-2014: 0.5 of a percentage point above the target	i.e. 99.5% for 2011-2014 2012-2014: 92.2%

## Edgar Filing: Sanofi - Form 20-F

March 5, 2013 plans	2013-2015: 83.2%	2013-2015: 0.2 of a percentage point above the target	2013-2015: 91.6%
March 5, 2014 plans	2014-2016: 101.5%	2014-2016: 0.7 of a percentage point above the target	2014-2016: 100.75%

During 2016, 132,219 stock options were exercised by individuals who were members of the Executive Committee when they exercised.

These exercises related to one option plan that pre-dates the creation of the Executive Committee (sanofi-aventis option plan of December 14, 2006 with an exercise price of \$66.91), and four others that post-date the creation of the Executive Committee (sanofi-aventis option plan of December 13, 2007 with an exercise price of \$62.33, sanofi-aventis option plan of March 3, 2009 with an exercise price of \$45.09, sanofi-aventis option plan of March 9, 2011 with an exercise price of \$50.48, and sanofi-aventis option plan of March 5, 2012 with an exercise price of \$56.44).

Under French law, Directors may not receive options or performance shares solely as compensation for service on our Board, and consequently our Company may grant options only to those Directors who are also our officers.

Because some of our non-executive Directors were formerly officers or executive officers of our Company or its predecessor companies, some of our non-executive Directors hold Sanofi stock options.

We do not have separate profit-sharing plans for key executives. As employees, they are able to participate in our voluntary and statutory profit-sharing schemes on the same terms as our other employees. These plans are described below under [Employees Profit-sharing schemes](#).

The total amount accrued as of December 31, 2016 in respect of corporate pension plans for (i) directors with current or past executive responsibilities at Sanofi or at companies whose obligations have been assumed by Sanofi and (ii) members of the Executive Committee was \$72 million, including \$7 million recognized in the income statement for the year ended December 31, 2016.

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****C. Board Practices**

Neither we nor our subsidiaries have entered into service contracts with members of our Board of Directors or corporate officers providing for benefits upon termination of employment. With respect to Olivier Brandicourt see also B. Compensation Compensation and arrangements for corporate officers above.

**Application of the AFEP-MEDEF Code**

The AFEP-MEDEF Code requires us to specifically report on the application of its recommendations and, if applicable, explain why any of them have not been applied. Sanofi follows the guidelines contained in the AFEP-MEDEF Code as amended. Currently our departures from this Code are as follows:

<b>Paragraph of the AFEP-MEDEF Code</b>	<b>Recommendation of the AFEP-MEDEF code</b>	<b>Application by Sanofi</b>
3.2. The Board of Directors and Strategy	The internal rules of the Board should specify the circumstances in which prior approval by the Board of Directors is required; these may differ between the various operating divisions of the corporation.	The limitations on the powers of the Chief Executive Officer are not contained in our Board Charter (the equivalent document to the internal rules of the Board as referred to in the AFEP-MEDEF Code), but rather in a Board decision of July 28, 2009 (see A. Directors and Senior Management Limitations on the powers of the Chief Executive Officer set by the Board ). Those limitations, like our Board Charter, are published every year in our annual report and on our corporate website. Because there is no difference in terms of transparency or decision making processes, this departure is technical and has no practical repercussions.
8.5.6. Independent Directors	The criteria to be reviewed by the committee and the Board in order for a director to qualify as independent and to prevent risks of conflicts of interest between the director and the management, the corporation, or its group, are the following:  not to have been a director of the corporation for more than twelve years.	Our Board of Directors does not strictly follow the recommendation according to which being a Board member for more than 12 consecutive years is of itself sufficient to automatically disqualify a director from being regarded as independent. The influence of the passage of time on the relationship between a director and the company and/or its management must be evaluated on a case by case basis, and not mechanically. It is only after reviewing all the factors that a director can be determined as being independent or non-independent. While length of service may in certain circumstances be associated with a loss of independence, in other circumstances it may enhance the capacity of a director to question senior management and give greater independence of mind.

In response to a question asked in 2014 by the *Haut Comité de Gouvernement d'Entreprise* (the body in charge of overseeing the implementation of the AFEP-MEDEF Code),

## Edgar Filing: Sanofi - Form 20-F

our Board explained that it considers that its Appointments and Governance Committee is best placed to assess the behavior and hence the true independence of a director.

Our Board of Directors takes the view that it is in no way favoring competence over independence but rather checking a director's willingness and ability to form an independent opinion, ask for

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

<b>Paragraph of the AFEP-MEDEF Code</b>	<b>Recommendation of the AFEP-MEDEF code</b>	<b>Application by Sanofi</b>
9.3. Evaluation of the Board of Directors	<p>The evaluation has three objectives:</p> <ul style="list-style-type: none"> <li>· assess the way in which the Board operates;</li> <li>· check that the important issues are suitably prepared and discussed;</li> <li>· measure the actual contribution of each director to the Board's work.</li> </ul>	<p>further information and question the decisions of Senior Management. Consequently, our Board of Directors provides explanations for the specific cases it reviews (see above, A. Directors and Senior Management – Independence of Board Members).</p> <p>Director independence is assessed on a yearly basis.</p> <p>The issue of competence and individual contribution to the work of the Board and its committees is addressed on a continuous basis with a specific review when a director is up for reappointment as a Board or committee member and not through the annual assessment.</p> <p>The Chairman of the Board continually assesses the involvement of each Board member; annual assessments include one on one interviews with the Secretary to the Board.</p>
24.3.3. Stock options and performance shares	<p>The Board should ensure that awards are made at the same time of year, e.g. after publication of the financial statements for the previous financial year, and preferably on an annual basis.</p>	<p>The Board of Directors retains an independent consultant to perform a formal evaluation every three years. Starting in 2009, our Board of Directors awarded stock options and performance shares at its early March meeting, and hence after publication of the financial statements for the previous year.</p> <p>The awards for 2015 were made at the end of June 2016, for two main reasons. Firstly, the new Chief Executive Officer had not yet joined the Group in March 2016, and it was considered preferable to make the awards to all beneficiaries on the same date. Secondly, the August 6, 2015 Act on Economic Growth, Business and Equal Opportunity (the Macron Act ) had not yet been enacted. In light of the date on which this Act passed into law, a new authorization was approved at the Annual General Meeting of May 4, 2016 in order to implement the provisions of the new Act. Consequently, the awards for 2016 took place after the Annual General Meeting.</p>

The Board intends to continue awarding such plans after the Annual General Meeting.

**Activities of the Board of Directors in 2016**

During 2016, the Board of Directors met ten times, with an overall attendance rate among Board members of over 92%. This attendance rate includes participation by conference call, though only a limited number of directors participated in this way. The individual attendance rates varied between 67% and 100%.

The following persons attended meetings of the Board of Directors in 2016:

- the directors;
- the Secretary to the Board;
- five employee representatives who attend Board meetings without voting rights, pursuant to the agreement of February 24, 2005 setting up a European Works Council; and
- frequently, members of the Executive Committee.

The agenda for each meeting of the Board is prepared by the Secretary after consultation with the Chairman, taking account of the agendas for the meetings of the specialist Committees and the suggestions of the directors.

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

Approximately one week prior to each meeting of the Board of Directors, the directors each receive a file containing the agenda, the minutes of the previous meeting, and documentation relating to the agenda.

The minutes of each meeting are expressly approved at the next meeting of the Board of Directors.

In compliance with our Board Charter, certain issues are examined in advance by the various Committees according to their areas of competence to enable them to make a recommendation; these issues are then submitted for a decision by the Board of Directors.

At the end of 2015, acting on a recommendation from the Appointments and Governance Committee, the Board decided to raise the number of executive sessions (i.e. Board meetings held without the Chief Executive Officer present) to two per year. The primary purpose of such sessions, which take place at the beginning of Board meetings, is to assess the performance of the Chief Executive Officer.

In 2016, the main activities of the Board of Directors related to the following issues:

· financial statements and financial matters:

review of the individual company and consolidated financial statements for the 2015 financial year, review of the individual company and consolidated financial statements for the first half of 2016 and the consolidated financial statements for the first three quarters of 2016, review of the draft press releases and presentations to analysts with respect to the publication of such financial statements, examination of documents relating to management forecasts;

financial arrangements provided for subsidiaries during the 2015 financial year;

delegation of authority to the Chief Executive Officer to issue bonds and guarantees, and renewal of the share repurchase program;

recording the amount of share capital, reducing the share capital through cancellation of treasury shares, and amending the Articles of Association accordingly;

· compensation matters:

determination of the 2015 variable compensation of the Chief Executive Officer, the 2016 fixed and variable compensation of the Chief Executive Officer and the 2016 fixed compensation of the Chairman of the Board, plus an update on fixed and variable compensation of members of the Executive Committee for 2015 and 2016. During the presentation of the report of the Compensation Committee on the compensation of executive officers, the Board of Directors deliberates in executive session in their absence: the Board of Directors first discusses the compensation of the Chairman of the Board in his absence, and then the compensation of the Chief Executive Officer with the Chairman present but the Chief Executive Officer still absent;

## Edgar Filing: Sanofi - Form 20-F

allocation of directors' attendance fees for 2015, principles of allocation for 2016 and allocation of attendance fees for the first half of 2016, and expenses of corporate officers;

adoption of equity-based compensation plans, consisting of stock option plans and performance share plans in respect of 2016, and determination of the fulfillment of performance conditions of previous equity-based compensation plans;

appointments and governance matters:

composition of the Board, proposed reappointment of directors and appointment of two new directors at the 2016 Annual General Meeting, and director independence;

appointment of a new Compensation Committee chairman, and review of the composition of the Committees in view of the new composition of the Board;

review of succession planning;

reviews of the Board of Directors' Management Report, the Chairman's Report and the reports of the statutory auditors;

the notice of meeting for the Annual General Meetings of Shareholders and of Holders of Participating Shares (Series issued in 1983, 1984 and 1987 and Series A participating shares issued in 1989), adoption of (i) the draft resolutions (ii) the report of the Board of Directors on the resolutions and (iii) the special reports on the awards of stock subscription options and performance shares, and examination of questions submitted in writing;

evaluation of the activities of the Board and its Committees;

review of previously-approved related party agreements;

presentations on the Vaccines segment, the diabetes business in the United States, and the diabetes franchise generally;

an update on Depakine®;

review of significant proposed alliances and acquisitions, and strategic opportunities;

Company policy on equal pay and opportunities; and

approval in principle of a share issue reserved for employees.



---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Activities of the Board Committees in 2016**

Since 1999, our Board of Directors has been assisted in its deliberations and decisions by specialist committees. Chairmen and members of these committees are chosen by the Board from among its members, based on their experience.

The Committees are responsible for the preparation of certain items on the agenda of the Board of Directors. Decisions of the Committees are adopted by a simple majority with the chairman of the Committee having a casting vote. Minutes are drafted, and approved by the Committee members.

The chairman of each Committee reports to the Board on the work of that Committee, so that the Board is fully informed whenever it takes a decision.

**Audit Committee**

As of December 31, 2016, this Committee comprised:

- Robert Castaigne, chairman;
- Fabienne Lecorvaisier;
- Christian Mulliez; and
- Carole Piwnica.

Three members of the Audit Committee are classified as independent pursuant to the criteria adopted by the Board of Directors: Robert Castaigne, Fabienne Lecorvaisier, and Carole Piwnica. In addition, all the members, including Christian Mulliez, fulfill the conditions required to be classified as independent under the Sarbanes-Oxley Act.

All four members of the Committee have financial or accounting expertise as a consequence of their education and professional experience, as reflected in their biographies. Furthermore, Robert Castaigne, Fabienne Lecorvaisier, and Christian Mulliez are deemed to be financial experts pursuant to the definition in the Sarbanes-Oxley Act and the definition in Article L. 823-19 of the French Commercial Code. See Item 16A. Audit Committee Financial Expert .

The Audit Committee met seven times in 2016, including prior to the meetings of the Board of Directors during which the financial statements were approved. In addition to the statutory auditors, the principal financial officers, the Senior Vice President Group Internal Audit and other members of the senior management team attended meetings of the Audit Committee, in particular when risk exposure and off-balance-sheet commitments were discussed.

Audit Committee meetings take place at least two days prior to any meetings of the Board of Directors during which the annual or interim financial statements are to be examined.

## Edgar Filing: Sanofi - Form 20-F

The Committee members have a good attendance record, with an overall attendance rate of nearly 93%. Individual attendance rates varied between 86% and 100%.

The statutory auditors attend all meetings of the Audit Committee; they presented their opinions on the annual and half yearly financial statements at the Committee meetings of February 4 and July 26, 2016, respectively.

In 2016, the main activities of the Audit Committee related to:

- preliminary review of the individual company and consolidated financial statements for the 2015 financial year, review of the individual company and consolidated financial statements for the first half of 2016 and of the consolidated financial statements for the first three quarters of 2016, a review of draft press releases and analysts presentations relating to the publication of such financial statements;
- Sanofi's financial position, indebtedness and liquidity;
- review of the investigation and evaluation of internal control for 2015 as certified by the statutory auditors pursuant to Section 404 of the Sarbanes-Oxley Act, and examination of the 2015 Annual Report on Form 20-F;
- reporting on guarantees;
- review of the draft financial resolutions for the May 4, 2016 Shareholders' Annual General Meeting;
- the principal risks facing Sanofi including an update on insurance coverage, report of the Risk Committee, impairment testing of goodwill, review of material whistleblowing and compliance investigations, review of tax risks and deferred tax assets, review of material litigation, and an update on pension funds and actuarial assumptions (meetings of April 26, October 24, and December 13, 2016);
- conclusions of Sanofi senior management on internal control procedures, the Board of Directors' Management Report, the 2015 Report under the French Financial Security Act, and the 2015 Chairman's Report, including the description of risk factors contained in the French-language *Document de Référence*;
- general update on the overall situation regarding information systems and information systems security, and the annual internal audit report; and
- the audit program, allocation of work and fees between the statutory auditors for 2016, and the budget for audit-related services and non-audit services.

The Committee did not have recourse to external consultants in 2016.

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

**Compensation Committee**

As of December 31, 2016, this Committee comprised:

- Patrick Kron, chairman (since May 4, 2016);
- Claudie Haigneré;
- Christian Mulliez; and
- Diane Souza (since May 4, 2016).

Of the four members of the Compensation Committee, three are deemed to be independent.

The Compensation Committee met three times in 2016.

The Committee members have a good attendance record, with an overall attendance rate of 92%. Individual attendance rates varied between 75% and 100%.

When the Committee discusses the compensation policy for members of senior management who are not corporate officers, i.e. members of the Executive Committee, the Committee invites those members of senior management who are corporate officers to attend.

In 2016, the main activities of the Compensation Committee related to:

- fixed and variable compensation of corporate officers and senior management;
- update on the 2015 and 2016 fixed and variable compensation of the members of the Executive Committee;
- setting the amount of directors' attendance fees for 2015, reviewing the expenses of corporate officers for 2015, and principles for allocating directors' attendance fees for 2016;
- review of the governance chapter of the 2015 French-language *Document de Référence*, which contains disclosures about compensation;

## Edgar Filing: Sanofi - Form 20-F

- implementation of the equity-based compensation policy, including both stock options and performance shares, which was discussed at more than one meeting largely because of the need to review termination clauses;
  - review of draft say on pay resolutions to be submitted to the shareholders in 2016, and renewal of the delegation of authority to the Board to award stock options and performance shares;
  - launch of an employee share ownership plan in June 2016, follow-up report on implementation of the plan, and consideration of the next plan;
  - update on changes in say on pay requirements in light of amendments to the AFEP-MEDEF corporate governance code and the Sapin 2 bill; and
  - the top-up defined-benefit pension plan of the Chief Executive Officer.
- The Committee did not have recourse to external consultants in 2016.

### **Appointments and Governance Committee**

As of December 31, 2016, this Committee comprised:

- Serge Weinberg, chairman;
- Claudie Haigneré; and
- Patrick Kron.

All three members of the Appointments and Governance Committee are deemed to be independent.

The Appointments and Governance Committee met five times in 2016.

The Committee's members have a very good attendance record, with an overall attendance rate of 100%.

In 2016, the main activities of the Appointments and Governance Committee related to:

- succession planning;
- results of the evaluation of activities of the Board and its Committees, in conjunction with external consultants;
- review of the Board of Directors Management Report, Chairman's Report, and the governance chapter of the French-language *Document de Référence*;
- changes in the composition of the Board and its Committees, director independence, proposed reappointments of directors, proposed appointments of new directors, appointment of the chairman of the Compensation Committee, update on the composition of the Committees after the May 4, 2016 Shareholders' Annual General Meeting, and update on the recruitment of directors;

## Edgar Filing: Sanofi - Form 20-F

- appointment of employee representative directors; and
  - update on the 2016 annual report of the *Haut Comité de Gouvernement d'Entreprise* (the body in charge of overseeing the implementation of the AFEP-MEDEF Code), on the 2016 AMF report on corporate governance and executive compensation in listed companies, and on the Sapin 2 bill.
- The Committee had recourse to external consultants in 2016 for the evaluation of the Board and its Committees.

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****Strategy Committee**

As of December 31, 2016, this Committee comprised:

- Serge Weinberg, chairman;
- Olivier Brandicourt;
- Laurent Attal; and
- Patrick Kron.

Two of the four members of the Strategy Committee are deemed to be independent.

In 2016, the Strategy Committee met fourteen times, including five times in expanded sessions that included other directors.

The Committee members have a very good attendance record, with an overall attendance rate of nearly 94%. Individual attendance rates varied between 93% and 100%.

The work of the Committee covered in particular an overview of strategy, and several proposed acquisitions and partnership opportunities.

The Committee did not have recourse to external consultants in 2016.

**D. Employees****Number of Employees**

In 2016, Sanofi employed 106,859 people worldwide, 2,230 less than in 2015. The tables below give a breakdown of employees by geographic area and function for the years ended December 31, 2016, 2015 and 2014.

**Employees by geographic area**

	2016		2015		As of December 31, 2014	
	Number	%	Number	%	Number	%
Europe	46,924	43.9%	47,326	43.4%	46,448	43.3%

## Edgar Filing: Sanofi - Form 20-F

Emerging Markets	39,308	36.8%	40,407	37.0%	39,800	37.1%
United States	15,181	14.2%	15,533	14.2%	15,197	14.2%
Rest of the World	5,446	5.1%	5,823	5.3%	5,942	5.5%
<b>Total<sup>(a)</sup></b>	<b>106,859</b>	<b>100.0%</b>	<b>109,089</b>	<b>100.0%</b>	<b>107,387</b>	<b>100.0%</b>

(a) Excludes workforce for the Animal Health business of 6,957 employees in 2016, 6,542 in 2015 and 6,109 in 2014.

### Employees by function

	2016		2015		As of December 31, 2014	
	2016	%	2015	%	2014	%
Sales Force	30,815	28.8%	32,771	30.0%	32,766	30.5%
Research and Development	15,148	14.2%	15,384	14.1%	15,394	14.3%
Production	41,867	39.2%	42,754	39.2%	41,717	38.8%
Marketing and Support Functions	19,029	17.8%	18,180	16.7%	17,510	16.3%
<b>Total<sup>(a)</sup></b>	<b>106,859</b>	<b>100.0%</b>	<b>109,089</b>	<b>100.0%</b>	<b>107,387</b>	<b>100.0%</b>

(a) Excludes workforce for the Animal Health business of 6,957 employees in 2016, 6,542 in 2015 and 6,109 in 2014.

### Industrial Relations

In all countries where we operate, we seek to strike a balance between our economic interests and those of our employees, which we regard as inseparable.

Our responsibility towards our employees is based on the basic principles of our Social Charter, which outlines the rights and duties of all Sanofi employees. The Social Charter addresses our key commitments towards our workforce: equal opportunity for all people without discrimination, the

right to health and safety, respect for privacy, the right to information and professional training, social protection for employees and their families, freedom of association and the right to collective bargaining, and respect for the principles contained in the Global Compact on labor relations and ILO treaties governing the physical and emotional well-being and safety of children.

Our labor relations are based on respect and dialogue. In this spirit, management and employee representatives meet

---

## **Table of Contents**

### **ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

regularly to exchange views, negotiate, sign agreements and ensure that agreements are being implemented.

Employee dialogue takes place in different ways from country to country, as dictated by specific local circumstances. Depending on the circumstances, employee dialogue relating to information, consultation and negotiation processes may take place at national, regional or company level. It may be organized on an interprofessional or sectorial basis, or both. Employee dialogue may be informal or implemented through a specific formal body, or a combination of both methods. Whatever the situation, Sanofi encourages employees to voice their opinions, help create a stimulating work environment and take part in decisions aiming to improve the way we work. These efforts reflect one of the principles of the Social Charter, whereby improving working conditions and the necessary adaptation to our business environment go hand-in-hand.

#### **Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership**

##### **Profit-sharing Schemes**

All employees of our French companies belong to voluntary and statutory profit-sharing schemes.

##### **Voluntary Scheme (*Intéressement des salariés*)**

These are collective schemes that are optional for the employer and contingent upon performance. The aim is to give employees an interest in the growth of the business and improvements in its performance.

The amount distributed by our French companies during 2016 in respect of voluntary profit-sharing for the year ended December 31, 2015 represented 3.10% of total payroll.

In June 2015, Sanofi entered into a two-year agreement, effective from the 2015 financial year, and applicable to all French companies more than 50% owned by Sanofi. Under the agreement, Sanofi will pay collective variable compensation determined on the basis of either (i) growth in our consolidated net sales (at constant exchange rates and on a constant structure basis) or (ii) the level of business net income, whichever is more favorable. For each of these criteria, a matrix will determine what percentage of total payroll is to be allocated to the scheme. This overall allocation is then reduced by the amount required by law to be transferred to a special profit-sharing reserve. The balance is then distributed between the employees, unless the transfer to the reserve exceeds the maximum amount determined under the specified criteria, in which case no profit share is paid to the employees.

##### **Statutory Scheme (*Participation des salariés aux résultats de l'entreprise*)**

The scheme is a French legal obligation for companies with more than 50 employees that made a profit in the previous financial year.

The amount distributed by our French companies during 2016 in respect of the statutory scheme for the year ended December 31, 2015 represented 6.38% of total payroll.

In November 2007, Sanofi entered into a new agreement for an indefinite period, covering all the employees of our French companies.

An amendment to this agreement was signed in April 2009, primarily to align the agreement on a change in French legislation (Law 2008-1258 of December 3, 2008) in order to protect against erosion in purchasing power, under which each qualifying employee can elect to receive some or all of his or her profit-sharing bonus without regard to the normally applicable mandatory lock-up period.

##### **Distribution Formula**

## Edgar Filing: Sanofi - Form 20-F

In order to favor lower-paid employees, the voluntary and statutory profit-sharing agreements entered into since 2005 split the benefit between those entitled as follows:

- 60% prorated on the basis of time spent in the Company's employment in the year; and
- 40% prorated on the basis of gross annual salary during the year, subject to a lower limit equal to the social security ceiling and an upper limit of three times the social security ceiling.

### **Employee Savings Schemes and Collective Retirement Savings Plan**

The employee savings arrangements operated by Sanofi are based on a Group savings scheme (*Plan Épargne Groupe*) and a collective retirement savings plan (*Plan Épargne pour la Retraite Collectif*). These schemes reinvest the sums derived from the statutory and voluntary profit-sharing schemes (compulsory investments), and voluntary contributions by employees.

In June 2016, more than 92% of the employees who benefited from the profit-sharing schemes had opted to invest in the collective savings scheme and nearly 83% of the employees who benefited from the profit-sharing schemes had opted to invest in the collective retirement savings plan.

In 2016, 123.6 million and 57.5 million were invested in the Group savings scheme and the collective retirement

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

savings plan respectively through the voluntary and statutory schemes for 2015, and through top-up contributions.

**Employee Share Ownership**

At December 31, 2016, shares held by employees of Sanofi and of related companies and by former employees under Group employee savings schemes amounted to 1.43% of the share capital.

**E. Share Ownership**

**Senior Management**

Members of the Executive Committee hold shares of our Company amounting in the aggregate to less than 1% of our share capital.

During 2016, 132,219 stock options were exercised by individuals who were members of the Executive Committee when they exercised.

These exercises related to one option plan that pre-dates the creation of the Executive Committee (sanofi-aventis option plan of December 14, 2006 with an exercise price of 66.91), and four others that post-date the creation of the Executive Committee (sanofi-aventis option plan of December 13, 2007 with an exercise price of 62.33, sanofi-aventis option plan of March 3, 2009 with an exercise price of 45.09, sanofi-aventis option plan of March 9, 2011 with an exercise price of 50.48, and sanofi-aventis option plan of March 5, 2012 with an exercise price of 56.44).

**Existing Option Plans as of December 31, 2016**

As of December 31, 2016, a total of 12,065,802 options were outstanding, including 136,843 options to purchase Sanofi shares and 11,928,959 options to subscribe for Sanofi shares. Out of this total, 9,646,903 were immediately exercisable, including 136,843 options to purchase shares and 9,510,060 options to subscribe for shares.

Equity-based compensation, consisting of share subscription option plans and performance share plans, aims to align our employees' objectives with those of our shareholders and to reinforce the link between our employees and Sanofi. Under French law, awarding such plans falls within the powers of the Board of Directors. Stock options are awarded to employees and executive officers by our Board of Directors on the basis of recommendations from the Compensation Committee.

Granting options is a way of recognizing the grantee's performance and contribution to the development of Sanofi, and also of securing his or her future commitment.

For each plan, the Compensation Committee and the Board of Directors assess whether it should take the form of options to subscribe for shares or options to purchase shares, based on criteria that are primarily financial.

A list of grantees is proposed by Senior Management to the Compensation Committee, which reviews the list and then submits it to the Board of Directors, which takes the decision to grant the options. The Board of Directors also sets the terms for the exercise of the options (including the exercise price) and the lock-up period. The exercise price never incorporates a discount, and is at least equal to the average of the quoted market prices on the 20 trading days preceding the date of grant. Stock option plans invariably specify a vesting period of four years and a total duration of ten years.

In 2011, the Board of Directors made substantial changes to our equity-based compensation policy. To limit the dilutive effect on our shareholders, the Board of Directors decided to primarily award performance shares, except for a limited number of high-level executives who could continue to receive options. Regardless of the identity of the grantee, any award of options or performance shares is fully contingent upon

performance targets being achieved over three financial years.

At its meeting of May 4, 2016 the Board of Directors (in addition to the 220,000 options awarded to Olivier Brandicourt) awarded 17 grantees a total of 182,750 stock options, each of which gives entitlement to subscribe for one of our shares. The 2016 awards represent a dilution of approximately 0.03% of our undiluted share capital as of December 31, 2016.

The entire award is contingent upon the same criteria, based on business net income<sup>(1)</sup> and return on assets (ROA), as the award made to members of the Executive Committee. The attainment levels are also the same as for the award made to members of the Executive Committee. Vesting is also subject to a non-compete clause.

The number of options awarded to the Chief Executive Officer in 2016 represents 3.61% of the total limit approved by the Shareholders' Annual General Meeting of May 4, 2016 (0.5% of our share capital) and 54.62% of the total award to all beneficiaries made on that date.

Not all of our employees were awarded stock options, but a new voluntary profit-sharing agreement was signed in June 2015 which gives all of our employees an interest in Sanofi's performance (for more details refer to Profit-sharing Schemes, Employee Savings Schemes and Employee Share Ownership above).

<sup>(1)</sup> For a definition, see Item 5. Operating and Financial Review and Prospects A.1.5. Segment Information 3/ Business Net Income .

**Table of Contents****ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES****Share Purchase Option Plans**

Origin	Date of shareholder authorization	Date of Board grant	Number of options initially granted to corporate officers <sup>(a)</sup>	- to the 10 employees		Start date of exercise period	Expiry date	Purchase price (in )	Number exercised as of 12/31/2016	Number canceled as of 12/31/2016	Number outstanding
				- to	granted the most options <sup>(b)</sup>						
Synthélabo	6/28/1990	1/12/1996	208,000	0	52,000	1/12/2001	1/12/2016	8.56	208,000	0	0
Synthélabo	6/28/1990	4/05/1996	228,800	0	67,600	4/05/2001	4/05/2016	10.85	228,000	0	0
Synthélabo	6/23/1998	3/30/1999	716,040	0	176,800	3/31/2004	3/30/2019	38.08	573,477	5,720	136,843

(a) Includes the Chairman and Chief Executive Officer, the Chief Executive Officer or equivalent officers as of the date of grant.

(b) Employed as of the date of grant.

**Share Subscription Option Plans**

Origin	Date of shareholder authorization	Date of Board grant	Number of options initially granted to corporate officers <sup>(a)</sup>	- to the 10 employees		Start date of exercise period	Subscription Expiry date	Subscription price (in )	Number exercised as of 12/31/2016	Number canceled as of 12/31/2016 <sup>(c)</sup>	Number outstanding
				- to	granted the most options <sup>(b)</sup>						
sanofi-aventis	5/31/2005	12/14/2006	11,772,050	450,000	585,000	12/15/2010	12/14/2016	66.91	9,985,659	1,793,251	0
sanofi-aventis	5/31/2007	12/13/2007	11,988,975	325,000	625,000	12/14/2011	12/13/2017	62.33	7,720,572	1,085,570	3,186,133
sanofi-aventis	5/31/2007	3/02/2009	7,736,480	250,000	655,000	3/04/2013	3/01/2019	45.09	5,084,893	633,045	2,019,542
sanofi-aventis	4/17/2009	3/01/2010	7,316,355	0	665,000	3/03/2014	2/28/2020	54.12	3,647,346	661,920	3,010,864
sanofi-aventis	4/17/2009	3/01/2010	805,000	275,000	805,000	3/03/2014	2/28/2020	54.12	606,150	50,000	148,850
sanofi-aventis	4/17/2009	3/09/2011	574,500	0	395,000	3/10/2015	3/09/2021	50.48	165,234	35,454	373,812
sanofi-aventis	4/17/2009	3/09/2011	300,000	300,000	0	3/10/2015	3/09/2021	50.48	150,000	7,800	142,200
Sanofi	5/06/2011	3/05/2012	574,050	0	274,500	3/06/2016	3/05/2022	56.44	66,154	83,957	423,939
Sanofi	5/06/2011	3/05/2012	240,000	240,000	0	3/06/2016	3/05/2022	56.44	0	35,280	204,720
Sanofi	5/06/2011	3/05/2013	548,725	0	261,000	3/06/2017	3/05/2023	72.19	0	89,371	459,354
Sanofi	5/06/2011	3/05/2013	240,000	240,000	0	3/06/2017	3/05/2023	72.19	0	64,080	175,920
Sanofi	5/03/2013	3/05/2014	769,250	0	364,500	3/06/2018	3/05/2024	73.48	0	61,375	707,875
Sanofi	5/03/2013	3/05/2014	240,000	240,000	0	3/06/2018	3/05/2024	73.48	0	0	240,000
Sanofi	5/03/2013	6/24/2015	12,500	0	12,500	6/25/2019	6/24/2025	89.38	0	1,500	11,000
Sanofi	5/03/2013	6/24/2015	202,500	0	202,500	6/25/2019	6/24/2025	89.38	0	0	202,500
Sanofi	5/03/2013	6/24/2015	220,000	220,000	0	6/25/2019	6/24/2025	89.38	0	0	220,000
Sanofi	5/04/2016	5/04/2016	17,750	0	17,750	5/05/2020	5/04/2026	75.90	0	500	17,250
Sanofi	5/04/2016	5/04/2016	165,000	0	165,000	5/05/2020	5/04/2026	75.90	0	0	165,000
Sanofi	5/04/2016	5/04/2016	220,000	220,000	0	5/05/2020	5/04/2026	75.90	0	0	220,000

## Edgar Filing: Sanofi - Form 20-F

*(a) Includes the Chairman and Chief Executive Officer, the Chief Executive Officer, or equivalent officers as of the date of grant.*

*(b) Employed as of the date of grant.*

*(c) Including 183,640 options canceled due to the partial non-fulfillment of the performance conditions.*

The main characteristics of our stock options are also described in Note D.15.8. to our consolidated financial statements, included in Item 18 of this annual report.

### **Existing Restricted Share Plans as of December 31, 2016**

Since 2009, the Board of Directors has awarded shares to certain employees in order to give them a direct stake in the Company's future and performances via trends in the share price, as a partial substitute for the granting of stock options.

Shares are awarded to employees on the basis of a list submitted to the Compensation Committee. This Committee then submits this list to the Board of Directors, which decides whether to award the shares. The Board of Directors sets

the continuing employment conditions to which vesting is subject, and any lock-up conditions for the shares.

In 2011, the Board of Directors made substantial changes to our equity-based compensation policy. To limit the dilutive effect on our shareholders, the Board of Directors decided to primarily award performance shares, except for a limited number of high-level executives who could continue to receive options. Under this new policy, any award of options or performance shares is fully contingent upon performance targets being achieved over three financial years, regardless of the identity of the grantee.

Our share plans have a three-year vesting period, with no lock-up period.

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

At its meeting of May 4, 2016, the Board of Directors awarded four plans, in addition to the plan awarded to the Chief Executive Officer:

- a France plan, under which 2,483 beneficiaries were awarded a total of 1,289,825 shares;
  - an Executive Committee France plan, under which seven beneficiaries were awarded a total of 132,000 shares;
  - an International plan, under which 5,220 beneficiaries were awarded a total of 2,553,100 shares; and
  - an Executive Committee International plan, under which six beneficiaries were awarded a total of 93,000 shares.
- The 2016 awards represent a dilution of approximately 0.32% of our undiluted share capital as of December 31, 2016.

The entirety of these awards is contingent upon the same criteria, based on business net income<sup>(1)</sup> and return on assets (ROA), as the award made to members of the Executive Committee. The attainment levels are also the same as for the award made to members of the Executive Committee. Vesting is now subject to a non-compete clause.

The number of performance shares awarded to the Chief Executive Officer in 2016 represents 0.26% of the total limit approved by the Shareholders' Annual General Meeting of May 4, 2016 (1.5% of the share capital) and 1.22% of the total amount awarded to all beneficiaries on that date.

Not all of our employees were awarded performance shares, but a new voluntary profit-sharing agreement was signed in June 2015 which gives all of our employees an interest in Sanofi's performance (for more details see Profit-Sharing Schemes, Employee Savings Schemes and Employee Share Ownership above).

**Restricted Share Plans**

Origin	Date of authorization	Date of award	Number			Date of award <sup>(c)</sup>	Vesting date	Availability date	Number transferred as of 12/31/2016	Number of rights canceled as of 12/31/2016 <sup>(d)</sup>	Number outstanding
			of shares initially awarded	- to corporate officers <sup>(a)</sup>	- to the 10 employees awarded the most shares <sup>(b)</sup>						
Sanofi	4/17/2009	3/05/2012	1,519,430	0	126,700	3/05/2012	3/06/2015	3/06/2017	1,377,886	141,790	0
Sanofi	4/17/2009	3/05/2012	5,670	0	5,670	3/05/2012	3/06/2016	3/06/2016	5,232	438	0
Sanofi	4/17/2009	3/05/2012	3,127,160	0	96,300	3/05/2012	3/06/2016	3/06/2016	2,378,237	759,891	0

## Edgar Filing: Sanofi - Form 20-F

Sanofi	4/17/2009	3/05/2012	42,000	42,000	0	3/05/2012	3/06/2015	3/06/2017	35,826	6,174	0
Sanofi	5/04/2012	3/05/2013	1,400,260	0	97,300	3/05/2013	3/06/2016	3/06/2018	1,248,635	152,041	0
Sanofi	5/04/2012	3/05/2013	11,650	0	1,550	3/05/2013	3/06/2017	3/06/2017	0	975	10,675
Sanofi	5/04/2012	3/05/2013	2,838,795	0	85,100	3/05/2013	3/06/2017	3/06/2017	6,200	621,217	2,218,214
Sanofi	5/04/2012	3/05/2013	45,000	45,000	0	3/05/2013	3/06/2016	3/06/2018	32,985	12,015	0
Sanofi	5/04/2012	3/05/2014	1,246,320	0	28,060	3/05/2014	3/06/2017	3/06/2019	0	33,900	1,212,420
Sanofi	5/04/2012	3/05/2014	2,605,515	0	35,400	3/05/2014	3/06/2017	3/06/2019	3,500	279,215	2,236,700
Sanofi	5/04/2012	3/05/2014	11,300	0	11,300	3/05/2014	3/06/2018	3/06/2018	0	0	11,300
Sanofi	5/04/2012	3/05/2014	45,000	45,000	0	3/05/2014	3/06/2017	3/06/2019	0	0	45,000
Sanofi	5/04/2015	6/24/2015	1,142,470	0	63,000	6/24/2015	6/25/2018	6/25/2020	0	20,300	1,122,170
Sanofi	5/04/2015	6/24/2015	129,000	0	129,000	6/24/2015	6/25/2018	6/25/2020	0	0	129,000
Sanofi	5/04/2015	6/24/2015	14,950	0	14,950	6/24/2015	6/25/2019	6/25/2019	0	0	14,950
Sanofi	5/04/2015	6/24/2015	2,310,920	0	84,500	6/24/2015	6/25/2019	6/26/2019	2,100	141,920	2,166,000
Sanofi	5/04/2015	6/24/2015	124,500	0	124,500	6/24/2015	6/25/2019	6/26/2019	0	0	124,500
Sanofi	5/04/2015	6/24/2015	66,000	66,000	0	6/24/2015	6/25/2019	6/26/2019	0	0	66,000
Sanofi	5/04/2015	6/24/2015	45,000	45,000	0	6/24/2015	6/25/2019	6/26/2019	0	0	45,000
Sanofi	5/04/2016	5/04/2016	1,289,825	0	74,400	5/04/2016	5/04/2019	5/05/2019	0	5,600	1,284,225
Sanofi	5/04/2016	5/04/2016	2,533,100	45,000	113,750	5/04/2016	5/04/2019	5/05/2019	0	41,000	2,492,100
Sanofi	5/04/2016	5/04/2016	132,000	66,000	132,000	5/04/2016	5/04/2019	5/05/2019	0	0	132,000
Sanofi	5/04/2016	5/04/2016	93,000	45,000	93,000	5/04/2016	5/04/2019	5/05/2019	0	0	93,000
Sanofi	5/04/2016	5/04/2016	50,000	50,000	0	5/04/2016	5/04/2019	5/05/2019	0	0	50,000

(a) Includes the Chief Executive Officer as of the date of grant.

(b) Employed as of the date of grant.

(c) Subject to vesting conditions.

(d) Including 684,672 rights canceled due to the partial non-fulfillment of the performance conditions.

(1) For a definition, see Item 5. Operating and Financial Review and Prospects A.1.5. Segment Information 3/Business Net Income .

---

**Table of Contents**

**ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

As of December 31, 2016, a total of 13,543,254 restricted shares were outstanding and contingent upon performance conditions.

**Shares Owned by Members of the Board of Directors**

As of December 31, 2016, members of our Board of Directors held in the aggregate 12,659 shares, or under 1% of the share capital and of the voting rights, excluding the beneficial ownership of 118,227,307 shares held by L. Oréal as of such date which may be attributed to Laurent Attal or Christian Mulliez (who disclaim beneficial ownership of such shares).

**Transactions in Shares by Members of the Board of Directors and equivalent persons in 2016**

As far as Sanofi is aware, transactions in our securities by Board members, senior executives who have the power to take managerial decisions affecting the future developments and business prospects of Sanofi<sup>(1)</sup> and persons with whom they have close personal ties (as per Article L. 621-18-2 of the French Monetary and Financial Code) during the year ended December 31, 2016 were as follows:

- On February 15, 2016 Olivier Brandicourt, Chief Executive Officer, acquired 1,000 shares at a price of 70.48 per share.
- On March 7, 2016 Elias Zerhouni, President Global Research and Development, sold 6,769 shares at a price of 68.09 per share.
- On May 30, 2016 Peter Guenter, Executive Vice President General Medicines and Emerging Markets, sold 5,164 shares at a price of 73.95 per share.
- On June 1, 2016 Karen Linehan, Executive Vice President Legal Affairs and General Counsel, sold 6,000 shares at a price of 73.81 per share.
- On June 1, 2016 Jérôme Contamine, Executive Vice President Chief Financial Officer, exercised 22,000 stock subscription options at an exercise price of 50.48 per share, and sold the resulting 22,000 shares at a price of 73.15 per share.
- On June 20, 2016 Diane Souza, Director, acquired 2,000 American Depositary Receipts (ADRs) at a price of \$39.49 per ADR.
- On July 22, 2016 Olivier Charmeil, Executive Vice President General Medicines and Emerging Markets, subscribed for 1,500 units in the FCPE Actions Sanofi fund at a price of 57.25 per unit in connection with the capital increase reserved for members of the Group savings scheme.
- On July 22, 2016 Jérôme Contamine, Executive Vice President Chief Financial Officer, subscribed for 1,500 units in the FCPE Actions Sanofi fund at a price of 57.25 per unit in connection with the capital increase reserved for members of the Group savings scheme.

## Edgar Filing: Sanofi - Form 20-F

On July 22, 2016 Peter Guenter, Executive Vice President Diabetes and Cardiovascular, subscribed for 1,500 units in the FCPE Actions Sanofi fund at a price of 57.25 per unit in connection with the capital increase reserved for members of the Group savings scheme.

On December 6, 2016 Thomas Südhof, Director, acquired 997.38 ADRs at a price of \$40.61 per ADR.

**178**

*(1) The list of these persons is regularly updated.*

**Table of Contents****ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS****Item 7. Major Shareholders and Related Party Transactions****A. Major Shareholders**

The table below shows the ownership of our shares as of January 31, 2017, indicating the beneficial owners of our shares. To the best of our knowledge and on the basis of the notifications received as disclosed below, except for L Oréal and BlackRock, Inc., no other shareholder currently holds more than 5% of our share capital or voting rights.

	Total number of issued shares		Number of actual voting rights (excluding treasury shares) <sup>(d)</sup>		Theoretical number of voting rights (including treasury shares) <sup>(e)</sup>	
	Number	%	Number	%	Number	%
<b>L Oréal</b>	118,227,307	9.15	236,454,614	16.81	236,454,614	16.46
<b>BlackRock<sup>(a)</sup></b>	65,042,862	5.03	65,042,862	4.62	65,042,862	4.53
<b>Treasury shares<sup>(b)</sup></b>	29,399,875	2.28			29,399,875	2.05
<b>Employees<sup>(c)</sup></b>	18,337,242	1.42	33,980,593	2.42	33,980,593	2.37
<b>Public</b>	1,061,130,498	82.12	1,071,333,632	76.15	1,071,333,632	74.59
<b>Total</b>	<b>1,292,137,784</b>	<b>100</b>	<b>1,406,811,701</b>	<b>100</b>	<b>1,436,211,576</b>	<b>100</b>

(a) Based on BlackRock's declaration as of January 31, 2017.

(b) Includes net position of share repurchases under the Group's liquidity contract which amounted to zero shares as of January 31, 2017. Amounts held under this contract vary over time.

(c) Shares held via the Sanofi Group Employee Savings Plan.

(d) Based on the total number of voting rights as of January 31, 2017.

(e) Based on the total number of voting rights as of January 31, 2017 as published in accordance with article 223-11 and seq. of the General Regulations of the Autorité des Marchés Financiers (i.e. including treasury shares, the voting rights of which are suspended).

## Edgar Filing: Sanofi - Form 20-F

Our Articles of Association provide for double voting rights for shares held in registered form for at least two years. All of our shareholders may benefit from double voting rights if these conditions are met, and no shareholder benefits from specific voting rights. For more information relating to our shares, see Item 10. Additional Information B. Memorandum and Articles of Association.

Neither L Oréal nor BlackRock holds different voting rights from those of our other shareholders.

To the best of our knowledge, no other shareholder currently holds, directly or indirectly and acting alone or in concert, more than 5% of our share capital or voting rights.

During the year ended December 31, 2016 we received a number of share ownership declarations informing us that a legal threshold had been passed, as required under Article L. 233-7 of the French Commercial Code.

Following purchases of our shares in the market, BlackRock, Inc., acting on its own behalf and on behalf of its affiliates, declared that it had passed first above and then below the threshold of 5% of our voting rights, and that at the time of

the most recent declaration held 5.54% of our share capital and 4.98% of our voting rights (declaration of August 26, 2016).

During the year ended December 31, 2016, we were informed pursuant to Article L. 233-7 of the French Commercial Code that the following share ownership declaration thresholds stipulated by our Articles of Association had been passed:

- Dodge & Cox declared that it had passed above the threshold of 4% of our share capital (declaration of May 27, 2016) and then above the 4% threshold of our voting rights, and at the time of the most recent declaration held 4.46% of our share capital and 4.01% of our voting rights (declaration of October 10, 2016);
- Franklin Resources, Inc. declared that it had passed above the threshold of 2% of our share capital, and at the time of the most recent declaration held 2.01% of our share capital and 1.81% of our voting rights (declaration of July 1, 2016);

---

**Table of Contents**

**ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

- Natixis Asset Management declared that it had passed above the threshold of 2% of our voting rights (declaration of April 22, 2016), then below the threshold of 2% of our voting rights (declaration of May 17, 2016), then above the threshold of 1% of our voting rights and finally below the 1% threshold of our voting rights (declaration of May 23, 2016), and at the time of the most recent declaration held 0.99% of our voting rights;
- Norges Bank declared that it had passed below the threshold of 2% of our share capital and at the time of the most recent declaration held 1.99% of our share capital (declaration of March 2, 2016); and
- Silchester International Investor LLP declared that it had passed above the threshold of 1% of our share capital and at the time of the most recent declaration held 1.01% of our share capital and 0.91% of our voting rights (declaration of August 12, 2016).

Since January 1, 2017 we have received the following share ownership declarations required by law:

Following purchases and sales of our shares in the market, BlackRock, Inc., acting on its own behalf and on behalf of its affiliates, declared that it had passed above and below the threshold of 5% of our share capital, and that at the time of the most recent declaration held 4.93% of our share capital and 4.44% of our voting rights (declaration of February 2, 2017).

Since January 1, 2017 we have received the following share ownership declarations required under our Articles of Association:

- Norges Bank declared that it had passed above the threshold of 2% of our share capital and at the time of the most recent declaration held 2.001% of our share capital (declaration of February 1, 2017); and
- Franklin Resources, Inc. declared that it had passed below the threshold of 2% of our share capital, and at the time of the most recent declaration held 1.98% of our share capital and 1.78% of our voting rights (declaration of February 16, 2017).

As of December 31, 2016, individual shareholders (including employees of Sanofi and its subsidiaries, as well as retired employees holding shares via the Sanofi Group Employee Savings Plan) held approximately 7.4% of our share capital. Institutional shareholders (excluding L'Oréal) held approximately 77.8% of our share capital. Such shareholders are primarily American (30.7%), French (13.7%) and British (13.2%). German institutions held 3.3% of our share capital, Swiss institutions held 2.5%, institutions from other European countries held 7.2% and Canadian institutions held 1.7% of our share capital. Other international institutional investors (excluding those from Europe and North America) held approximately 5.5% of our share capital. In France, our home country, we have 24,743 identified shareholders of record. In the United States, our host country, we have 51 identified shareholders of record and 18,385 identified ADS holders of record.

(Source: a survey conducted by Euroclear France as of December 31, 2016, and internal information).

**Shareholders Agreement**

We are unaware of any shareholders agreement currently in force.

**B. Related Party Transactions**

See Note D.33. to our consolidated financial statements included at Item 18 of this annual report.

**C. Interests of Experts and Counsel**

N/A

**180**

**Table of Contents****ITEM 8. FINANCIAL INFORMATION****Item 8. Financial Information****A. Consolidated Financial Statements and Other Financial Information**

Our consolidated financial statements as of and for the years ended December 31, 2016, 2015, and 2014 are included in this annual report at Item 18. Financial Statements.

**Dividends on Ordinary Shares**

We paid annual dividends for the years ended December 31, 2012, 2013, 2014 and 2015 and our shareholders will be asked to approve the payment of an annual dividend of 2.96 per share for the 2016 fiscal year at our next annual shareholders' meeting. If approved, this dividend will be paid on May 18, 2017.

We expect that we will continue to pay regular dividends based on our financial condition and results of operations. The proposed 2016 dividend equates to a distribution of 52% of our business earnings per share. For information on the non-GAAP financial measure business earnings per share see Item 5. Operating and Financial Review and Prospects Business Net Income. The proposed dividend distribution will subject Sanofi to a 3% additional corporate tax charge on the amount distributed.

The following table sets forth information with respect to the dividends paid by our Company in respect of the 2012, 2013, 2014 and 2015 fiscal years and the dividend that will be proposed for approval by our shareholders in respect of the 2016 fiscal year at our May 10, 2017 shareholders meeting.

	2016 <sup>(a)</sup>	2015	2014	2013	2012
Dividend per Share (in €)	2.96	2.93	2.85	2.80	2.77
Dividend per Share (in \$) <sup>(b)</sup>	3.12	3.19	3.46	3.86	3.65

(a) Proposal, subject to shareholder approval.

(b) Based on the relevant year-end exchange rate.

The declaration, amount and payment of any future dividends will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Any declaration will depend on our results of operations, financial condition, cash requirements, future prospects and other factors deemed relevant by our shareholders. Accordingly, we cannot assure you that

## Edgar Filing: Sanofi - Form 20-F

we will pay dividends in the future on a continuous and regular basis. Under French law, we are required to pay dividends approved by an ordinary general meeting of shareholders within nine months following the meeting at which they are approved.

### **Disclosure pursuant to Section 13(r) of the United States Exchange Act of 1934**

Sanofi conducts limited business relating to human and animal health products with Iran contributing well under 1% of Sanofi's consolidated net sales in 2016. These activities, which are not financially material to Sanofi, are being disclosed pursuant to Section 13(r) of the United States Exchange Act of 1934, as amended. Sales consisted of bulk and branded pharmaceuticals, vaccines, and animal health supplies. U.S. affiliates of Sanofi, or foreign affiliates controlled by U.S. affiliates of Sanofi, are either not involved in these activities or operate under humanitarian licenses issued by the U.S. Treasury Department's Office of Foreign Assets Control. Limited business amounting to approximately 12.2 million in gross revenues has been conducted by non-U.S. subsidiaries of Sanofi not requiring an OFAC license with entities such as public hospitals or distributors tied to the Ministry of Health or Ministry of Agriculture. It is estimated that this activity contributed no

more than 5 million to net profits. A representative office in Tehran incurs incidental expenses from state-owned utilities.

In January 2016, Sanofi and the Iran Food and Drug Administration, affiliated with the Ministry of Health and Medical Education of the Islamic Republic of Iran, signed a Memorandum of Cooperation (MoC) regarding (i) potential future projects to reinforce current partnerships with reputable Iranian manufacturers (in particular to enhance industrial quality standards), (ii) collaborating with the Ministry of Health on programs for the prevention and control of certain chronic and non-communicable diseases (in particular diabetes) and (iii) potential future collaboration on epidemiological studies. The MoC did not generate any revenue, nor any net profit.

Sanofi believes its activities are compliant with applicable law. In light of the nature of the activities concerned, Sanofi and its affiliates intend to continue their activities in Iran.

### **Information on Legal or Arbitration Proceedings**

This Item 8 incorporates by reference the disclosures found in Note D.22. to the consolidated financial statements found at Item 18 of this annual report; material updates thereto as of the date of this annual report are found below under the heading **B. Significant Changes** Updates to Note D.22 .

Sanofi and its subsidiaries are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial

**Table of Contents****ITEM 8. FINANCIAL INFORMATION**

claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. As a result, the Group may become subject to substantial liabilities that may not be covered by insurance and could affect our business and reputation. While we do not currently believe that any of these legal proceedings will have a material adverse effect on our financial position, litigation is inherently unpredictable. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on results of operations, cash flows and/or our reputation.

**Patents*****Co-Aprovel® Patent Infringement Actions (Europe)***

Sanofi has been involved since early 2012 in a number of legal proceedings involving generic companies that attempted to launch or launched generic versions of Sanofi's Co-Aprovel® in several European countries including the United Kingdom, Belgium, France, Germany, the Netherlands, Italy and Norway. Sanofi filed for and was granted preliminary injunctions (PI) against several generic companies based on Sanofi's Supplemental Protection Certificate (SPC) covering Co-Aprovel® until October 15, 2013. The UK Court referred the question on the validity of the Co-Aprovel® SPC to the Court of Justice of the European Union (CJEU) in October 2012.

Following the CJEU decision of December 12, 2013 that declared the Co-Aprovel® SPC invalid, generic companies (whose products were withdrawn from the market due to national preliminary injunctions or cross-undertakings) have filed damages claims against Sanofi in several countries.

***Lantus® and Lantus® SoloSTAR® Patent Litigation (United States, France and Japan)***

In December 2013, January 2014 and May 2014, Sanofi received notifications from Eli Lilly and Company (Lilly), stating that Lilly had filed two NDAs (505(b)(2) New Drug Application) with the FDA for two insulin glargine drug products. Lilly's NDAs also included Paragraph IV certifications directed to Sanofi patents listed in the FDA Orange Book for Sanofi's Lantus® and/or Lantus® SoloStar® products. In 2014, Sanofi filed patent infringement suits against Lilly in the United States District Court for the District of Delaware. The second of these two lawsuits was dismissed in May 2015 in light of Lilly's withdrawal of its second 505(b)(2) New Drug Application from FDA review.

In August 2014, Sanofi filed patent infringement law suits against Lilly in France, based on different patents (protecting the insulin glargine, a manufacturing process and a device). In June 2015, Sanofi unilaterally withdrew the lawsuit in France against Lilly regarding the compound and the process patent.

On December 8, 2014, Sanofi filed a petition for a preliminary injunction against Lilly's insulin glargine biosimilar pre-loaded in its MirioPen® with the Tokyo District

Court based on a Japanese device patent that Sanofi subsequently withdrew. In January 2015, Lilly filed an invalidation action concerning this Sanofi Japanese device patent with the Japanese Patent Office.

In September 2015, Sanofi entered into a settlement agreement with Lilly with respect to certain Sanofi patents relating to the Lantus® SoloStar® (insulin glargine) product. The settlement resolves the US patent infringement lawsuit regarding Lilly's application for marketing approval for a competing product to Lantus® SoloStar®. Sanofi and Lilly agreed to dismiss this US patent infringement lawsuit and to discontinue similar disputes worldwide. Under the terms of the settlement, Lilly will make royalty payments to Sanofi in exchange for a license to certain Sanofi

patents. Lilly did not sell its insulin glargine product in the US before December 15, 2016. The agreement does not extend to the Lantus<sup>®</sup> vial product, Toujeo<sup>®</sup> or combination products.

Following the settlement with Lilly, all of the US, French and Japanese disputes with Lilly with respect to Lantus<sup>®</sup> SoloStar<sup>®</sup> were discontinued.

***Lantus<sup>®</sup> Merck Patent Litigation (United States)***

Sanofi-Aventis Deutschland GmbH, Sanofi-Aventis US LLC, and Sanofi Winthrop Industries initiated suit against Merck Sharp & Dohme Corp. ( Merck ) on September 16, 2016 in the United States District Court for the District of Delaware in response to receipt of notification from Merck that it had filed an NDA 505(b)(2) New Drug Application with the FDA for an insulin glargine drug product which included paragraph IV certifications challenging all ten patents Sanofi had listed in the FDA Orange Book for Sanofi s Lantus<sup>®</sup> and Lantus<sup>®</sup> SoloStar<sup>®</sup> products. The 30-month stay preventing the FDA from approving Merck s insulin glargine drug product expires on the earlier of (i) February 8, 2019 or (ii) a court decision in favor of Merck. The Court has scheduled a bench trial to begin on May 29, 2018, a claim construction hearing for August 21, 2017 and briefing on Summary Judgment Motions on certain issues pertaining to some of the patents-in-suit to begin on October 2, 2017.

***Multaq<sup>®</sup> Patent Litigation (United States)***

From January 2014 to November 2014, several generic manufacturers notified Sanofi that they had filed Abbreviated New Drug Applications (ANDAs) seeking FDA approval to market generic versions of Multaq<sup>®</sup> (dronedarone hydrochloride) in the US. In April 2015, Sanofi received a tenth notice directed to Multaq<sup>®</sup> from Lupin. The notices challenged some, but not all, of the patents listed by Sanofi in the FDA s Orange Book in connection with Multaq<sup>®</sup>. None of the ANDA filers challenged the patent directed to the active ingredient in Multaq<sup>®</sup>, US Patent No. 5,223,510 (the 510 patent).

Sanofi brought suit against all of the ANDA filers in the United States District Court for the District of Delaware for patent infringement. Depending on the contents of the particular Paragraph IV Certification, Sanofi has brought suit for infringement of at least three and sometimes four of its

**Table of Contents****ITEM 8. FINANCIAL INFORMATION**

Orange Book listed patents. Having settled with all but two generic manufacturers, Sanofi went to trial against Sandoz and Watson in early June 2016 alleging infringement of US patents 8,318,800 (formulation) and 8,410,167 (method of use). In August 2016, the Court ruled in Sanofi's favor finding the 800 patent infringed and the 167 patent valid and infringed by both Sandoz and Watson. In September 2016, Sandoz and Watson filed a Notice of Appeal to the Court of Appeals for the Federal Circuit.

On October 13, 2015, Sanofi amended its complaint against Lupin to include US Patent 9,107,900 which was listed in the Orange Book in September 2015. In December 2015, Sanofi filed separate patent infringement actions against six of the other defendants based on this patent. Having settled with all but three generic manufacturers, Sanofi is scheduled to go to trial on the 900 patent in April 2017 against Sandoz, Watson and Lupin.

***Genzyme Myozyme®/Lumizyme® Patent Litigation (United States)***

BioMarin filed petitions with the PTAB (Patent Trial and Appeal Board) requesting institution of an IPR (Inter Partes Review) of the patentability of all claims of US Patent No. 7,351,410 and all but one claims of US Patent No. 7,655,226 regarding Myozyme®/Lumizyme®. Those petitions were granted. In February 2015, the PTAB ordered inter alia that claim 1 of the 410 patent and that claims 1 and 3-6 of the 226 patent are determined to be un-patentable. Genzyme filed a Notice of Appeal to the Federal Circuit in April 2015. The United States Patent and Trademark Office (USPTO) filed a Notice of Intervention in September 2015.

In June 2016, the Federal circuit upheld the PTAB decision ordering inter alia that claim 1 of the 410 patent and that claims 1 and 3-6 of the 226 patent are determined to be un-patentable. Genzyme filed a Petition for Rehearing in August 2016. The Federal Circuit denied Genzyme's Petition in September 2016.

***Genzyme Aubagio® Patent Litigation (United States)***

Aubagio® is covered by three Orange Book listed patents: US 6,794,410, US 8,802,735, and US 9,186,346. In November/December 2016, a number of generic manufacturers separately notified Sanofi Genzyme that they had filed ANDA applications for Aubagio® with Paragraph IV certifications challenging the 410, 735 and 346 patents. Sanofi Genzyme filed suit against each ANDA filer within 45 days of receipt of each notification in the US District Court for the District of Delaware. The associated 30-month stay of FDA approval on each ANDA expires on the earlier of (i) March 12, 2020 or (ii) a court decision in favor of one of the generics manufacturers.

***Dupixent (dupilumab)-related Patent Opposition and Revocation (Europe)***

Immunex Corporation, an Amgen affiliate, is the registered proprietor of European Patent number EP2292665. The claims of this patent relate to, among other things, human monoclonal antibodies that are capable of inhibiting IL-4 induced biological activity and which compete with one of

four reference antibodies for binding to a cell that expresses human IL-4R. In April 2016, Sanofi and Regeneron each filed an opposition in the European Patent Office against EP2292665, seeking its revocation on the basis that, inter alia, the claims are overly broad. In September 2016, Sanofi also filed a civil action in the U.K. High Court (Chancery Division/Patents Court) seeking revocation of the U.K. designation of EP2292665 on similar grounds. In January 2017, at the joint request of Sanofi and Immunex, the U.K. High Court ordered that the revocation action be stayed pending the final determination of the pending European Patent Office opposition proceedings.

**Government Investigations and Related Litigation**

## Edgar Filing: Sanofi - Form 20-F

From time to time, subsidiaries of Sanofi are subject to governmental investigations and information requests from regulatory authorities inquiring as to the practices of Sanofi with respect to the sales, marketing, and promotion of its products.

In December 2013, Genzyme entered into a settlement agreement to resolve civil claims arising out of the investigation into promotional practices of Septrafilm<sup>®</sup> and paid in that respect approximately \$23 million. As part of this settlement, and as part of the settlement entered into by Sanofi US in December 2012 relating to civil claims arising out of an investigation into sampling of its former product Hyalgan<sup>®</sup> for which Sanofi US paid \$109 million, the companies entered into a Corporate Integrity Agreement ( CIA ) with the Office of the Inspector General of the United States Department of Health and Human Services in September 2015. Also in September 2015, Genzyme entered into a Deferred Prosecution Agreement ( DPA ) with the US Department of Justice and paid in that respect approximately \$33 million to resolve the Septrafilm matter completely. The CIA and the DPA are currently in effect.

In March 2016, Sanofi US received a civil investigative demand from the US Attorney's Office for the Southern District of New York requesting documents and information relating to contracts with, services performed by and payments to pharmacy benefit managers regarding Lantus<sup>®</sup> and Apidra<sup>®</sup> from January 1, 2006 forward. Sanofi US is cooperating with this investigation.

In June 2016, the United States declined to intervene in a False Claims Act action filed in Federal Court in New Jersey regarding the sale and marketing of and variability of response to Plavix<sup>®</sup>. Sanofi US is defending this and another False Claims Act action relating to Plavix<sup>®</sup> pending in the same court. Five State Attorney General actions (Hawaii, Louisiana, Mississippi, New Mexico and West Virginia) concerning the sale and marketing of Plavix<sup>®</sup> also remain pending.

In December 2016 and January 2017, two putative class actions were filed against Sanofi US and Sanofi GmbH in Federal Court in Massachusetts on behalf of direct-purchasers of Lantus<sup>®</sup> alleging certain antitrust violations.

In January 2017, the Minnesota State Attorney General's office issued a civil investigative demand calling for the production of documents and information relating to pricing

**Table of Contents****ITEM 8. FINANCIAL INFORMATION**

and trade practices for Lantus® and Toujeo®, from January 1, 2008 through present. Sanofi US is cooperating with this investigation.

In February 2017, two actions were filed against Sanofi US in Federal Court in New Jersey on behalf of a putative class of diabetes patients alleging violations of the Racketeer Influenced and Corrupt Organizations Act, the Sherman Act and various state unfair/deceptive trade practices statutes in connection with the pricing of Lantus®.

In France, in the claim concerning allegations that Sanofi's communication and promotional practices inhibited the entry on the market of generics of clopidogrel (the active ingredient of Plavix®), the French Antitrust Authority issued its decision on May 14, 2013, imposing on Sanofi a fine of 40.6 million. In December 2014, the Paris Court of Appeal rejected Sanofi's appeal and confirmed in totality the decision. Sanofi filed a *pourvoi* with the French Supreme Court (*Cour de Cassation*) in January 2015. As a consequence of the May 2013 ruling, claims were filed by Sandoz and by Teva in 2014 before the Commercial Court of Paris for compensation of their alleged damages: loss of margin and other ancillary damages (legal fees to external counsel, image and reputation). In June and November 2016 respectively, settlement agreements were entered into with Sandoz and Teva. Consequently, they subsequently withdrew their civil claims, jointly and severally. On October 18, 2016, the Supreme Court confirmed the Court of Appeals' decision. Therefore, the Court of Appeals' decision became definitive.

Sanofi is engaged in discussions with the US Department of Justice and the US Securities and Exchange Commission regarding allegations that certain subsidiaries outside the United States made improper payments in connection with the sale of pharmaceutical products and whether those payments, if made, fall within the US Foreign Corrupt Practices Act. Sanofi also received anonymous allegations of wrongdoing related to improper payments to healthcare professionals in connection with the sale of pharmaceutical products that may have occurred between 2007 and 2015 in certain parts of the Middle East and Africa. Sanofi proactively notified the US Department of Justice and the US Securities and Exchange Commission of all of the allegations. The Company has voluntarily provided and will continue to provide information to the DOJ and SEC, and will cooperate with the agencies' reviews of these matters.

**B. Significant Changes****Updates to Note D.22*****Praluent® (alirocumab)-related Amgen Patent Litigation in Europe***

On February 7, 2017, the UK action was stayed (suspended) on terms agreed by the parties.

***Praluent® (alirocumab)-related Amgen Patent Litigation in the US***

On February 8, 2017, the US Court of Appeals for the Federal Circuit stayed (suspended) the permanent injunction

for Praluent® (alirocumab) Injection pending Sanofi and Regeneron's appeal.

***Other changes***

On February 27, 2017, Sanofi and Lonza announced that they had entered into a strategic partnership to build and operate a large-scale mammalian cell culture facility for monoclonal antibody production in Visp, Switzerland. The initial investment will be around CHF 290 million (€ 270 million), to be split equally between each company.

## Edgar Filing: Sanofi - Form 20-F

At its meeting held on March 2, 2017, the Board of Directors of Sanofi proposed the appointment of Melanie Lee, PhD and Bernard Charlès as new independent Directors during the General Shareholders' meeting of May 10, 2017, as well as the renewal of the term of Fabienne Lecorvaisier.

Melanie Lee, PhD, CBE, is Chief Scientific Officer at BTG plc (since November 2014), a company which operates in interventional medicine in vascular disease, oncology and pulmonology. Following her academic career she spent 10 years at Glaxo/GlaxoWellcome (1988-1998). In 1998, Melanie joined Celltech plc as Executive Director of Research. Celltech plc was subsequently acquired by UCB where she became Executive Vice President, Research and Development. After leaving UCB in 2009 she had a successful tenure as CEO at Syntaxin Ltd, a UK based biotech and following the sale to Ipsen, founded NightstaRx Ltd, a Syncona backed company in 2014. Melanie received an undergraduate degree in Biology from the University of York and then a Ph.D. at National Institute for Medical Research in London. She worked as a molecular genetics postdoc, first at Imperial College London on yeast and then from 1985 with Sir Paul Nurse, a Nobel Prize winner, at the Imperial Cancer Research Fund's Lincoln's Inn Laboratories. Melanie received her CBE for services to medical science in 2009.

Bernard Charlès has served since May 2016 as Vice-Chairman and Chief Executive Officer of Dassault Systèmes, a world leader in 3D software with over 220,000 customers in 12 industry sectors. He has been CEO of Dassault Systèmes since September 1995. He joined the company in 1983 and created the New Technology, Research and Strategy division, before being appointed Director for Strategy, Research and Development in 1988. Through his contributions to digital mock-up, product lifecycle management and 3DEXPERIENCE®, Bernard Charlès helped instill a culture of ongoing innovation to further consolidate Dassault Systèmes' scientific capabilities and make science part of the company's identity. Bernard Charlès is a member of the Academy of Technology (France) and of the National Academy of Engineering (United States). He is a graduate of the Ecole Normale Supérieure engineering school in Cachan and has a Ph.D. in mechanical engineering majoring in automation engineering and information science. He also holds an Aggregation in mechanical engineering; this is the most senior teaching qualification achievable in France.

**Table of Contents****ITEM 9. THE OFFER AND LISTING****Item 9. The Offer and Listing****A. Offer and Listing Details**

We have one class of shares. Each American Depositary Share, or ADS, represents one-half of one share. The ADSs are evidenced by American Depositary Receipts, or ADRs, which are issued by JPMorgan Chase Bank, N.A.

Our shares trade on Compartment A of the regulated market of Euronext Paris, and our ADSs trade on the New York Stock Exchange, or NYSE.

In 2011, in connection with our acquisition of Genzyme, we issued contingent value rights ( CVRs ) under a CVR agreement entered into by and between us and the American Stock Transfer & Trust Company, LLC ( AST ), as

trustee (see Item 10.C. Material Contracts – The Contingent Value Rights Agreement). Our CVRs trade on the NASDAQ Global Market.

As of June 30, 2016, UMB Bank, National Association replaced AST and is the successor trustee under the CVR agreement.

**Trading History**

The table below sets forth, for the periods indicated, the reported high and low market prices of our shares on Euronext Paris and our ADSs on the NYSE (source: Bloomberg).

<i>Calendar period</i>	<b>Shares, as traded on Euronext Paris</b>		<b>ADSs, as traded on the NYSE</b>	
	<b>High</b>	<b>Low</b>	<b>High</b>	<b>Low</b>
	<b>(price per share in €)</b>		<b>(price per ADS in \$)</b>	
<b>Monthly</b>				
February 2017	82.45	74.51	43.72	40.18
January 2017	78.92	73.39	41.77	39.42
December 2016	77.78	73.72	41.32	38.45
November 2016	78.68	70.39	42.42	38.80
October 2016	73.98	67.22	39.37	36.81
September 2016	71.47	66.72	40.18	37.67
<b>2016</b>				
First quarter	79.13	66.44	42.34	37.63

Edgar Filing: Sanofi - Form 20-F

Second quarter	79.07	62.50	44.50	37.41
Third quarter	77.30	66.72	42.75	37.67
Fourth quarter	78.68	67.22	42.42	36.81
Full Year	79.13	62.50	44.50	36.81
<b>2015</b>				
First quarter	94.40	72.94	51.47	43.57
Second quarter	99.23	84.90	53.00	48.23
Third quarter	101.10	80.19	54.98	46.02
Fourth quarter	93.82	74.59	51.88	41.13
Full Year	101.10	72.94	54.98	41.13
<b>2014</b>				
Full Year	89.95	68.29	57.42	44.24
<b>2013</b>				
Full Year	87.03	65.91	55.94	44.50
<b>2012</b>				
Full Year	72.38	53.20	47.97	33.03

## **Table of Contents**

### **ITEM 9. THE OFFER AND LISTING**

Fluctuations in the exchange rate between the euro and the U.S. dollar will affect any comparisons of euro share prices and U.S. ADS prices.

#### **B. Plan of Distribution**

N/A

#### **C. Markets**

##### **Shares and ADSs**

Our shares are listed on Euronext Paris under the symbol `SAN` and our ADSs are listed on the NYSE under the symbol `SNY`.

As of the date of this annual report, our shares are included in a large number of indices, including the CAC 40 Index, the principal French index published by Euronext Paris. This index contains 40 stocks selected among the top 100 companies based on free-float capitalization and the most active stocks listed on the Euronext Paris market. The CAC 40 Index indicates trends in the French stock market as a whole and is one of the most widely followed stock price indices in France. Our shares are also included in the S&P Global 100 Index, the Dow Jones Euro STOXX 50, the Dow Jones STOXX 50, the FTS Eurofirst 100, the FTS Eurofirst 80 and the MSCI Pan-Euro Index, among other indices.

##### **CVRs**

Our CVRs trade on the NASDAQ Global Market under the symbol `GCVRZ`.

##### **Trading by Sanofi in our own Shares**

Under French law, a company may not issue shares to itself, but it may purchase its own shares in the limited cases described at Item 10. Additional Information B. Memorandum and Articles of Association Trading in Our Own Shares.

#### **D. Selling Shareholders**

N/A

#### **E. Dilution**

N/A

#### **F. Expenses of the Issue**

N/A



---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

## **Item 10. Additional Information**

### **A. Share Capital**

N/A

### **B. Memorandum and Articles of Association**

#### **General**

Our Company is a *société anonyme*, a form of limited liability company, organized under the laws of France.

In this section, we summarize material information concerning our share capital, together with material provisions of applicable French law and our Articles of Association (*statuts*), an English translation of which has been filed as an exhibit to this annual report. For a description of certain provisions of our Articles of Association relating to our Board of Directors and statutory auditors, see Item 6. Directors, Senior Management and Employees. You may obtain copies of our Articles of Association in French from the *greffe* (Clerk) of the *Registre du Commerce et des Sociétés de Paris* (Registry of Commerce and Companies of Paris, France, registration number: 395 030 844). Please refer to that full document for additional details.

Our Articles of Association specify that our corporate affairs are governed by:

- applicable laws and regulations (in particular, Title II of the French Commercial Code); and
- the Articles of Association themselves.

Article 3 of our Articles of Association specifies that the Company's corporate purpose, in France and abroad, is:

- acquiring interests and holdings, in any form whatsoever, in any company or enterprise, in existence or to be created, connected directly or indirectly with the health and fine chemistry sectors, human and animal therapeutics, nutrition and bio-industry; in the following areas:

- purchase and sale of all raw materials and products necessary for these activities;

- research, study and development of new products, techniques and processes;
  - manufacture and sale of all chemical, biological, dietary and hygiene products;
  - obtaining or acquiring all intellectual property rights related to results obtained and, in particular, filing all patents, trademarks and models, processes or inventions;
  - operating directly or indirectly, purchasing, and transferring for free or for consideration pledging or securing all intellectual property rights, particularly all patents, trademarks and models, processes or inventions;
  - obtaining, operating, holding and granting all licenses;
  - within the framework of a group-wide policy and subject to compliance with the relevant legislation, participating in treasury management transactions, whether as lead company or otherwise, in the form of centralized currency risk management or intra-group netting, or any other form permitted under the relevant laws and regulations;
- and, more generally:

- all commercial, industrial, real or personal property, financial or other transactions, connected directly or indirectly, totally or partially, with the activities described above and with all similar or related activities or having any other purposes likely to encourage or develop the Company's activities.

## **Directors**

### **Transactions in Which Directors Are Materially Interested**

Under French law, any agreement entered into (directly or through an intermediary) between our Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions is subject to the prior authorization of the disinterested members of the Board of Directors. The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

The Board of Directors must also authorize any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer (*directeur général*) or his delegates (*directeurs généraux délégués*) pursuant to which such persons will or may be granted compensation, benefit or any other advantage as a result of the termination of or a change in their offices or following such termination or change.

In addition, except with respect to any non-compete indemnity or certain pension benefits, any such termination package: (i) must be authorized by our shareholders through the adoption of a separate general shareholders meeting resolution for each such beneficiary, which authorization must be renewed at each renewal of such beneficiary's mandate, and (ii) cannot be paid to such beneficiary unless (a) the Board of Directors decides that such beneficiary has satisfied certain conditions, linked to such beneficiary's performance measured by our Company's performance, that must have been defined by the Board of Directors when granting such package, and (b) such decision is publicly disclosed.

---

## **Table of Contents**

### **ITEM 10. ADDITIONAL INFORMATION**

#### **Directors Compensation**

The aggregate amount of attendance fees (*jetons de présence*) of the Board of Directors is determined at the Shareholders' Ordinary General Meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at Transactions in Which Directors Are Materially Interested. The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also Item 6. Directors, Senior Management and Employees.

#### **Board of Directors Borrowing Powers**

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the Shareholders' General Meeting. There are currently no limits imposed on the amounts of loans or borrowings that the Board of Directors may approve.

#### **Directors Age Limits**

For a description of the provisions of our Articles of Association relating to age limits applicable to our Directors, see Item 6. Directors, Senior Management and Employees.

#### **Directors Share Ownership Requirements**

Pursuant to the Board Charter, our Directors are required to hold at least 1,000 shares during the term of their appointment.

#### **Share Capital**

As of December 31, 2016, our share capital amounted to 2,584,044,648, divided into 1,292,022,324 outstanding shares with a par value of 2 per share. All of our outstanding shares are of the same class and are fully paid. Of these shares, we or entities controlled by us held 20,084,045 shares (or 1.55% of our outstanding share capital), as treasury shares as of such date. As of December 31, 2016, the carrying amount of such shares was 1,505 million.

At an extraordinary general meeting held on May 4, 2015, our shareholders authorized our Board of Directors to increase our share capital, through the issuance of shares or other securities giving access to the share capital with or without preemptive rights, by an aggregate maximum nominal amount of 1.3 billion. See Changes in Share Capital Increases in Share Capital, below.

The maximum total number of authorized but unissued shares as of December 31, 2016 was 155 million, reflecting the unused part of the May 4, 2015 and May 4, 2016 shareholder authorizations to issue shares without preemptive rights, outstanding options to subscribe for shares, and awards of shares.

#### **Stock Options**

##### **Types of Stock Options**

## Edgar Filing: Sanofi - Form 20-F

We have two types of stock options outstanding: options to subscribe for shares (*options de souscription d'actions*) and options to purchase shares (*options d'achat d'actions*). Upon exercise of an option to subscribe for shares, we issue new shares, whereas upon exercise of an option to purchase shares, the option holder receives existing shares. We purchase our shares on the market prior to the vesting of the options to purchase in order to provide the option holder with shares upon exercise.

Because the exercise of options to purchase shares will be satisfied with existing shares repurchased on the market or held in treasury, the exercise of options to purchase shares has no impact on the amount of our share capital.

### Stock Option Plans

Our combined general meeting held on May 4, 2016 authorized our Board of Directors for a period of 38 months to grant, on one or more occasions, options to subscribe for shares and options to purchase shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or groupings of economic interest of the Group in accordance with Article L. 225-180 of the French Commercial Code.

The aggregate number of options to subscribe for shares and options to purchase shares that may be granted under this authorization may not give entitlement to a total number of shares exceeding 0.5% of the share capital as of the date of the decision by the Board of Directors to grant such options.

The Board of Directors sets the exercise price of options to subscribe for shares and options to purchase shares. However, the exercise price never incorporates a discount and must be at least equal to the average of the quoted market prices on the 20 trading sessions preceding the date of grant by the Board of Directors.

Stock option plans generally provide for a lock-up period of four years and have a duration of ten years.

Under such authorization the shareholders expressly waive, in favor of the grantees of options to subscribe for shares, their preemptive rights in respect of shares that are to be issued as and when options are exercised.

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

The Board of Directors is granted full power to implement this authorization and to set the terms and conditions on which options are granted and the arrangements with respect to the dividend entitlement of the shares.

See Item 6. Directors, Senior Management and Employees E. Share Ownership for a description of our option plans currently in force.

**Awards of Shares**

Our combined general meeting held on May 4, 2016 authorized our Board of Directors for a period of 38 months to allot, on one or more occasions, existing or new restricted shares in favor of persons to be chosen by the Board of Directors from among the salaried employees and corporate officers of our Company or of companies or economic interest groupings of the Group in accordance with Articles L. 225-197-1 *et seq.* of the French Commercial Code.

The existing or new shares allotted under this authorization may not represent more than 1.5% of our share capital as of the date of the decision by the Board of Directors to allot such shares.

The authorization provides that allotment of shares to the allottees will become irrevocable at the end of a minimum vesting period of three years.

In the case of newly issued shares, the authorization entails the express waiver by the shareholders, in favor of the allottees of restricted shares, of their preemptive rights in respect of shares that are to be issued as and when restricted shares vest.

The Board of Directors sets the terms on which restricted shares are granted and the arrangements with respect to the dividend entitlement of the shares.

See Item 6. Directors, Senior Management and Employees E. Share Ownership for a description of our restricted shares plans currently in force.

**Changes in Share Capital in 2016**

See Note D.15.1. to our consolidated financial statements included at Item 18 of this annual report.

**Voting Rights**

In general, each shareholder is entitled to one vote per share at any shareholders' general meeting. Our Articles of Association do not provide for cumulative voting rights. However, our Articles of Association provide that any fully paid-up shares that have been held in registered form under the name of the same shareholder for at least two years acquire double voting rights. The double voting rights cease automatically for any share converted into bearer form or transferred from one owner to another, subject to certain exceptions permitted by law.

As of December 31, 2016, there were 144,093,673 shares that were entitled to double voting rights, representing 11.15% of our total share capital, and approximately 20.35% of the voting rights which can be cast at our shareholders' general meeting as of that date.

Double voting rights are not taken into account in determining whether a quorum exists.

Under the French Commercial Code, treasury shares or shares held by entities controlled by that company are not entitled to voting rights and do not count for quorum purposes.

## Edgar Filing: Sanofi - Form 20-F

Our Articles of Association allow us to obtain from Euroclear France the name, nationality, address and number of shares held by holders of our securities that have, or may in the future have, voting rights. If we have reason to believe that a person on any list provided by Euroclear France holds securities on behalf of another person, our Articles of Association allow us to request information regarding beneficial ownership directly from such person. See B. Memorandum and Articles of Association Form, Holding and Transfer of Shares, below.

Our Articles of Association provide that Board members are elected on a rolling basis for a maximum tenure of four years.

### **Shareholders Agreement**

We are not aware of any shareholder s agreement currently in force concerning our shares.

### **Shareholders Meetings**

#### **General**

In accordance with the provisions of the French Commercial Code, there are three types of shareholders meetings: ordinary, extraordinary and special.

Ordinary general meetings of shareholders are required for matters such as:

- electing, replacing and removing directors;
- appointing independent auditors;
- approving the annual financial statements;
- declaring dividends or authorizing dividends to be paid in shares, provided the Articles of Association contain a provision to that effect; and
- approving share repurchase programs.

Extraordinary general meetings of shareholders are required for approval of matters such as amendments to our Articles of Association, including any amendment required in connection with extraordinary corporate actions. Extraordinary corporate actions include:

- changing our Company s name or corporate purpose;

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

- increasing or decreasing our share capital;
- creating a new class of equity securities;
- authorizing the issuance of:
  - shares giving access to our share capital or giving the right to receive debt instruments, or
  - other securities giving access to our share capital;
- establishing any other rights to equity securities;
- selling or transferring substantially all of our assets; and
- the voluntary liquidation of our Company.

Special meetings of shareholders of a certain category of shares or shares with certain specific rights (such as shares with double voting rights) are required for any modification of the rights derived from that category of shares. The resolutions of the shareholders' general meeting affecting these rights are effective only after approval by the relevant special meeting.

**Annual Ordinary Meetings**

The French Commercial Code requires the Board of Directors to convene an annual ordinary general shareholders' meeting to approve the annual financial statements. This meeting must be held within six months of the end of each fiscal year. This period may be extended by an order of the President of the Commercial Court. The Board of Directors may also convene an ordinary or extraordinary general shareholders' meeting upon proper notice at any time during the year. If the Board of Directors fails to convene a shareholders' meeting, our independent auditors may call the meeting. In case of bankruptcy, the liquidator or court-appointed agent may also call a shareholders' meeting in some instances. In addition, any of the following may request the court to appoint an agent for the purpose of calling a shareholders' meeting:

- one or several shareholders holding at least 5% of our share capital;
- duly qualified associations of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights;

- the works council in cases of urgency; or

- any interested party in cases of urgency.

#### **Notice of Shareholders Meetings**

All prior notice periods provided for below are minimum periods required by French law and cannot be shortened, except in case of a public tender offer for our shares.

We must announce general meetings at least thirty-five days in advance by means of a preliminary notice (*avis de réunion*), which is published in the *Bulletin des Annonces Légales Obligatoires*, or *BALO*. The preliminary notice must

first be sent to the French Financial markets authority (*Autorité des marchés financiers*, the AMF), with an indication of the date on which it will be published in the *BALO*. It must be published on our website at least twenty-one days prior to the general meeting. The preliminary notice must contain, among other things, the agenda, a draft of the resolutions to be submitted to the shareholders for consideration at the general meeting and a detailed description of the voting procedures (proxy voting, electronic voting or voting by mail), the procedures permitting shareholders to submit additional resolutions or items to the agenda and to ask written questions to the Board of Directors. The AMF also recommends that, prior to or simultaneously with the publication of the preliminary notice, we publish a summary of the notice indicating the date, time and place of the meeting in a newspaper of national circulation in France and on our website.

At least fifteen days prior to the date set for a first convening, and at least ten days prior to any second convening, we must send a final notice (*avis de convocation*) containing the final agenda, the date, time and place of the meeting and other information related to the meeting. Such final notice must be sent by mail to all registered shareholders who have held shares in registered form for more than one month prior to the date of the final notice and by registered mail, if shareholders have asked for it and paid the corresponding charges. The final notice must also be published in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*, with prior notice having been given to the AMF for informational purposes. Even if there are no proposals for new resolutions or items to be submitted to the shareholders at the meeting, we must publish a final notice in a newspaper authorized to publish legal announcements in the local administrative department (*département*) in which our Company is registered as well as in the *BALO*.

#### **Other issues**

In general, shareholders can only take action at shareholders meetings on matters listed on the agenda. As an exception to this rule, shareholders may take action with respect to the appointment and dismissal of directors even if this action has not been included on the agenda.

Additional resolutions to be submitted for approval by the shareholders at the shareholders meeting may be proposed to the Board of Directors, for recommendation to the shareholders at any time from the publication of the preliminary notice in the *BALO* until twenty-five days prior to the general meeting and in any case no later than twenty days following the publication of the preliminary notice in the *BALO* by:

- one or several shareholders together holding a specified percentage of shares;

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

· a duly qualified association of shareholders who have held their shares in registered form for at least two years and who together hold at least 1% of our voting rights; or

· the works council.

Within the same period, the shareholders may also propose additional items (*points*) to be submitted and discussed during the shareholders meeting, without a shareholders' vote. The shareholders must substantiate the reasons for their proposals of additional items.

The resolutions and the list of items added to the agenda of the shareholders' meeting must be promptly published on our website.

The Board of Directors must submit the resolutions to a vote of the shareholders after having made a recommendation thereon. The Board of Directors may also comment on the items that are submitted to the shareholders' meeting.

Following the date on which documents must be made available to the shareholders (including documents to be submitted to the shareholders meeting and resolutions proposed by the Board of Directors, which must be published on our website at least twenty-one days prior to the general meeting), shareholders may submit written questions to the Board of Directors relating to the agenda for the meeting until the fourth business day prior to the general meeting. The Board of Directors must respond to these questions during the meeting or may refer to a Q&A section located on our website in which the question submitted by a shareholder has already been answered.

**Attendance at Shareholders' Meetings; Proxies and Votes by Mail**

In general, all shareholders may participate in general meetings either in person or by proxy. Shareholders may vote in person, by proxy or by mail.

The right of shareholders to participate in general meetings is subject to the recording (*inscription en compte*) of their shares on the second business day, zero hour (Paris time), preceding the general meeting:

· for holders of registered shares: in the registered shareholder account held by the Company or on its behalf by an agent appointed by it; and

· for holders of bearer shares: in the bearer shareholder account held by the accredited financial intermediary with whom such holders have deposited their shares; such financial intermediaries shall deliver to holders of bearer shares a shareholding certificate (*attestation de participation*) enabling them to participate in the general meeting.

**Attendance in Person**

Any shareholder may attend ordinary general meetings and extraordinary general meetings and exercise its voting rights subject to the conditions specified in the French Commercial Code and our Articles of Association.

**Proxies and Votes by Mail**

Proxies are sent to any shareholder upon a request received between the publication of the final notice of meeting and six days before the general meeting and must be made available on our website at least twenty-one days before the general meeting. In order to be counted, such proxies must be received at our registered office, or at any other address indicated on the notice of the meeting or by any electronic mail indicated on the notice of the meeting, prior to the date of the meeting (in practice, we request that shareholders return proxies at least three business days prior to

## Edgar Filing: Sanofi - Form 20-F

the meeting; electronic proxies must be returned before 3 p.m. Paris time, on the day prior to the general meeting). A shareholder may grant proxies to any natural person or legal entity. The agent may be required to disclose certain information to the shareholder or to the public.

Alternatively, the shareholder may send us a blank proxy without nominating any representative. In this case, the chairman of the meeting will vote the blank proxies in favor of all resolutions proposed or approved by the Board of Directors and against all others.

With respect to votes by mail, we must send shareholders a voting form upon request or must make available a voting form on our website at least twenty-one days before the general meeting. The completed form must be returned to us at least three days prior to the date of the shareholders' meeting. For holders of registered shares, in addition to traditional voting by mail, instructions may also be given via the internet.

### **Quorum**

The French Commercial Code requires that shareholders holding in the aggregate at least 20% of the shares entitled to vote must be present in person, or vote by mail or by proxy, in order to fulfill the quorum requirement for:

- an ordinary general meeting; and
  - an extraordinary general meeting where the only resolutions pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code).
- For any other extraordinary general meeting the quorum requirement is at least 25% of the shares entitled to vote, held by shareholders present in person, voting by mail or by proxy.

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

For a special meeting of holders of a certain category of shares, the quorum requirement is one third of the shares entitled to vote in that category, held by shareholders present in person, voting by mail or by proxy.

If a quorum is not present at a meeting, the meeting is adjourned. However, only questions that were on the agenda of the adjourned meeting may be discussed and voted upon once the meeting resumes.

When an adjourned meeting is resumed, there is no quorum requirement for meetings cited in the first paragraph of this *Quorum* section. In the case of any other reconvened extraordinary general meeting or special meeting, the quorum requirement is 20% of the shares entitled to vote (or voting shares belonging to the relevant category for special meetings of holders of shares of such specific category), held by shareholders present in person or voting by mail or by proxy. If a quorum is not met, the reconvened meeting may be adjourned for a maximum of two months with the same quorum requirement. No deliberation or action by the shareholders may take place without a quorum.

**Votes Required for Shareholder Action**

The affirmative vote of a simple majority of the votes cast may pass a resolution at either an ordinary general meeting or an extraordinary general meeting where the only resolution(s) pertain to either (a) a proposed increase in our share capital through incorporation of reserves, profits or share premium, or (b) the potential issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code). At any other extraordinary general shareholders' meeting and at any special meeting of holders of a specific category of shares, the affirmative vote of two-thirds of the votes cast is required.

Abstention from voting by those present or those represented by proxy or voting by mail is counted as a vote against the resolution submitted to a shareholder vote.

**Changes to Shareholders' Rights**

Under French law, the affirmative vote of two-thirds of the votes cast at an extraordinary shareholders' meeting is required to change our Articles of Association, which set out the rights attached to our shares, except for capital increases through incorporation of reserves, profits or share premium, or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code).

The rights of a class of shareholders can be amended only after a special meeting of the class of shareholders affected has taken place. The voting requirements applicable to this type of special meeting are the same as those applicable to an extraordinary general shareholders' meeting. The quorum requirements for a special meeting are one-third of the

voting shares, or 20% upon resumption of an adjourned meeting.

A unanimous shareholders' vote is required to increase the liabilities of shareholders.

**Financial Statements and Other Communications with Shareholders**

In connection with any shareholders' meeting, we must provide a set of documents which includes our annual report.

We must also provide on our website at least twenty-one days before a shareholders' meeting certain information and a set of documents that includes the preliminary notice, the proxies and voting forms, the resolutions proposed by the Board of Directors, and the documents to be

## Edgar Filing: Sanofi - Form 20-F

submitted to the shareholders meeting pursuant to articles L225-115 and R. 225-83 of the French Commercial Code, etc. The resolutions and the list of items added to the agenda of the shareholders meeting must be promptly published on our website.

### **Dividends**

We may only distribute dividends out of our distributable profits, plus any amounts held in our reserves that the shareholders decide to make available for distribution, other than those reserves that are specifically required by law or our Articles of Association. Distributable profits consist of our unconsolidated net profit in each fiscal year, as increased or reduced by any profit or loss carried forward from prior years, less any contributions to the reserve accounts pursuant to law or our Articles of Association.

### **Legal Reserve**

The French Commercial Code requires us to allocate 5% of our unconsolidated net profit for each year to our legal reserve fund before dividends may be paid with respect to that year. Funds must be allocated until the amount in the legal reserve is equal to 10% of the aggregate par value of the issued and outstanding share capital. This restriction on the payment of dividends also applies to each of our French subsidiaries on an unconsolidated basis. At December 31, 2016, our legal reserve amounted to 282,280,863, representing 10.92% of the aggregate par value of our issued and outstanding share capital as of that date. The legal reserve of any company subject to this requirement may serve to allocate losses that may not be allocated to other reserves, or may be distributed to shareholders upon liquidation of the company.

### **Approval of Dividends**

According to the French Commercial Code, our Board of Directors may propose a dividend for approval by shareholders at the annual general shareholders meeting. If we have earned distributable profits since the end of the

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

preceding fiscal year, as reflected in an interim income statement certified by our independent auditors, our Board of Directors may distribute interim dividends to the extent of the distributable profits for the period covered by the interim income statement. Our Board of Directors exercises this authority subject to French law and regulations and may do so without obtaining shareholder approval.

**Distribution of Dividends**

Dividends are distributed to shareholders *pro rata* according to their respective holdings of shares. In the case of interim dividends, distributions are made to shareholders on the date set by our Board of Directors during the meeting in which the distribution of interim dividends is approved. The actual dividend payment date is decided by the shareholders at an ordinary general shareholders' meeting or by our Board of Directors in the absence of such a decision by the shareholders. Shareholders that own shares on the actual payment date are entitled to the dividend.

Dividends may be paid in cash or, if the shareholders' meeting so decides, in kind, provided that all shareholders receive a whole number of assets of the same nature paid in lieu of cash. Our Articles of Association provide that, subject to a decision of the shareholders' meeting taken by ordinary resolution, each shareholder may be given the choice to receive his dividend in cash or in shares.

**Timing of Payment**

According to the French Commercial Code, we must pay any existing dividends within nine months of the end of our fiscal year, unless otherwise authorized by court order. Dividends on shares that are not claimed within five years of the date of declared payment revert to the French State.

**Changes in Share Capital**

**Increases in Share Capital**

As provided for by the French Commercial Code, our share capital may be increased only with shareholders' approval at an extraordinary general shareholders' meeting following the recommendation of our Board of Directors. The shareholders may delegate to our Board of Directors either the authority (*délégation de compétence*) or the power (*délégation de pouvoir*) to carry out any increase in share capital. Our Board of Directors may further delegate this power to our Chief Executive Officer or, subject to our Chief Executive Officer's approval, to his delegates (*directeurs généraux délégués*).

Increases in our share capital may be effected by:

- issuing additional shares;
- increasing the par value of existing shares;
- creating a new class of equity securities; or
- exercising the rights attached to securities giving access to the share capital.

## Edgar Filing: Sanofi - Form 20-F

Increases in share capital by issuing additional securities may be effected through one or a combination of the following:

- in consideration for cash;
- in consideration for assets contributed in kind;
- through an exchange offer;
- by conversion of previously issued debt instruments;
- by capitalization of profits, reserves or share premium; or
- subject to various conditions, in satisfaction of debt incurred by our Company.

Decisions to increase the share capital through the capitalization of reserves, profits and/or share premium or through the issuance of free share warrants in the event of a public tender offer for our shares (article L. 233-32 of the French Commercial Code) require shareholders' approval at an extraordinary general shareholders' meeting, acting under the quorum and majority requirements applicable to ordinary shareholders' meetings. Increases effected by an increase in the par value of shares require unanimous approval of the shareholders, unless effected by capitalization of reserves, profits or share premium. All other capital increases require shareholders' approval at an extraordinary general shareholders' meeting acting under the regular quorum and majority requirements for such meetings. See [Quorum](#) and [Votes Required for Shareholder Action](#) above.

On May 4, 2015, our shareholders approved various resolutions delegating to the Board of Directors the authority to increase our share capital through the issuance of shares or securities giving access to the share capital, subject to an overall cap set at 1.3 billion. This cap applies to all the resolutions whereby the extraordinary shareholders' meeting delegated to the Board of Directors the authority to increase the share capital, it being also specified that:

- the maximum aggregate par value of capital increases that may be carried out with preemptive rights maintained was set at 1.3 billion;
- the maximum aggregate par value of capital increases that may be carried out by public offering without preemptive rights was set at 260 million;
- the maximum aggregate par value of capital increases that may be carried out by private placement without preemptive rights was set at 260 million;
- capital increases resulting in the issuance of securities to members of employee savings plans are limited to 1% of the share capital as computed on the date of the Board of Directors' decision to issue such securities, and such issuances may be made at a discount of 20% (or 30%) if certain French law restrictions on resales were to apply, i.e. a lock up period of five years (or 10 years).

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

At its meeting of March 3, 2016, our Board of Directors decided to delegate to the Chief Executive Officer the powers necessary to carry out a capital increase reserved for members of the Group savings program. Every employee subscribing for at least five shares received one additional new share as an employer top-up contribution, and every employee subscribing for an additional five shares (i.e. ten shares in total) received two additional shares as an employer top-up contribution for the first ten shares. Beyond the first ten shares there was no entitlement to any further shares by way of employer top-up contribution. The subscription period was open during June 2016.

24,218 employees from over 80 countries subscribed for a total of 1,756,972 shares. Of these, 747,330 were subscribed via FCPE Actions Sanofi, the dedicated employee share ownership fund for employees of our French subsidiaries; 399,646 via FCPE Sanofi Shares, the dedicated employee share ownership fund for employees of our foreign subsidiaries; and 609,996 directly by employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

A total of 47,014 shares were issued by way of employer top-up contribution. Of these, 17,388 were issued to FCPE Actions Sanofi; 14,102 to FCPE Sanofi Shares; and 15,524 directly to employees who were eligible for the employee share ownership plan but were in countries where local regulations did not allow the use of a dedicated employee share ownership fund.

Voting rights attached to shares held by FCPE Actions Sanofi are exercised individually by the employees who hold units in the fund; fractional rights are exercised by the fund's supervisory board.

Voting rights attached to shares held by FCPE Sanofi Shares are also exercised individually by the employees who hold units in the fund; any rights not exercised by them are exercised by the fund's supervisory board.

In each case, the supervisory board includes an equal number of representatives of employees and of Sanofi management.

On May 4, 2016, our shareholders approved resolutions delegating to the Board of Directors the authority to increase the share capital by granting options to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization is valid for a period of 38 months, and any options granted may not give entitlement to a total number of shares exceeding 0.5% of the share capital as computed on the date of the decision of the Board of Directors to grant such options; see [Stock Options](#) above; On May 4, 2016, our shareholders also approved resolutions delegating to the Board of Directors the authority to increase

the share capital by granting existing or new restricted shares to our employees and/or corporate officers, subject to the overall cap mentioned above and under the following terms and conditions:

the authorization is valid for a period of 38 months, and is subject to a limit of 1.5% of the share capital as computed on the date of the decision of the Board of Directors to allot such shares; see [Awards of Shares](#) above. See also [Item 6. Directors, Senior Management and Employees](#) [E. Share Ownership](#).

**Decreases in Share Capital**

## Edgar Filing: Sanofi - Form 20-F

In accordance with the provisions of the French Commercial Code, any decrease in our share capital requires approval by the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the par value of the outstanding shares or by reducing the number of outstanding shares. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation of shares. Holders of each class of shares must be treated equally unless each affected shareholder agrees otherwise.

In addition, specific rules exist to permit the cancellation of treasury shares, by which the shareholders' meeting may authorize the cancellation of up to a maximum of 10% of a company's share capital within any 24-month period. On May 4, 2015, our shareholders delegated to our Board of Directors for 26 months the right to reduce our share capital by canceling our own shares.

### **Preemptive Rights**

According to the French Commercial Code, if we issue additional securities to be paid in cash, current shareholders will have preemptive rights to these securities on a *pro rata* basis. These preemptive rights require us to give priority treatment to current shareholders. The rights entitle the individual or entity that holds them to subscribe to the issuance of any securities that may increase the share capital of our Company by means of a cash payment or a set-off of cash debts. Preemptive rights are transferable during the subscription period relating to a particular offering. These rights may also be listed on Euronext Paris Stock Exchange.

Preemptive rights with respect to any particular offering may be waived by the affirmative vote of shareholders holding two-thirds of the shares entitled to vote at an extraordinary general meeting. Our Board of Directors and our independent auditors are required by French law to present reports that specifically address any proposal to waive preemptive rights. In the event of a waiver, the issue of securities must be completed within the period prescribed by law. Shareholders may also notify us that they wish to waive their own preemptive rights with respect to any particular offering if they so choose.

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

The shareholders may decide at extraordinary general meetings to give the existing shareholders a non-transferable priority right to subscribe to the new securities, for a limited period of time.

In the event of a capital increase without preemptive rights to existing shareholders, French law requires that the capital increase be made at a price equal to or exceeding the weighted average market prices of the shares for the last three trading days on Euronext Paris Stock Exchange prior to the determination of the subscription price of the capital increase less 5%.

**Form, Holding and Transfer of Shares**

**Form of Shares**

Our Articles of Association provide that the shares may be held in either bearer form or registered form at the option of the holder.

**Holding of Shares**

In accordance with French law relating to the dematerialization of securities, shareholders' ownership rights are represented by book entries instead of share certificates. We maintain a share account with Euroclear France (a French clearing system, which holds securities for its participants) for all shares in registered form, which is administered by BNP Paribas Securities Services. In addition, we maintain separate accounts in the name of each shareholder either directly or, at a shareholder's request, through the shareholder's accredited intermediary. Each shareholder account shows the name of the holder and the number of shares held. BNP Paribas Securities Services issues confirmations (*attestations d'inscription en compte*) to each registered shareholder as to shares registered in the shareholder's account, but these confirmations are not documents of title.

Shares of a listed company may also be issued in bearer form. Shares held in bearer form are held and registered on the shareholder's behalf in an account maintained by an accredited financial intermediary and are credited to an account at Euroclear France maintained by such intermediary. Each accredited financial intermediary maintains a record of shares held through it and provides the account holder with a securities account statement. Transfers of shares held in bearer form may only be made through accredited financial intermediaries and Euroclear France.

Shares held by persons who are not domiciled in France may be registered in the name of intermediaries who act on behalf of one or more investors. When shares are so held, we are entitled to request from such intermediaries the names of the investors. Also, we may request any legal entity (*personne morale*) which holds more than 2.5% of our shares or voting rights to disclose the name of any person

who owns, directly or indirectly, more than one-third of its share capital or of its voting rights. A person not providing the complete requested information in time, or who provides incomplete or false information, will be deprived of its voting rights at shareholders' meetings and will have its payment of dividends withheld until it has provided the requested information in strict compliance with French law. If such person acted willfully, the person may be deprived by a French court of either its voting rights or its dividends or both for a period of up to five years.

**Transfer of Shares**

Our Articles of Association do not contain any restrictions relating to the transfer of shares.

Registered shares must be converted into bearer form before being transferred on the Euronext Paris Stock Exchange on the shareholders' behalf and, accordingly, must be registered in an account maintained by an accredited financial intermediary on the shareholders' behalf. A shareholder may initiate a transfer by giving instructions to the relevant accredited financial intermediary.

## Edgar Filing: Sanofi - Form 20-F

A fee or commission is payable to the broker involved in the transaction, regardless of whether the transaction occurs within or outside France. Registration duty is currently payable in France if a written deed of sale and purchase (*acte*) is executed in France or outside France with respect to the shares of the Company.

### **Redemption of Shares**

Under French law, our Board of Directors is entitled to redeem a set number of shares as authorized by the extraordinary shareholders' meeting. In the case of such an authorization, the shares redeemed must be cancelled within one month after the end of the offer to purchase such shares from shareholders. However, shares redeemed on the open market do not need to be cancelled if the company redeeming the shares grants options on or awards those shares to its employees within one year following the acquisition. See also "Trading in Our Own Shares" below.

### **Sinking Fund Provisions**

Our Articles of Association do not provide for any sinking fund provisions.

### **Liability to Further Capital Calls**

Shareholders are liable for corporate liabilities only up to the par value of the shares they hold; they are not liable to further capital calls.

### **Liquidation Rights**

If we are liquidated, any assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will first be distributed to repay in full the par

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

value of our shares. Any surplus will be distributed *pro rata* among shareholders in proportion to the par value of their shareholdings.

**Requirements for Holdings Exceeding Certain Percentages**

The French Commercial Code provides that any individual or entity, acting alone or in concert with others, that becomes the owner, directly or indirectly, of more than 5%, 10%, 15%, 20%, 25%, 30%, 33 $\frac{1}{3}$ %, 50%, 66 $\frac{2}{3}$ %, 90% or 95% of the outstanding shares or voting rights of a listed company in France, such as our Company, or that increases or decreases its shareholding or voting rights above or below any of those percentages, must notify the company, before the end of the fourth trading day following the date it crosses the threshold, of the number of shares it holds and their voting rights. The individual or entity must also notify the AMF before the end of the fourth trading day following the date it crosses any such threshold. The AMF makes the notice public.

Pursuant to the French Commercial Code and the AMF General Regulation, the participation thresholds shall be calculated on the basis of the shares and voting rights owned, and shall take into account the shares and voting rights which are deemed to be shares and voting rights owned, even if the individual or entity does not itself hold shares or voting rights. In accordance with this deemed ownership principle, the individual or entity must take into account specific situations where shares and voting rights are deemed to be shares and voting rights owned when calculating the number of shares owned to be disclosed in the notifications to the Company and to the AMF. It includes among others situations where an individual or entity is entitled to acquire issued shares at its own initiative, immediately or at the end of a maturity period, under an agreement or a financial instrument, without set-off against the number of shares that this individual or entity is entitled to sell under another agreement or financial instrument. The individual or entity required to make such notification shall also take into account issued shares covered by an agreement or cash-settled financial instrument and having an economic effect for said individual or entity that is equivalent to owning such shares. In the cases of deemed ownership described above, the notification shall mention the type of deemed ownership and include a description of the main characteristics of the financial instrument or agreement with specific details required by the AMF General Regulation.

The AMF General Regulation provides that shares and voting rights subject to multiple cases of deemed ownership shall only be counted once.

When an individual or entity modifies the allocation between the shares it owns and its financial instruments or agreements deemed to be owned shares, it must disclose that change in a new notification. However, the change must

only be disclosed if the acquisition of owned shares due to the settlement of the financial instruments or agreements causes the investor to cross a threshold.

Subject to certain limited exceptions, French law and AMF regulations impose additional reporting requirements on persons who acquire more than 10%, 15%, 20%, or 25% of the outstanding shares or voting rights of a company listed in France. These persons must file a report with the company and the AMF before the end of the fifth trading day following the date they cross any such threshold.

In the report, the acquirer will have to specify its intentions for the following six months including:

- whether it acts alone or in concert with others;
- the means of financing of the acquisition (the notifier shall indicate in particular whether the acquisition is being financed with equity or debt, the main features of that debt, and, where applicable, the main guarantees given or received by the notifier. The notifier shall also

## Edgar Filing: Sanofi - Form 20-F

indicate what portion of its holding, if any, it obtained through securities loans);

· whether or not it intends to continue its purchases;

· whether or not it intends to acquire control of the company in question;

· the strategy it contemplates *vis-à-vis* the issuer;

· the way it intends to implement its strategy, including: (i) any plans for a merger, reorganization, liquidation, or partial transfer of a substantial part of the assets of the issuer or of any other entity it controls within the meaning of article L. 233-3 of the French Commercial Code, (ii) any plans to modify the business of the issuer, (iii) any plans to modify articles of association of the issuer, (iv) any plans to delist a category of the issuer's financial instruments, and (v) any plans to issue the issuer's financial instruments;

· any agreement for the temporary transfer of shares or voting rights of the issuer;

· the way it intends to settle its agreements or instruments on the shares or voting rights of the issuer mentioned in Article L. 233-9,4° and 4° bis of the French Commercial Code; and

· whether it seeks representation on the Board of Directors.

The AMF makes the report public. Upon any change of intention within the six-month period following the filing of the report, it will have to file a new report for the following six-month period.

In order to enable shareholders to give the required notice, we must each month publish on our website and send the AMF a written notice setting forth the total number of our shares and voting rights (including treasury shares) whenever they vary from the figures previously published.

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

If any shareholder fails to comply with an applicable legal notification requirement, the shares in excess of the relevant threshold will be deprived of voting rights for all shareholders' meetings until the end of a two-year period following the date on which the owner complies with the notification requirements. In addition, any shareholder who fails to comply with these requirements may have all or part of its voting rights suspended for up to five years by the Commercial Court at the request of our Chairman, any shareholder or the AMF, and may be subject to criminal fines.

Under AMF regulations, and subject to limited exemptions granted by the AMF, any person or entity, acting alone or in concert, that crosses the threshold of 30% of the share capital or voting rights of a French listed company must initiate a public tender offer for the balance of the shares and securities giving access to the share capital or voting rights of such company. Cash-settled derivative instruments or agreements mentioned in Article L. 233-9, 4° bis of the French Commercial Code are not included in the calculation of the number of shares related to the mandatory public tender offer.

In addition, our Articles of Association provide that any person or entity, acting alone or in concert with others, who becomes the owner of 1%, or any multiple of 1% of our share capital or our voting rights, even beyond the minimum declaration limits permitted by the legal and regulatory provisions, must notify us by certified mail, return receipt requested, within five trading days, of the total number of shares and securities giving access to our share capital and voting rights that such person then owns. The same provisions of our Articles of Association apply whenever such owner increases or decreases its ownership of our share capital or our voting rights to such extent that it goes above or below one of the thresholds described in the preceding sentence. Any person or entity that fails to comply with such notification requirement will, upon the request of one or more shareholders holding at least 5% of our share capital or of our voting rights made at the general shareholders' meeting, be deprived of voting rights with respect to the shares in excess of the relevant threshold for all shareholders' meetings until the end of a two-year period following the date on which such person or entity complies with the notification requirements.

**Change in Control/Anti-takeover**

There are no provisions in our Articles of Association that would have the effect of delaying, deferring or preventing a change in control of our Company or that would operate only with respect to a merger, acquisition or corporate restructuring involving our Company or any of our subsidiaries. Further, there are no provisions in our Articles of Association that allow the issuance of preferred stock upon the occurrence of a takeover attempt or the addition of other anti-takeover measures without a shareholder vote.

Our Articles of Association do not include any provisions discriminating against any existing or prospective holder of our securities as a result of such shareholder owning a substantial number of shares.

**Trading in Our Own Shares**

Under French law, Sanofi may not issue shares to itself. However, we may, either directly or through a financial intermediary acting on our behalf, acquire up to 10% of our issued share capital within a maximum period of 18 months, provided our shares are listed on a regulated market. Prior to acquiring our shares, we must publish a description of the share repurchase program (*descriptif du programme de rachat d'actions*).

We may not cancel more than 10% of our issued share capital over any 24-month period. Our repurchase of shares must not result in our Company holding, directly or through a person acting on our behalf, more than 10% of our issued share capital. We must hold any shares that we repurchase in registered form. These shares must be fully paid up. Shares repurchased by us continue to be deemed issued under French law but are not entitled to dividends or voting rights so long as we hold them directly or indirectly, and we may not exercise the preemptive rights attached to them.

The shareholders, at an extraordinary general shareholders meeting, may decide not to take these shares into account in determining the preemptive rights attached to the other shares. However, if the shareholders decide to take them into account, we must either sell the rights

attached to the shares we hold on the market before the end of the subscription period or distribute them to the other shareholders on a *pro rata* basis.

On May 4, 2016, our shareholders approved a resolution authorizing us to repurchase up to 10% of our shares over an 18-month period. Under this authorization, the purchase price for each Sanofi ordinary share may not be greater than 120.00 and the maximum amount that Sanofi may pay for the repurchases is 15,668,361,000. This authorization was granted for a period of 18 months from May 4, 2016 and cancelled and replaced the authorization granted to the Board of Directors by the combined general meeting held on May 4, 2015. A description of this share repurchase program as adopted by the combined general meeting held on May 4, 2016 (*descriptif du programme de rachat d'actions*) was published on March 4, 2016.

#### **Purposes of Share Repurchase Programs**

Under the European regulation 596/2014, dated April 16, 2014 on market abuse and its delegated regulation 2016/1052 on repurchase programs and stabilization measures, dated March 8, 2016 (which we refer to in this section as the Regulation ), an issuer will benefit from a safe harbor for share transactions that comply with certain conditions relating in particular to the pricing, volume and

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

timing of transactions (see below) and that are made in connection with a share repurchase program the purpose of which is:

- to reduce the share capital through the cancellation of treasury shares;
- to meet obligations arising from debt financial instruments that are exchangeable into equity instruments; and/or
- to meet obligations arising from share option programs or other allocations of shares to employees or to members of the administrative, management or supervisory bodies of the issuer or of an associate company.

Safe harbor transactions will by definition not be considered market abuses under the Regulation. Transactions that are carried out for other purposes than those mentioned above do not qualify for the safe harbor.

However, as permitted by the Regulation, which provides for a presumption of legitimacy for existing market practices that do not constitute market manipulation and that conform with certain criteria, the AMF has established as a French accepted market practice, which therefore benefits from a presumption of legitimacy, the use of liquidity agreements for share purchases that are entered into with a financial services intermediary and that comply with the code of conduct (*charte de déontologie*) approved by the AMF.

The AMF confirmed that all transactions directed at maintaining the liquidity of an issuer's shares must be conducted pursuant to a liquidity agreement with a financial services intermediary acting independently.

As of July 3, 2016, the purchase of shares that are subsequently used as acquisition currency in a business combination transaction, which the AMF previously permitted as an accepted market practice, is no longer considered as such, although such practice, while not benefiting from the presumption of legitimacy, is not prohibited under the Regulation.

**Pricing, Volume and Other Restrictions**

In order to qualify for the safe harbor described above, the issuer must generally comply with the following pricing and volume restrictions:

- a share purchase must not be made at a price higher than the higher of the price of the last independent trade and the highest current independent bid on the trading venues where the purchase is carried out; and
- subject to certain exceptions for illiquid securities, the issuer must not purchase on any trading day more than 25% of the average daily volume of the shares on the regulated market on which the purchase is carried out. The average daily volume figure must be based on the average daily volume traded in the month preceding the month of public disclosure of the share repurchase program and fixed on that basis for the authorized period of that program. If the program does not make reference to this volume, the average daily volume figure must be based on the average daily volume traded in the 20 trading days preceding the date of purchase.

In addition, unless the issuer has in place a time-scheduled repurchase program or the repurchase program is lead-managed by an investment firm or a credit institution which makes its trading decisions concerning the timing of the purchase of the issuer's shares independently of the issuer, the issuer must not, for the duration of the repurchase program, engage in the following activities:

- selling its own shares;
- effecting any transaction during a closed period imposed by the applicable law of the Member State in which the transaction occurs (i.e. under French law, during the period between the date on which the company has knowledge of insider information and the date on which such information is made public and during the 30 calendar day period before the announcement of an interim financial report or a year-end report which the issuer is obliged to make public); or
- effecting any transaction in securities with respect to which the issuer has decided to delay the public disclosure of inside information, in accordance with applicable rules.

#### **Use of Share Repurchase Programs**

Pursuant to the AMF rules, issuers must immediately allocate the repurchased shares to one of the purposes provided for in the Regulation and must not subsequently use the shares for a different purpose. As an exception to the foregoing, shares repurchased with a view to covering stock option plans may, if no longer needed for this purpose, be re-allocated for cancellation or sold in compliance with AMF requirements relating in particular to blackout periods. Shares repurchased in connection with one of the market practices authorized by the AMF (see above) may also be re-allocated to one of the purposes contemplated by the Regulation or sold in compliance with AMF requirements. Shares repurchased with a view to their cancellation must be cancelled within 24 months following their acquisition.

During the year ended December 31, 2016, we used the authority delegated by our shareholders to repurchase our shares on the stock market.

Pursuant to our share repurchase programs authorized by our shareholders on May 4, 2015 and on May 4, 2016, we repurchased 38,711,435 of our shares for a weighted average price of 74.91, i.e. a total cost of 2,900 million (including 20,000 shares purchased with a view to covering restricted share plans). Brokerage fees and financial transaction taxes (net of income taxes) amounted to 5.4 million. Our Company did not resort to derivatives to repurchase our own shares.

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

On April 28, 2016, the Board of Directors cancelled 22,561,090 treasury shares repurchased between December 2015 and the end of February 2016 pursuant to the share repurchase program of the Company.

During 2016, pursuant to the liquidity contract, Exane BNP Paribas (until May 9, 2016) and Rothschild & Cie (since that date):

- purchased 2,110,240 of our shares at an average weighted price of 73.80 for a total amount of 155,744,083; and

- sold 2,110,240 of our shares at an average weighted price of 73.83 for a total amount of 155,805,292.

In 2016, of the 159,851 shares allocated to stock purchase option plans outstanding at December 31, 2015, 23,008 shares were transferred to grantees of options.

As a result, as of December 31, 2016, out of the 20,084,045 treasury shares, representing 1.55% of our share capital, 156,843 were allocated to outstanding stock purchase option plans and restricted share plans and 19,927,202 were allocated to the purpose of cancellation. At the same date, none of the shares was allocated to the liquidity account, even though the liquidity contract was outstanding.

As of December 31, 2016, we directly owned 20,084,045 Sanofi shares with a par value of 2 representing around 1.55% of our share capital and with an estimated value of 1,505 million, based on the share price at the time of purchase.

**Reporting Obligations**

Pursuant to the Regulation, the AMF Regulation and the French Commercial Code, issuers trading in their own shares are subject to the following reporting obligations:

- issuers must report all transactions in their own shares to the competent authority of each trading venue on which the shares are admitted to trading or are traded within seven trading days of the transaction in a prescribed format, unless such transactions are carried out pursuant to a liquidity agreement that complies with the ethical code approved by the AMF;
- issuers must declare to the AMF on a monthly basis all transactions completed under the share repurchase program unless they provide the same information on a weekly basis; and
- post on its website the transactions disclosed and keep that information available to the public for at least a 5-year period from the date of public disclosure.

**Ownership of Shares by Non-French Persons**

The French Commercial Code and our Articles of Association currently do not limit the right of non-residents of France or non-French persons to own or, where applicable, to vote our securities. However, non-residents of France must file an administrative notice with the French authorities in connection with certain direct and indirect investments in us, including the acquisition of a controlling interest in our Company. Under existing administrative rulings, ownership of 33<sup>1</sup>/<sub>3</sub>% or more of our share capital or voting rights is regarded as a controlling interest, but

a lower percentage might be held to be a controlling interest in certain circumstances depending upon factors such as:

- the acquiring party's intentions;
- the acquiring party's ability to elect directors; or
- financial reliance by the company on the acquiring party.

Moreover, certain foreign investments in companies incorporated under French laws are subject to prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

### **Enforceability of Civil Liabilities**

We are a limited liability company (*société anonyme*) organized under the laws of France, and most of our officers and directors reside outside the United States. In addition, a substantial portion of our assets is located in France.

As a result, investors may find it difficult or be unable to effect service of process within the United States upon or obtain jurisdiction over our Company or our officers and directors in U.S. courts in actions predicated on the civil liability provisions of U.S. securities law. It may also be difficult to enforce against them, either inside or outside the United States, judgments obtained against them in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the United States, in any action based on civil liabilities under U.S. federal securities laws. There is doubt as to the enforceability against such persons in France, whether in original actions or in actions to enforce judgments of U.S. courts, of liabilities based solely on U.S. federal securities laws. In addition, actions in the United States under U.S. federal securities laws could be affected under certain circumstances by French law No. 68-678 of July 26, 1968 as amended by French Law No. 80-538 of July 16, 1980, which may preclude or restrict the obtaining of evidence in France or from French persons in connection with those actions. Additionally, awards of punitive damages in actions brought in the United States or elsewhere may be unenforceable in France.

## Table of Contents

### ITEM 10. ADDITIONAL INFORMATION

#### C. Material Contracts

##### The Contingent Value Rights Agreement

In connection with its acquisition of Genzyme Corporation, now a wholly-owned subsidiary of Sanofi, Sanofi issued one CVR per Genzyme share. On March 30, 2011, Sanofi and American Stock Transfer & Trust Company, LLC ( AST ), as trustee, entered into a Contingent Value Rights Agreement (the CVR Agreement ) governing the terms of the CVRs. On May 13, 2016, AST tendered its resignation as trustee under the CVR Agreement to Sanofi. As of June 30, 2016, UMB Bank, National Association replaced AST and is the successor trustee under the CVR Agreement.

Pursuant to the terms of the CVR Agreement, a holder of a CVR is entitled to cash payments upon the achievement of contractually defined milestones. The first three milestones (related, respectively, to (i) manufacturing of Cerezyme<sup>®</sup> and Fabrazyme<sup>®</sup> (ii) U.S. regulatory approval on or before March 31, 2014 of Lemtrada<sup>®</sup> for the treatment of MS (the Approval Milestone ) and (iii) Product Sales Milestone #1, pursuant to which a holder of a CVR would have been entitled to receive \$2 per CVR if Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) post launch equaled or exceeded a total of \$400 million within certain specified periods and territories) were not met.

The remaining milestone payments will be triggered on achievement of certain Lemtrada<sup>®</sup> sales thresholds within certain defined periods, as summarized below:

- *Product Sales Milestone #2 Payment.* \$3 per CVR upon the first instance in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of \$1.8 billion. Given that the Approval Milestone was not achieved, an additional \$1 per CVR will be paid should Product Sales Milestone #2 be achieved, totaling \$4 per CVR.
- *Product Sales Milestone #3 Payment.* \$4 per CVR upon the first instance in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of \$2.3 billion (however, no quarter in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) were used to determine the achievement of Product Sales Milestone #1 or #2 shall be included in the calculation of sales for determining whether Product Sales Milestone #3 has been achieved).
- *Product Sales Milestone #4 Payment.* \$3 per CVR upon the first instance in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) for a four calendar quarter period are equal to or in excess of \$2.8 billion (however, no quarter in which Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) were used to determine the achievement of Product Sales Milestone #1, #2 or #3 shall be included in the calculation of sales for determining whether Product Sales Milestone #4 has been achieved).

The CVR Agreement will terminate on the earlier of (a) December 31, 2020 and (b) the date that Product Sales Milestone #4 is paid (the Termination Date ), provided that if any milestone has been achieved prior to the Termination Date, but the associated CVR payment has not been paid on or prior to the Termination Date, the CVR Agreement shall not terminate until such payment has been paid in full in accordance with the terms of the CVR Agreement.

Sanofi has agreed to use diligent efforts (as defined in the CVR Agreement), until the CVR Agreement is terminated, to achieve each of the remaining milestones. However, we are not required to take all possible actions to achieve these goals. There can be no assurance that the remaining product sales milestones will be achieved. Sanofi has also agreed to use its commercially reasonable efforts to maintain a listing for trading of the CVRs on the NASDAQ market.

## Edgar Filing: Sanofi - Form 20-F

For more information on Lemtrada<sup>®</sup> see Item 4.B Business Overview Pharmaceutical Products Multiple Sclerosis .

The CVR Agreement does not prohibit Sanofi or any of its subsidiaries or affiliates (as defined in the CVR Agreement) from acquiring the CVRs, whether in open market transactions, private transactions or otherwise. Sanofi has certain disclosure obligations in connection with such acquisitions under the CVR Agreement. On or after April 1, 2017, Sanofi may also, subject to certain terms and conditions as set forth in the CVR Agreement, optionally purchase and cancel all (but not less than all) of the outstanding CVRs at a cash price as set forth in the CVR Agreement if (i) the volume-weighted average price paid per CVR for all CVRs traded over the forty-five trading days prior to such date is less than fifty cents and (ii) Lemtrada<sup>®</sup> sales (as defined in the CVR Agreement) in the four calendar quarters ended immediately prior to such date are less than \$1 billion in the aggregate.

A copy of the form of CVR Agreement is on file with the SEC as Annex B to Amendment No. 2 to the Registration Statement on Form F-4 filed with the Securities and Exchange Commission on March 24, 2011. Reference is made to such exhibit for a more complete description of the terms and conditions of the CVR Agreement, and the foregoing summary of such terms and conditions is qualified in its entirety by such exhibit.

### D. Exchange Controls

French exchange control regulations currently do not limit the amount of payments that we may remit to non-residents of France. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

**Table of Contents****ITEM 10. ADDITIONAL INFORMATION****E. Taxation****General**

The following generally summarizes the material French and U.S. federal income tax consequences to U.S. holders (as defined below) of purchasing, owning and disposing of our ADSs and ordinary shares (collectively the Securities). This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of our Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

*This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any U.S. federal, state, local or other national tax laws.*

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide *inter alia* for the inclusion of trust assets in the settlor's net assets for purpose of applying the French wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets of foreign trusts not already subject to the French wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

The description of the French and U.S. federal income tax consequences set forth below is based on the laws (including, for U.S. federal income tax purposes, the Internal Revenue Code of 1986, as amended (the Code), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the Treaty), which entered into force on December 30, 1995 (as amended by any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities within the *Bulletin Officiel des Finances Publiques- Impôts* (the Regulations) in force as of the date of this report. *U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the Limitations on Benefits provision, in light of their own particular circumstances.*

For the purposes of this discussion, a U.S. holder is a beneficial owner of Securities that is (i) an individual who is a U.S. citizen or resident for U.S. federal income tax purposes, (ii) a U.S. domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) otherwise subject to U.S. federal income taxation on a net income basis in respect of Securities. A non-U.S. holder is a person other than a U.S. holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon the status of the partner and the activities of the partnership. *If a U.S. holder is a partner in a partnership that holds Securities, the holder is urged to consult its own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold our Securities as capital assets that have the U.S. dollar as their functional currency, that are entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal

## Edgar Filing: Sanofi - Form 20-F

income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of our voting stock or 5% or more of our outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for U.S. federal income tax purposes, persons that acquire ADSs in pre-release transactions (i.e. prior to deposit of the relevant ordinary shares) and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below.  *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and U.S. federal income tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

---

**Table of Contents****ITEM 10. ADDITIONAL INFORMATION****French Taxes****Estate and Gift Taxes and Transfer Taxes**

In general, a transfer of Securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of Securities are subject to a 0.3% French tax on financial transactions (the FTFF ) provided that Sanofi's market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year used to be published annually by the French Ministry of Economy. It is now published by the French tax authorities, and could be amended at any time. Pursuant to Regulations BOI-ANNX-000467-20161220 issued on December 20, 2016, purchases of Sanofi's Securities in 2017 should be subject to the FTFF as the market capitalization of Sanofi exceeded 1 billion euros as of December 1, 2016. In accordance with Article 726-II of the French General Tax Code, purchases which are subject to the FTFF should however not be subject to transfer taxes (*droits d'enregistrement*) in France.

**Wealth Tax**

The French wealth tax *impôt de solidarité sur la fortune* applies only to individuals and does not generally apply to the Securities if the holder is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 25% of the financial rights.

**U.S. Taxes****Ownership of the Securities**

Deposits and withdrawals by a U.S. holder of ordinary shares in exchange for ADSs, will not be taxable events for U.S. federal income tax purposes. For U.S. tax purposes, holders of ADSs will be treated as owners of the ordinary shares represented by such ADSs. Accordingly, the discussion that follows regarding the U.S. federal income tax consequences of acquiring, owning and disposing of ordinary shares is equally applicable to ADSs.

**Information Reporting and Backup Withholding Tax**

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non-U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

**Foreign Asset Reporting**

In addition, a U.S. holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to recently-enacted reporting obligations with respect to ordinary shares and ADSs if the aggregate value of these and certain other specified foreign financial assets exceeds \$50,000. If required, this disclosure is made by filing Form 8938 with the U.S. Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and fail to do so. In addition, a U.S. holder should consider the possible obligation to file online a FinCEN Form 114 Foreign Bank and Financial Accounts Report as a result of holding ordinary shares or ADSs. Holders are encouraged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of ordinary shares and ADSs.

**State and Local Taxes**

In addition to U.S. federal income tax, U.S. holders of Securities may be subject to U.S. state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of U.S. state and local income tax law to their particular situation.*

---

**Table of Contents****ITEM 10. ADDITIONAL INFORMATION****ADSs-Ordinary Shares****French Taxes****Taxation of Dividends**

Under French law, dividends paid by a French corporation, such as Sanofi, to non-residents of France are generally subject to French withholding tax at a rate of 30% (21% for distributions made to individuals that are resident in the European Economic Area, and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206-5 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the Regulations BOI-RPPM-RCM-30-30-10-70-20120912, n° 130). Dividends paid by a French corporation, such as Sanofi, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally be subject to French withholding tax at a rate of 75%, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such States or territories; however, eligible U.S. holders entitled to Treaty benefits under the Limitation on Benefits provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, will not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the ordinary shares or ADSs is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France, is reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuing company; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For U.S. holders that are not individuals but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the Limitation on Benefits provision of the Treaty, are complicated, and certain technical changes were made to these requirements by the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depository with a treaty form (Form 5000). Dividends paid to a U.S. holder that has not filed the Form 5000 before the dividend payment date will be subject to French

withholding tax at the rate of 30% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during which the dividend is paid. Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

The depository agrees to use reasonable efforts to follow the procedures established, or that may be established, by the French tax authorities (i) to enable eligible U.S. holders to qualify for the reduced withholding tax rate provided by the Treaty, if available at the time the dividends are paid, or (ii) to recover any excess French withholding taxes initially withheld or deducted with respect to dividends and other distributions to which such U.S. holders may be eligible from the French tax authorities and (iii) to recover any other available tax credits. In particular, associated forms (including Form 5000 and Form 5001, together with their instructions), will be made available by the depository to all U.S. holders registered with the depository, and are also generally available from the U.S. Internal Revenue Service.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

**Tax on Sale or Other Disposition**

## Edgar Filing: Sanofi - Form 20-F

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of ordinary shares or ADSs unless the ordinary shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. Special rules apply to holders who are residents of more than one country.

### U.S. Taxes

#### Taxation of Dividends

For U.S. federal income tax purposes, the gross amount of any distribution paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of Sanofi (as determined under U.S. federal income tax principles). Dividends paid by Sanofi will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an

**Table of Contents****ITEM 10. ADDITIONAL INFORMATION**

individual U.S. holder with respect to the ADSs or our ordinary shares is currently subject to taxation at a maximum rate of 20% if the dividends are qualified dividends. Dividends paid on the ordinary shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company (PFIC). The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we believe Sanofi was not a PFIC for U.S. federal income tax purposes with respect to its 2015 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate that Sanofi will become a PFIC for its 2016 or 2017 taxable years. *Holders of ordinary shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

If you are a U.S. holder, dividend income received by you with respect to ADSs or ordinary shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or ordinary shares generally will be treated as passive category income (or, in the case of certain U.S. holders, general category income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or ordinary shares may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in Securities and may not be allowed in respect of certain arrangements in which a U.S. holder's expected economic profit is insubstantial. *The U.S. federal income tax rules governing the availability and computation of foreign tax credits are complex. U.S. holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a U.S. holder exceeds the allocable share of our current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder's tax basis in its ordinary shares or

ADSs and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such ordinary shares or ADSs (see Tax on Sale or Other Disposition, below).

The amount of any distribution paid in euros will be equal to the U.S. dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of ordinary shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into U.S. dollars on such date. *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a U.S. holder that are converted into U.S. dollars on a date subsequent to receipt.*

Distributions to holders of additional ordinary shares (or ADSs) with respect to their ordinary shares (or ADSs) that are made as part of a pro rata distribution to all ordinary shareholders generally will not be subject to U.S. federal income tax. However, if a U.S. holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder's tax basis in the distributed shares (or ADSs) will be equal to such amount.

**Tax on Sale or Other Disposition**

In general, for U.S. federal income tax purposes, a U.S. holder that sells, exchanges or otherwise disposes of its ordinary shares or ADSs will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the ordinary shares or ADSs and the U.S. holder's adjusted tax basis (determined in U.S. dollars and under U.S. federal income tax rules) in the ordinary shares or ADSs. Such gain or loss generally will be U.S.-source gain or loss, and will be treated as long-term capital gain or loss if the U.S. holder's holding period in the ordinary shares or ADSs exceeds one year at the time of disposition. If the U.S. holder is an individual, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 20%) if specified minimum holding periods are

met. The deductibility of capital losses is subject to significant limitations.

**Medicare Tax**

Certain U.S. holders who are individuals, estates or trusts are now required to pay a Medicare tax of 3.8% (in addition to taxes they would otherwise be subject to) on their net investment income which would include, among other things, dividends and capital gains from the ordinary shares and ADSs.

---

**Table of Contents**

**ITEM 10. ADDITIONAL INFORMATION**

*F. Dividends and Paying Agents*

N/A

*G. Statement by Experts*

N/A

*H. Documents on Display*

We are subject to the information requirements of the U.S. Securities Exchange Act of 1934, as amended, or Exchange Act, and, in accordance therewith, we are required to file reports, including this annual report on Form 20-F, and other information with the U.S. Securities and Exchange Commission, or Commission, by electronic means.

You may review a copy of our filings with the Commission, as well as other information furnished to the Commission, including exhibits and schedules filed with it, at the Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information. In addition, the Commission maintains an Internet site at <http://www.sec.gov> that contains reports and other information regarding issuers that file electronically with the Commission (these documents are not incorporated by reference in this annual report).

*I. Subsidiary Information*

N/A

---

**Table of Contents**

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

**Item 11. Quantitative and Qualitative Disclosures about Market Risk<sup>(1)</sup>**

**General Policy**

Liquidity risk, foreign exchange risk and interest rate risk, as well as related counterparty risks, are managed centrally by our dedicated treasury team within the Group Finance Department. Where it is not possible to manage those risks centrally in particular due to regulatory restrictions (such as foreign exchange controls) or local tax restrictions credit facilities and/or currency lines, guaranteed whenever necessary by the parent company, are contracted by our subsidiaries locally with banks, under the supervision of the central treasury team.

Our financing and investment strategies, and our interest rate and currency hedging strategies, are reviewed monthly by the Group Finance Department.

Our policy prohibits the use of derivatives for speculative purposes.

**Liquidity Risk**

We operate a centralized treasury platform whereby all surplus cash and financing needs of our subsidiaries are invested with or funded by the parent company (where permitted by local legislation). The central treasury department manages our current and projected financing, and ensures that Sanofi is able to meet its financial commitments by maintaining sufficient cash and confirmed credit facilities for the size of our operations and the maturity of our debt (see Notes D.17.c and D.17.g to the consolidated financial statements).

We diversify our short-term investments with leading counterparties using money-market products with instant access or with a maturity of less than three months. As of December 31, 2016, cash and cash equivalents amounted to 10,273 million, and our short-term investments predominantly comprised:

- collective investments in short-term money market and money market euro-denominated funds based on the European classification used by the *Autorité des Marchés Financiers*. All such funds can be traded on a daily basis and the amount invested in each fund may not exceed 10% of the aggregate amount invested in such funds;
- amounts invested directly with banks in the form of instant access deposits, term deposits, and certificates of deposit with a maturity of no more than three months;
-

## Edgar Filing: Sanofi - Form 20-F

amounts invested directly with non-financial institutions in the form of commercial paper and euro commercial paper with a maturity of no more than three months.

As of December 31, 2016, the Group also had 8 billion of undrawn general corporate purpose confirmed credit facilities, half expiring December 2020 and half December 2021. Those credit facilities are not subject to financial covenant ratios.

Our policy is to diversify our sources of funding through public or private issuances of debt securities, in the United States (shelf registration statement) and Europe (Euro Medium Term Note program). In addition, our A-1+/P-1 short-term rating gives us access to commercial paper programs in the United States and, to a lesser extent, in France. The average maturity of our total debt was 5.1 years as of December 31, 2016, compared with 4.5 years as of December 31, 2015. During 2016, we did not draw down on our French commercial paper program. Average drawdowns under the US commercial paper program during 2016 were 2.6 billion (maximum 5.4 billion); the average maturity of those drawdowns was three months. As of December 31, 2016, neither of those programs was being utilized.

In the event of a liquidity crisis, we could be exposed to difficulties in calling up our available cash, a scarcity of sources of funding including the above-mentioned programs, and/or a deterioration in their terms. This situation could damage our capacity to refinance our debt or to issue new debt on reasonable terms.

### **Interest Rate Risk**

We manage our net debt mainly in two currencies: the euro and the US dollar (see note D.17 to the consolidated financial statements). The floating-rate portion of this debt exposes Sanofi to rises in interest rates, primarily in the Eonia and Euribor benchmark rates (for the euro) and in the US Libor and Federal Fund Effective rates (for the US dollar). To optimize (or reduce the volatility of) our cost of debt, we use interest rate swaps, cross-currency swaps and where appropriate interest rate options, that alter the fixed/floating rate split of our debt. Those derivative instruments are predominantly denominated in euros and in US dollars.

<sup>(1)</sup> *The disclosures in this section supplement those provided in Note B.8.8. to the consolidated financial statements as regards the disclosure requirements of IFRS 7, and are covered by the statutory auditors' opinion on the consolidated financial statements.*

**Table of Contents****ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The projected full-year sensitivity to interest rate fluctuations of our debt, net of cash and cash equivalents for 2017 is as follows:

	Impact on pre-tax net income ( million)	Impact on pre-tax income/(expense) recognized directly in equity ( million)
<i>Change in EUR and USD short-term interest rates</i>		
+100 bp	54	
+25 bp	14	
-25 bp	(14)	
-100 bp	(54)	

**Foreign Exchange Risk****a. Operating Foreign Exchange Risk**

A substantial portion of our net sales is generated in countries where the euro, which is our reporting currency, is not the functional currency. In 2016, for example, 36.6% of our net sales were generated in the United States, 28.4% in Emerging Markets (including countries that are, or may in future become, subject to exchange controls), and 5% in Japan. Although we also incur expenses in those countries, the impact of those expenses is not enough wholly to offset the impact of exchange rates on our net sales. Consequently, our operating income may be materially affected by fluctuations in exchange rates between the euro and other currencies.

We operate a foreign exchange risk hedging policy to reduce the exposure of our operating income to exchange rate

movements. This policy involves regular assessments of our worldwide foreign currency exposure, based on foreign-currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those transactions to exchange rate movements, we contract hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also currency swaps.

The table below shows operating currency hedging instruments in place as of December 31, 2016, with the notional amount translated into euros at the relevant closing exchange rate (see Note D.20. to the consolidated financial statements for the accounting classification of those instruments as of December 31, 2016).

**Operating foreign exchange derivatives as of December 31, 2016**

( million)	Notional amount	Fair value
------------	-----------------	------------

Edgar Filing: Sanofi - Form 20-F

<b>Forward currency sales</b>	<b>3,963</b>	<b>(25)</b>
of which US dollar	1,850	(17)
of which Chinese yuan renminbi	453	(2)
of which Swiss franc	253	(1)
of which Japanese yen	206	5
of which Singapore dollar	156	1
<b>Forward currency purchases</b>	<b>1,517</b>	
of which US dollar	400	1
of which Japanese yen	283	(2)
of which Singapore dollar	233	1
of which Swiss franc	84	
of which Hungarian forint	82	
<b>Total</b>	<b>5,480</b>	<b>(25)</b>

**Table of Contents****ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The above positions mainly hedge future material foreign-currency cash flows arising after the end of the reporting period in relation to transactions carried out during the year ended December 31, 2016 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) have been and will continue to be calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange gain or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2017.

**b. Financial Foreign Exchange Risk**

The cash pooling arrangements for our foreign subsidiaries outside the euro zone, and some of our financing activities, expose certain of our entities to financial foreign exchange risk (i.e. the risk of changes in the value of borrowings and

loans denominated in a currency other than the functional currency of the borrower or lender). That foreign exchange exposure is hedged by the parent company using firm financial instruments (usually currency swaps or forward contracts) contracted with banking counterparties.

Although we incur more of our costs in euros than in any other currency, the US dollar accounts for a higher proportion of our revenues than any other currency. Consequently, we maintain a significant portion of our indebtedness in US dollars.

The table below shows financial currency hedging instruments in place as of December 31, 2016, with the notional amounts translated into euros at the relevant closing exchange rate (see also Note D.20 to the consolidated financial statements for the accounting classification of these instruments as of December 31, 2016).

**Financial foreign exchange derivatives as of December 31, 2016**

<i>( million)</i>	<b>Notional amount</b>	<b>Fair value</b>	<b>Expiry</b>
<b>Forward currency sales</b>	<b>5,298</b>	<b>(28)</b>	
of which US dollar	3,356	(37)	2017
of which Japanese yen <sup>(a)</sup>	1,036		2017
of which Pound sterling	317	7	2017
<b>Forward currency purchases</b>	<b>5,980</b>	<b>31</b>	
of which US dollar <sup>(b)</sup>	3,967	30	2017
of which Singapore dollar	878	5	2017
of which Czech koruna	332	(1)	2017
<b>Total</b>	<b>11,278</b>	<b>3</b>	

(a) Includes JPY 41,712 million as of December 31, 2016 designated as a cash flow hedge in respect of cash flows forecast for 2017.

*(b) Includes \$3,116 million as of December 31, 2016 designated as a cash flow hedge in respect of cash flows forecast for 2017 and the first quarter of 2018.*

These forward currency contracts generate a net financial foreign exchange gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowing and loans is offset by the change in the intrinsic value of the hedging instruments.

We may also hedge some future foreign-currency investment or divestment cash flows.

### **c. Other Foreign Exchange Risks**

A significant proportion of our net assets is denominated in US dollars (see Note D.35. to the consolidated financial statements). As a result, any fluctuation in the exchange rate of the US dollar against the euro automatically impacts the amount of our equity as expressed in euros. As of December 31, 2016, we had no derivative instruments in place to limit the effect of such fluctuations, but a significant proportion of our debt is still denominated in US dollars.

In addition, we use the euro as our reporting currency. Consequently, if one or more European Union member states were to abandon the euro as a currency, the resulting economic upheavals in particular, fluctuations in exchange rates could have a significant impact on the terms under which we can obtain financing and on our financial results, the extent and consequences of which are not currently foreseeable.

### **Counterparty Risk**

Our financing and investing transactions, and our currency and interest rate hedges, are contracted with leading counterparties. We set limits for investment and derivative transactions with individual financial institutions, depending on the rating of each institution. Compliance with these limits, which are based on notional amounts weighted by the residual maturity and the nature of the commitment, is monitored on a daily basis.

**Table of Contents****ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The table below shows our total exposure as of December 31, 2016 by rating and in terms of our percentage exposure to the dominant counterparty.

	Cash and cash equivalents (excluding mutual funds) <sup>(a)</sup>	Notional amounts of currency hedges <sup>(b)</sup>	Notional amounts of interest rate hedges <sup>(b)</sup>	General corporate purpose credit facilities
( million)				
AA-	195			
A+	1,917	9,175	2,399	3,500
A	1,038	4,743	628	2,000
A-	357	1,749		1,000
BBB+	220	1,091	200	1,500
BBB	81			
Unallocated	255	1		
Total	4,063	16,759	3,227	8,000
% / rating of dominant counterparty	17% / A+	15% / A+	36% / A+	6% /BBB+

(a) Cash equivalents include mutual fund investments of 6,210 million.

(b) The notional amounts are translated into euros at the relevant closing exchange rate as of December 31, 2016.

As of December 31, 2016, we held investments in short-term money market and money market euro-denominated funds based on the European classification used by the *Autorité des Marchés Financiers*. Those instruments have low volatility, low sensitivity to interest rate risk, and a very low probability of loss of principal. The depositary banks of the mutual funds, and of Sanofi itself, have a long-term rating of at least A.

Realization of counterparty risk could impact our liquidity in certain circumstances.

**Stock Market Risk**

It is our policy not to trade on the stock market for speculative purposes.



**Table of Contents**

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

**Item 12. Description of Securities other than Equity Securities**

**12.A Debt Securities**

Not applicable.

**12.B Warrants and Rights**

Not applicable.

**12.C Other Securities**

Not applicable.

**12.D American Depositary Shares**

**General**

JPMorgan Chase Bank, N.A. ( JPMorgan ), as depositary, issues Sanofi ADSs in certificated form (evidenced by an ADR) or book-entry form. Each ADR is a certificate evidencing a specific number of Sanofi ADSs. Each Sanofi ADS represents one-half of one Sanofi ordinary share (or the right to receive one-half of one Sanofi ordinary share) deposited with the Paris, France office of BNP Paribas, as custodian. Each Sanofi ADS also represents an interest in any other securities, cash or other property that may be held by the depositary under the deposit agreement. The depositary's office is located at 4 New York Plaza, 12<sup>th</sup> Floor, New York, New York 10004.

A holder may hold Sanofi ADSs either directly or indirectly through his or her broker or other financial institution. The following description assumes holders hold their Sanofi ADSs directly, in certificated form evidenced by ADRs. Holders who hold the Sanofi ADSs indirectly must rely on the procedures of their broker or other financial institution to assert the rights of ADR holders described in this section. Holders should consult with their broker or financial institution to find out what those procedures are.

Holders of Sanofi ADSs do not have the same rights as holders of Sanofi shares. French law governs shareholder rights. The rights of holders of Sanofi ADSs are set forth in the deposit agreement between Sanofi and JPMorgan and in the ADR. New York law governs the deposit agreement and the ADRs.

The following is a summary of certain terms of the deposit agreement, as amended. Our form of second amended and restated deposit agreement was filed as an exhibit to our Post-Effective Amendment No. 1 to Form F-6 filed on February 13, 2015. To the extent any portion of the amendment and restatement would prejudice any substantial existing right of holders of ADSs under the first amended and restated deposit agreement, such portion shall not become effective as to such holders until 30 days after

holders have received notice thereof. For more complete information, holders should read the entire second amended and restated deposit agreement and the ADR itself. Holders may also inspect a copy of the current deposit agreement at the depositary's office.

## Share Dividends and Other Distributions

### Receipt of dividends and other distributions

The depositary has agreed to pay to holders of Sanofi ADSs the cash dividends or other distributions that it or the custodian receives on the deposited Sanofi ordinary shares and other deposited securities after deducting its fees and expenses. Holders of Sanofi ADSs will receive these distributions in proportion to the number of Sanofi ADSs that they hold.

*Cash.* The depositary will convert any cash dividend or other cash distribution paid on the shares into U.S. dollars if, in its judgment, it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If the depositary determines that such a conversion and transfer is not possible, or if any approval from the French government is needed and cannot be obtained within a reasonable period, then the depositary may (1) distribute the foreign currency received by it to the holders of Sanofi ADSs or (2) hold the foreign currency distribution (uninvested and without liability for any interest) for the account of holders of Sanofi ADSs.

In addition, if any conversion of foreign currency, in whole or in part, cannot be effected to some holders of Sanofi ADSs, the deposit agreement allows the depositary to distribute the dividends only to those ADR holders to whom it is possible to do so. It will hold the foreign currency it cannot convert into U.S. dollars for the account of the ADR holders who have not been paid. It will not invest the funds it holds and it will not be liable for any interest.

Before making a distribution, any withholding taxes that must be paid under French law will be deducted. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents down to the nearest whole cent. ***Exchange rate fluctuations during a period when the depositary cannot convert euros into U.S. dollars may result in holders losing some or all of the value of a distribution.***

*Shares.* The depositary may, and at our request will, distribute new ADRs representing any shares we distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. At its option, the depositary may distribute fractional Sanofi ADSs. If the depositary does not distribute additional Sanofi ADSs,

---

**Table of Contents**

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

the outstanding ADRs will also represent the new shares. The depositary may withhold any tax or other governmental charges, or require the payment of any required fees and expenses, prior to making any distribution of additional Sanofi ADSs.

*Rights to Receive Additional Shares.* If we offer holders of Sanofi ordinary shares any rights to subscribe for additional shares or any other rights, the depositary, after consultation with us, will, in its discretion, either (1) make these rights available to holders or (2) dispose of such rights on behalf of holders and make the net proceeds available to holders. The depositary may make rights available to certain holders but not others if it determines it is lawful and feasible to do so. However, if, under the terms of the offering or for any other reason, the depositary may not make such rights available or dispose of such rights and make the net proceeds available, it will allow the rights to lapse. In that case, holders of Sanofi ADSs will receive no value for them.

In circumstances where rights would not otherwise be distributed by the depositary to holders of Sanofi ADSs, a holder of Sanofi ADSs may nonetheless request, and will receive from the depositary, any instruments or other documents necessary to exercise the rights allocable to that holder if the depositary first receives written notice from Sanofi that (1) Sanofi has elected, in its sole discretion, to permit the rights to be exercised and (2) such holder has executed the documents Sanofi has determined, in its sole discretion, are reasonably required under applicable law.

If the depositary makes rights available to holders of Sanofi ADSs, upon instruction from such holders, it will exercise the rights and purchase the shares on such holder's behalf. The depositary will then deposit the shares and deliver ADRs to such holders. It will only exercise rights if holders of Sanofi ADSs pay it the exercise price and any other charges the rights require such holders to pay.

U.S. securities laws may restrict the sale, deposit, cancellation or transfer of ADRs issued upon exercise of rights. For example, holders of Sanofi ADSs may not be able to trade Sanofi ADSs freely in the United States. In this case, the depositary may deliver Sanofi ADSs under a separate restricted deposit agreement that will contain the same provisions as the deposit agreement, except for changes needed to implement the required restrictions.

*Other Distributions.* The depositary will distribute to holders of Sanofi ADSs anything else we may distribute on deposited securities (after deduction or upon payment of fees and expenses or any taxes or other governmental charges) by any means it thinks is legal, equitable and practical. If, for any reason, it cannot make the distribution in that way, the depositary may sell what we distributed and distribute the net proceeds of the sale in the same way it

distributes cash dividends, or it may choose any other method to distribute the property it deems equitable and practicable.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of Sanofi ADSs. We have no obligation to register Sanofi ADSs, shares, rights or other securities under the U.S. Securities Act of 1933, as amended. We also have no obligation to take any other action to permit the distribution of ADRs, shares, rights or anything else to holders of Sanofi ADSs. This means that holders may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for the depositary to make them available to such holders.

*Elective Distributions.* Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to holders of Sanofi ADSs. In that case, we will assist the depositary in determining whether that distribution is lawful and reasonably practicable. The depositary will make the election available to holders of Sanofi ADSs only if it is reasonably practicable and if we have provided all the documentation contemplated in the deposit agreement. In that case, the depositary will establish procedures to enable holders of Sanofi ADSs to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement. If the election is not made available to holders of Sanofi ADSs, such holders will receive either cash or additional Sanofi ADSs, depending on what a shareholder in France would receive for failing to make an election, as more fully described in the deposit agreement.

**Deposit, Withdrawal and Cancellation**

**Delivery of ADRs**

The depositary will deliver ADRs if the holder or his or her broker deposit shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of Sanofi ADSs in the names the holder requests and will deliver the ADRs to the persons the holder requests at its office.

**Obtaining Sanofi ordinary shares**

A holder may turn in his or her ADRs at the depositary's office. Upon payment of its fees and expenses and any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver (1) the underlying shares to an account designated by the holder and (2) any

---

**Table of Contents****ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

other deposited securities underlying the ADR at the office of a custodian or, at the holder's request, risk and expense, the depositary will deliver the deposited securities at its office.

**Voting Rights**

A holder may instruct the depositary to vote the Sanofi ordinary shares underlying his or her Sanofi ADSs at any meeting of Sanofi shareholders, but only if we request that the depositary ask for holder instructions. Otherwise, holders will not be able to exercise their right to vote unless they withdraw the underlying ordinary shares from the ADR program and vote as an ordinary shareholder. However, holders may not know about the meeting sufficiently in advance to timely withdraw the underlying ordinary shares.

If we ask for holder instructions in connection with a meeting of Sanofi shareholders, the depositary will provide materials to holders of Sanofi ADSs in the manner described under the heading "Notices and Reports; Rights of Holders to Inspect Books" below. For any instructions to be valid, the depositary must receive them on or before the date specified in the materials distributed by the depositary. The depositary will endeavor, in so far as practical, subject to French law and the provisions of our *statuts*, to vote or to have its agents vote the shares or other deposited securities as holders may validly instruct. The depositary will only vote or attempt to vote shares as holders validly instruct.

We cannot guarantee holders that they will receive the voting materials with sufficient time to enable them to return any voting instructions to the depositary in a timely manner to vote their shares. As long as they act in good faith, neither the depositary nor its agents will be responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. ***This means that holders may not be able to exercise their right to vote and there may be nothing holders can do if their shares are not voted as they requested.***

Similar to our shares, Sanofi ADSs evidenced by ADRs that are registered in the name of the same owner for at least two (2) years are eligible for double voting rights so long as certain procedures are followed, as set out in the deposit agreement. For additional information regarding double voting rights, see "Item 10. Additional Information – B. Memorandum and Articles of Association – Voting Rights."

The deposit agreement allows the depositary and Sanofi to change the voting procedures or require additional voting procedures in addition to the ones described above if necessary or appropriate. ***For example, holders might be required to arrange to have their Sanofi ADSs deposited in a blocked account for a specified period of time prior to a shareholders' meeting in order to be allowed to give voting instructions.***

**Notices and Reports; Rights of Holders to Inspect Books**

On or before the first date on which we give notice, by publication or otherwise, of any meeting of holders of shares or other deposited securities, or of any adjourned meeting of such holders, or of the taking of any action in respect of any cash or other distributions or the offering of any rights, we will transmit to the depositary a copy of the notice.

Upon notice of any meeting of holders of shares or other deposited securities, if requested in writing by Sanofi, the depositary will, as soon as practicable, mail to the holders of Sanofi ADSs a notice, the form of which is in the discretion of the depositary, containing (1) a summary in English of the information contained in the notice of meeting provided by Sanofi to the depositary, (2) a statement that the holders as of the close of business on a specified record date will be entitled, subject to any applicable provision of French law and of our *statuts*, to instruct the depositary as to the exercise of the voting rights, if any, pertaining to the amount of shares or other deposited securities represented by their respective ADSs and (3) a statement as to the manner in which such instructions may be given. Notwithstanding the above, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the NYSE, in lieu of distribution of the materials provided to the depositary as described above, distribute to the holders a notice that provides holders with, or otherwise publicizes to holders, instructions on how to retrieve such materials or receive such materials upon request (i.e., by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

## Edgar Filing: Sanofi - Form 20-F

The depositary will make available for inspection by ADS holders at the depositary's office any reports and communications, including any proxy soliciting material, received from us that are both (1) received by the depositary as the holder of the deposited securities and (2) made generally available to the holders of such deposited securities by us. The depositary will also, upon written request, send to ADS holders copies of such reports when furnished by us pursuant to the deposit agreement. Any such reports and communications, including any such proxy soliciting material, furnished to the depositary by us will be furnished in English to the extent such materials are required to be translated into English pursuant to any regulations of the SEC.

The depositary will keep books for the registration of ADRs and transfers of ADRs that at all reasonable times will be open for inspection by the holders provided that such inspection is not for the purpose of communicating with holders in the interest of a business or object other than our business or a matter related to the deposit agreement or the ADRs.

**Table of Contents**

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

**Fees and Expenses**

**Fees Payable By ADS Holders**

Pursuant to the deposit agreement, holders of our ADSs may have to pay to JPMorgan, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

**Associated Fee**

\$5.00 or less per 100 ADSs (or portion thereof)

\$0.05 or less per ADS (or portion thereof)

Registration fees in effect for the registration of transfers of shares generally on the share register of the company or foreign registrar and applicable to transfers of shares to or from the name of JPMorgan or its nominee to the custodian or its nominee on the making of deposits and withdrawals

A fee equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities  
 A fee for the reimbursement of such fees, charges and expenses as are incurred by JPMorgan, its agents (and their agents), including BNP Paribas, as custodian (by deductions from cash dividends or other cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them)  
 Expenses incurred by JPMorgan

**Depository Action**

Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the deposit agreement

Any cash distribution made pursuant to the deposit agreement, including, among other things:

- cash distributions or dividends,
- distributions other than cash, shares or rights,
- distributions in shares, and
- rights of any other nature, including rights to subscribe for additional shares.

As applicable

Distributions of securities other than cash, shares or rights

Compliance with foreign exchange control regulations or any law or regulation relating to foreign investment, servicing of shares or other deposited securities, sale of securities, delivery of deposited securities or otherwise

- Cable, telex and facsimile transmission (where expressly provided for in the deposit agreement)
- Foreign currency conversion into U.S. dollars

In addition to the fees outlined above, each holder will be responsible for any taxes or other governmental charges payable on his or her Sanofi ADSs or on the deposited securities underlying his or her Sanofi ADSs. The depository may refuse to transfer a holder's Sanofi ADSs or allow a holder to withdraw the deposited securities underlying his or her Sanofi ADSs until such taxes or other charges are paid. It may apply payments owed to a holder or sell deposited securities underlying a holder's Sanofi ADSs to pay any taxes owed, and the holder will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of Sanofi ADSs to reflect the sale and pay to the holder any

proceeds, or send to the holder any property, remaining after it has paid the taxes. For additional information regarding taxation, see Item 10. Additional Information E. Taxation .

**Fees Paid to Sanofi by the Depositary**

JPMorgan, as depositary, has agreed to reimburse Sanofi for certain expenses (subject to certain limits) Sanofi incurs relating to legal fees, investor relations servicing, investor-related presentations, ADR-related advertising and public relations in those jurisdictions in which the ADRs may be listed or otherwise quoted, investor relations channel, perception studies, accountants fees in relation to our annual report on Form 20-F or any other expenses directly or indirectly relating to managing the program or servicing the ADR holders. The depositary has also agreed to provide additional amounts to us based on certain performance indicators relating to the ADR facility and fees collected by it. From January 1, 2016 to December 31, 2016, we received a total amount of \$15,628,303.86 from JPMorgan. In addition to these payments, JPMorgan has agreed to waive servicing

---

**Table of Contents**

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

fees we may incur in connection with routine corporate actions such as annual general meetings and dividend distributions, as well as for other assistance JPMorgan may provide to us, such as preparation of tax and regulatory compliance documents for holders and investor relations advisory services.

**Changes Affecting Deposited Securities**

If we:

- change the nominal or par value of our Sanofi ordinary shares;
- recapitalize, reorganize, merge or consolidate, liquidate, sell assets, or take any similar action;
- reclassify, split up or consolidate any of the deposited securities; or
- distribute securities on the deposited securities that are not distributed to holders; then either:
  - the cash, shares or other securities received by the depositary will become deposited securities and each Sanofi ADS will automatically represent its equal share of the new deposited securities; or
  - the depositary may, and will if we ask it to, distribute some or all of the cash, shares or other securities it receives. It may also deliver new ADRs or ask holders to surrender their outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

**Disclosure of Interests**

The obligation of a holder or other person with an interest in our shares to disclose information under French law and under our *statuts* also applies to holders and any other persons, other than the depositary, who have an interest in the Sanofi ADSs. The consequences for failing to comply with these provisions are the same for holders and any other persons with an interest as a holder of our ordinary shares. For additional information regarding these obligations, see Item 10. Additional Information B. Memorandum and Articles of Association Requirements for Holdings Exceeding Certain Percentages .

**Amendment and Termination**

We may agree with the depositary to amend the deposit agreement and the ADRs without the consent of the ADS holders for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices a substantial right of holders of Sanofi ADSs, it will only become effective 30 days after the depositary notifies such holders of the amendment. However, we may

not be able to provide holders of Sanofi ADSs with prior notice of the effectiveness of any modifications or supplements that are required to accommodate compliance with applicable provisions of law, whether or not those modifications or supplements could be considered to be materially prejudicial to the substantial rights of holders of Sanofi ADSs. *At the time an amendment becomes effective, such holders will be considered, by continuing to hold their ADR, to have agreed to the amendment and to be bound by the ADR and the deposit agreement as amended.*

The depositary will terminate the agreement if we ask it to do so. The depositary may also terminate the agreement if the depositary has told us that it would like to resign and we have not appointed a new depositary bank within 90 days. In both cases, the depositary must notify holders of Sanofi ADSs at least 30 days before termination.

After termination, the depositary and its agents will be required to do only the following under the deposit agreement: (1) collect distributions on the deposited securities, (2) sell rights and other property as provided in the deposit agreement and (3) deliver shares and other deposited securities upon cancellation of ADRs. Six months or more after termination, the depositary may sell any remaining deposited securities by public or private sale. After that, the depositary will hold the money it receives on the sale, as well as any other cash it is holding under the deposit agreement, for the pro rata benefit of the holders of Sanofi ADSs that have not surrendered their Sanofi ADSs. It will have no liability for interest. Upon termination of the deposit agreement, the depositary's only obligations will be to account for the proceeds of the sale and other cash and with respect to indemnification. After termination, our only obligation will be with respect to indemnification and to pay certain amounts to the depositary.

#### **Limitations on Obligations and Liability to Holders of Sanofi ADSs**

The deposit agreement expressly limits our obligations and the obligations of the depositary, and it limits our liability and the liability of the depositary. In particular, please note the following:

- we and the depositary are obligated only to take the actions specifically set forth in the deposit agreement without gross negligence or bad faith;
- we and the depositary are not liable if either is prevented or delayed by law or circumstances beyond its control from performing its obligations under the deposit agreement;
- we and the depositary are not liable if either exercises, or fails to exercise, any discretion permitted under the deposit agreement;
- we and the depositary have no obligation to become involved in a lawsuit or other proceeding related to the Sanofi ADSs or the deposit agreement on holders' behalf

---

**Table of Contents**

**ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

or on behalf of any other party, unless indemnity satisfactory to it against all expense and liability is furnished as often as may be required;

we and the depositary are not liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system or the custodian, subject to certain exceptions and to the extent the custodian is not a branch or affiliate of JPMorgan;

the depositary is not liable for the price received in connection with any sale of securities, the timing thereof or any delays, acts, omissions to act, errors, defaults or negligence on the part of the party so retained in connection with any such sale or proposed sale;

we and the depositary may rely without any liability upon any written notice, request, direction, instruction or other document believed by either of us to be genuine and to have been signed or presented by the proper parties; and

we and the depositary are not liable for any action or nonaction taken in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any ADS holder, or any other person believed in good faith to be competent to give such advice or information.

In addition, the depositary will not be liable for any acts or omissions made by a successor depositary. Moreover, neither we nor the depositary nor any of our respective agents will be liable to any holder of Sanofi ADSs for any indirect, special, punitive or consequential damages.

Pursuant to the terms of the deposit agreement, we and the depositary have agreed to indemnify each other under certain circumstances.

**Requirements for Depositary Actions**

Before the depositary will deliver or register the transfer of Sanofi ADSs, make a distribution on Sanofi ADSs or process a withdrawal of shares, the depositary may require:

payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;

production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and

compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver Sanofi ADSs, register transfers of Sanofi ADSs or permit withdrawals of shares when the transfer books of the depositary or our transfer books are closed, or at any time if the depositary or we think it advisable to do so.

**Right to Receive the Shares Underlying the Sanofi ADSs**

Holders have the right to cancel their Sanofi ADSs and withdraw the underlying Sanofi ordinary shares at any time except:

- when temporary delays arise when we or the depositary have closed our transfer books or the deposit of shares in connection with voting at a shareholders' meeting, or the payment of dividends;
  - when the holder or other holders of Sanofi ADSs seeking to withdraw shares owe money to pay fees, taxes and similar charges; or
  - when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to Sanofi ADSs or to the withdrawal of shares or other deposited securities.
- This right of withdrawal may not be limited by any other provision of the deposit agreement.

#### **Pre-Release of Sanofi ADSs**

Unless we instruct the depositary not to, the deposit agreement permits the depositary to deliver Sanofi ADSs before deposit of the underlying shares. This is called a pre-release of the Sanofi ADSs. The depositary may also deliver shares upon cancellation of pre-released Sanofi ADSs (even if the Sanofi ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive Sanofi ADSs instead of shares to close out a pre-release. Unless otherwise agreed in writing, the depositary may pre-release Sanofi ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to the depositary in writing that it or its customer (i) owns the shares or Sanofi ADSs to be deposited, (ii) assigns all beneficial rights, title and interest in such shares or ADRs to the depositary in its capacity as depositary and (iii) will not take any action with respect to such shares or ADRs that is inconsistent with the transfer of beneficial ownership, other than in satisfaction of such pre-release; (2) the pre-release must be fully collateralized with cash, U.S. government securities or other collateral that the depositary considers appropriate; (3) the depositary must be able to close out the pre-release on not more than five business days' notice; and (4) the depositary may require such further indemnities and credit regulations as it deems appropriate. In addition, the depositary will limit the number of Sanofi ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time, if it thinks it is appropriate to do so. The depositary may retain for its own account any compensation received by it in connection with the foregoing. Any holder of pre-release ADRs should consult its tax and other advisors about the implications of pre-release for its particular situation.

**Table of Contents**

**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

**PART II**

**Item 13. Defaults, Dividend Arrearages and Delinquencies**

N/A

**Item 14. Material Modifications to the Rights of Security Holders**

N/A

**Item 15. Controls and Procedures**

(a) Our Chief Executive Officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Form 20-F, have concluded that, as of such date, our disclosure controls and procedures were effective to ensure that material information relating to Sanofi was timely made known to them by others within Sanofi.

(b) Report of Management on Internal Control Over Financial Reporting.

Management

## Edgar Filing: Sanofi - Form 20-F

of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2016 based on the framework in Internal Control Integrated Framework (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that assessment, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2016 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

The effectiveness of the Company's internal control over financial reporting has been audited by PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, as stated in their report on the Company's internal control over financial reporting as of December 31, 2016, which is included herein. See paragraph (c) of the present Item 15, below.

(c) See report of PricewaterhouseCoopers Audit and Ernst & Young et Autres, independent registered public accounting firms, included under Item 18. Financial Statements on page 3.

(d) There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 16.

[Reserved]

**Table of Contents**

**ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

## **Item 16A. Audit Committee Financial Expert**

Our Board of Directors has determined that Robert Castaigne, Fabienne Lecorvaisier and Christian Mulliez, directors serving on the Audit Committee, are independent financial experts within the meaning of paragraph 407 of the Sarbanes-Oxley Act of 2002.

The Board of Directors determined that Robert Castaigne qualifies as a financial expert based on his education and his experience as Chief Financial Officer of Total, a major corporation. The Board of Directors deemed Fabienne Lecorvaisier to be a financial expert taking into account her experience in corporate finance in various international banks and as Chief Financial Officer of Essilor and now Air

Liquide. The Board of Directors deemed Christian Mulliez to be a financial expert taking into account his experience as Vice President, General Manager Administration and Finance of L'Oréal and graduate of the *Ecole Supérieure des Sciences Economiques et Commerciales* (ESSEC).

The Board of Directors has determined that all four directors meet the independence criteria of U.S. Securities and Exchange Commission Rule 10A-3, although only Robert Castaigne, Fabienne Lecorvaisier and Carole Piwnica meet the French AFEP-MEDEF Code criteria of independence applied by the Board of Directors for general corporate governance purposes (see Item 16G, below).

## **Item 16B. Code of Ethics**

We have adopted a financial code of ethics, as defined in Item 16B. of Form 20-F under the Exchange Act. Our financial code of ethics applies to our Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, as designated from time to time. Our financial code of ethics is available on our Website at [www.sanofi.com](http://www.sanofi.com) (information on our website

is not incorporated by reference in this annual report). A copy of our financial code of ethics may also be obtained free of charge by addressing a written request to the attention of Individual Shareholder Relations at our headquarters in Paris. We will disclose any amendment to the provisions of such financial code of ethics on our website.

## Item 16C. Principal Accountants Fees and Services

See Note E. to our consolidated financial statements included at Item 18 of this annual report.

## Item 16D. Exemptions from the Listing Standards for Audit Committees

N/A

## Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2016, Sanofi made the following purchases of its ordinary shares.

Period	(A) Total Number of Shares Purchased	(B) Average Price Paid per Share	(C) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs <sup>(a)</sup>	(D) Approximate Value of Shares that May Yet Be Purchased Under the Plans or Programs <sup>(b)</sup>
January 2016	13,265,706	75.38	13,265,706	14,668
February 2016	5,498,527	72.75	5,498,527	14,268
November 2016	10,747,049	75.13	10,747,049	13,460
December 2016	9,200,153	75.27	9,200,153	12,768

(a) The Company was authorized to repurchase up to 15,668,361,000 of shares for a period of eighteen months (i.e., through November 4, 2017) by the Annual Shareholders Meeting held on May 4, 2016.

(b) Millions of euros.

**Table of Contents**

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

This schedule does not include purchases and sales conducted by Exane (until May 9, 2016) and then Rothschild & Cie Banque under a liquidity contract and that

is still in effect. For more information see Item 10.B *Memorandum and Articles of Association – Use of Share Repurchase Programs*.

**Item 16F. Change in Registrant's Certifying Accountant**

N/A

**Item 16G. Corporate Governance**

Sanofi is incorporated under the laws of France, with securities listed on regulated public markets in the United States (New York Stock Exchange) and France (Euronext Paris). Consequently, as described further in our annual report, our corporate governance framework reflects the mandatory provisions of French corporate law, the securities laws and regulations of France and the United States and the rules of the aforementioned public markets. In addition, we generally follow the AFEP-MEDEF corporate governance recommendations for French listed issuers (hereafter referred to as the AFEP-MEDEF Code). As a result, our corporate governance framework is similar in many respects to, and provides investor protections that are comparable to or in some cases, more stringent than the corresponding rules of the New York Stock Exchange. Nevertheless, there are important differences to keep in mind.

In line with New York Stock Exchange rules applicable to domestic issuers, Sanofi maintains a board of directors of which at least half of the members are independent. Sanofi evaluates the independence of members of our Board of Directors using the standards of the French AFEP-MEDEF Code as the principal reference. We believe that AFEP-MEDEF's overarching criteria for independence – no relationship of any kind whatsoever with the Company, its group or the management of either that is such as to color a Board member's judgment – are on the whole consistent with the goals of the New York Stock Exchange's rules although the specific tests proposed under the two standards may vary on some points. We have complied with the audit committee independence and other requirements of the Rule 10A-3 under the U.S. Securities Exchange

## Edgar Filing: Sanofi - Form 20-F

Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. Our Compensation Committee includes one non-independent member, Christian Mulliez, which is permitted under the AFEP-MEDEF Code but would not be compliant with the rules of the New York Stock Exchange for domestic issuers.

Under French law, the committees of our Board of Directors are advisory only, and where the New York Stock Exchange Listed Company Manual would vest certain decision-making

powers with specific committees by delegation (e.g. appointment or audit committees), under French law our Board of Directors remains the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the Shareholders' General Meeting of Sanofi that is competent to appoint our auditors upon the proposal of our Board of Directors, although our Board Charter provides that the Board of Directors will make its proposal on the basis of the recommendation of our Audit Committee. We believe that this requirement of French law, together with the additional legal requirement that two sets of statutory auditors be appointed, share the New York Stock Exchange's underlying goal of ensuring that the audit of our accounts be conducted by auditors independent from company management.

In addition to the oversight role of our Compensation Committee for questions of management compensation including by way of equity, under French law any option or restricted share plans or other share capital increases, whether for the benefit of senior management or employees, may only be adopted by the Board of Directors pursuant to and within the limits of a shareholder resolution approving the related capital increase and delegating to the Board the authority to implement such operations.

As described above, a number of issues, which could be resolved directly by a board or its committees in the United States, require the additional protection of direct shareholder consultation in France. Our Audit Committee is entirely composed of independent directors as that term is defined in Rule 10A-3 under the U.S. Securities Exchange Act of 1934, as amended, adopted pursuant to the Sarbanes-Oxley Act of 2002. The composition of our Audit Committee, Compensation Committee, and Appointments and Governance Committee includes directors who are also officers of our largest shareholder.

As a foreign private issuer under the U.S. securities laws, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by §302 and §906 of the Sarbanes Oxley Act of 2002 on an annual basis (with the filing of our annual report on U.S. Form 20-F) rather than on

**Table of Contents**

**ITEM 16G. CORPORATE GOVERNANCE**

a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on U.S. Form 10-Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of transactions that could potentially create conflicts of interest between Sanofi on the one hand and its Directors and Chief Executive Officer on the other hand, which are then

presented to shareholders for approval at the next annual meeting. This legal safeguard provides shareholders with an opportunity to approve significant aspects of the Chief Executive Officer's compensation package, and it operates in place of certain provisions of the NYSE Listed Company Manual.

## **Item 16H. Mine Safety Disclosure**

N/A

**Table of Contents**

**ITEM 17. FINANCIAL STATEMENTS**

**PART III**

**Item 17. Financial Statements**

See Item 18.

**Item 18. Financial Statements**

See pages F-1 through F-110 incorporated herein by reference.

**Item 19. Exhibits**

- 1.1 Articles of association (*statuts*) of Sanofi (English translation)
- 1.2 Board Charter (*Règlement Intérieur*) of Sanofi (English translation)
2. The total amount of long-term debt securities authorized under any instrument does not exceed 10% of the total assets of the Company and its subsidiaries on a consolidated basis. We hereby agree to furnish to the SEC, upon its request, a copy of any instrument defining the rights of holders of long-term debt of the Company or of its subsidiaries for which consolidated or unconsolidated financial statements are required to be filed.

## Edgar Filing: Sanofi - Form 20-F

- 4.1 Form of Contingent Value Rights Agreement by and among Sanofi and Trustee (*on file with the SEC as Annex B to Amendment No.2 to the Registration Statement on Form F-4 filed on March 24, 2011*)
  
- 8.1 List of significant subsidiaries, see Item 4. Information on the Company C. Organizational Structure of ~~2014~~ 2015.
  
- 12.1 Certification by Olivier Brandicourt, Chief Executive Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
  
- 12.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 302 of the Sarbanes-Oxley Act of 2002
  
- 13.1 Certification by Olivier Brandicourt, Chief Executive Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
  
- 13.2 Certification by Jérôme Contamine, Principal Financial Officer, required by Section 906 of the Sarbanes-Oxley Act of 2002
  
- 23.1 Consent of Ernst & Young et Autres dated March 2, 2017
  
- 23.2 Consent of PricewaterhouseCoopers Audit dated March 2, 2017
  
- 99.1 Report of the Chairman of the Board of Directors for 2016 as required by Art. L. 225-37 paragraph 6 of the French Commercial Code

Table of Contents

## SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

Sanofi  
By: /s/ OLIVIER BRANDICOURT  
Name: **Olivier Brandicourt**  
Title: **Chief Executive Officer**

Date: March 2, 2017

221

**Table of Contents**

# 2016 ANNUAL CONSOLIDATED FINANCIAL STATEMENTS

The financial statements are presented in accordance with International Financial Reporting Standards (IFRS).

<b><u>CONSOLIDATED BALANCE SHEETS ASSETS</u></b>	<b>F-4</b>
<b><u>CONSOLIDATED BALANCE SHEETS LIABILITIES AND EQUITY</u></b>	<b>F-5</b>
<b><u>CONSOLIDATED INCOME STATEMENTS</u></b>	<b>F-6</b>
<b><u>CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME</u></b>	<b>F-7</b>
<b><u>CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY</u></b>	<b>F-8</b>
<b><u>CONSOLIDATED STATEMENTS OF CASH FLOWS</u></b>	<b>F-10</b>
<b><u>NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS</u></b>	<b>F-12</b>
<b><u>A/ BASIS OF PREPARATION</u></b>	<b>F-12</b>
<b><u>B/ SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES</u></b>	<b>F-13</b>
<b><u>C/ PRINCIPAL ALLIANCES</u></b>	<b>F-31</b>
<b><u>D/ PRESENTATION OF THE FINANCIAL STATEMENTS</u></b>	<b>F-32</b>
<b><u>E/ PRINCIPAL ACCOUNTANTS FEES AND SERVICES</u></b>	<b>F-104</b>
<b><u>F/ LIST OF PRINCIPAL COMPANIES INCLUDED IN THE CONSOLIDATION FOR THE YEAR ENDED DECEMBER 31, 2016</u></b>	<b>F-105</b>
<b><u>G/ EVENTS SUBSEQUENT TO DECEMBER 31, 2016</u></b>	<b>F-110</b>

---

**Table of Contents**

# REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRMS

To the Board of Directors and Shareholders of Sanofi,

We have audited the accompanying consolidated balance sheets of Sanofi and its subsidiaries (together the Group) as of December 31, 2016, 2015 and 2014, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America (the PCAOB). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of the Group as of December 31, 2016, 2015 and 2014, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

We also have audited, in accordance with the standards of the PCAOB, the effectiveness of the Group's internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) and our report dated March 2, 2017 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, France, March 2, 2017

PricewaterhouseCoopers Audit  
/s/ Philippe Vogt                      /s/ Stéphane Basset

Ernst & Young et Autres

**F- 2**

Table of Contents

## REPORT OF INDEPENDENT REGISTERED

## PUBLIC ACCOUNTING FIRMS

## SANOFI

To the Board of Directors and Shareholders of Sanofi,

We have audited internal control over financial reporting of Sanofi and its subsidiaries (together the Group ) as of December 31, 2016, based on criteria established in **Internal Control - Integrated Framework** issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) (the COSO criteria). The Group s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Report of Management on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board of the United States of America (the PCAOB ). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Group maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the PCAOB, the consolidated balance sheets of the Group as of December 31, 2016, 2015 and 2014, and the related consolidated statements of income, comprehensive income, changes in equity and cash flows for each of the three years in the period ended December 31, 2016 and our report dated March 2, 2017 expressed an unqualified opinion thereon.

Neuilly-sur-Seine and Paris-La Défense, France, March 2, 2017

PricewaterhouseCoopers Audit  
/s/ Philippe Vogt

/s/ Stéphane Basset

Ernst & Young et Autres

F- 3

**Table of Contents****CONSOLIDATED BALANCE SHEETS ASSETS**

		December 31,	December 31,	December 31,
	Note	2016	2015	2014
( million)				
Property, plant and equipment	D.3.	10,019	9,943	10,396
Goodwill	D.4.	40,287	39,557	39,197
Other intangible assets	D.4.	10,879	12,026	14,543
Investments in associates and joint ventures	D.6.	2,890	2,676	2,384
Other non-current assets	D.7.	2,820	2,725	2,575
Deferred tax assets	D.14.	4,669	4,714	4,860
<b>Non-current assets</b>		<b>71,564</b>	<b>71,641</b>	<b>73,955</b>
Inventories	D.9.	6,892	6,516	6,562
Accounts receivable	D.10.	7,311	7,386	7,149
Other current assets	D.11.	2,211	1,878	2,375
Cash and cash equivalents	D.13. - D.17.	10,273	9,148	7,341
<b>Current assets</b>		<b>26,687</b>	<b>24,928</b>	<b>23,427</b>
Assets held for sale or exchange	D.8. - D.36.	6,421	5,752	10
<b>TOTAL ASSETS</b>		<b>104,672</b>	<b>102,321</b>	<b>97,392</b>

F- 4

**Table of Contents****CONSOLIDATED BALANCE SHEETS LIABILITIES AND EQUITY**

		December 31,	December 31,	December 31,
( million)	Note	2016	2015	2014
Equity attributable to equity holders of Sanofi	<b>D.15.</b>	57,554	58,049	56,120
Equity attributable to non-controlling interests	<b>D.16.</b>	170	161	148
<b>Total equity</b>		<b>57,724</b>	<b>58,210</b>	<b>56,268</b>
Long-term debt	<b>D.17.</b>	16,815	13,118	13,276
Non-current liabilities related to business combinations and to non-controlling interests	<b>D.18.</b>	1,378	1,121	1,133
Provisions and other non-current liabilities	<b>D.19.</b>	8,834	9,169	9,578
Deferred tax liabilities	<b>D.14.</b>	2,292	2,895	4,105
<b>Non-current liabilities</b>		<b>29,319</b>	<b>26,303</b>	<b>28,092</b>
Accounts payable		4,297	3,817	3,651
Other current liabilities	<b>D.19.4.</b>	10,175	9,442	7,712
Current liabilities related to business combinations and to non-controlling interests	<b>D.18.</b>	198	130	131
Short-term debt and current portion of long-term debt	<b>D.17.</b>	1,764	3,436	1,538
<b>Current liabilities</b>		<b>16,434</b>	<b>16,825</b>	<b>13,032</b>
Liabilities related to assets held for sale or exchange	<b>D.8. - D.36.</b>	1,195	983	-
<b>TOTAL LIABILITIES AND EQUITY</b>		<b>104,672</b>	<b>102,321</b>	<b>97,392</b>

F- 5

**Table of Contents****CONSOLIDATED INCOME STATEMENTS**

( million)	Note	2016 <sup>(a)</sup>	2015 <sup>(a)(b)</sup>	2014 <sup>(a)(b)</sup>
<b>Net sales</b>	<b>D.35.1.</b>	<b>33,821</b>	<b>34,060</b>	<b>31,380</b>
Other revenues		887	801	619
Cost of sales		(10,702)	(10,919)	(10,230)
<b>Gross profit</b>		<b>24,006</b>	<b>23,942</b>	<b>21,769</b>
Research and development expenses		(5,172)	(5,082)	(4,667)
Selling and general expenses		(9,486)	(9,382)	(8,425)
Other operating income	<b>D.25.</b>	355	254	301
Other operating expenses	<b>D.26.</b>	(482)	(462)	(157)
Amortization of intangible assets		(1,692)	(2,137)	(2,081)
Impairment of intangible assets	<b>D.5.</b>	(192)	(767)	31
Fair value remeasurement of contingent consideration liabilities	<b>D.18.</b>	(135)	53	(303)
Restructuring costs and similar items	<b>D.27.</b>	(879)	(795)	(404)
Other gains and losses, and litigation	<b>D.28.</b>	211		
<b>Operating income</b>		<b>6,534</b>	<b>5,624</b>	<b>6,064</b>
Financial expenses	<b>D.29.</b>	(924)	(559)	(598)
Financial income	<b>D.29.</b>	68	178	192
<b>Income before tax and associates and joint ventures</b>	<b>D.35.1.</b>	<b>5,678</b>	<b>5,243</b>	<b>5,658</b>
Income tax expense	<b>D.30.</b>	(1,326)	(709)	(1,214)
Share of profit/(loss) of associates and joint ventures	<b>D.31.</b>	134	(22)	(52)
<b>Net income excluding the held-for-exchange Animal Health business</b>		<b>4,486</b>	<b>4,512</b>	<b>4,392</b>
Net income/(loss) of the held-for-exchange Animal Health business	<b>D.36.</b>	314	(124)	117
<b>Net income</b>		<b>4,800</b>	<b>4,388</b>	<b>4,509</b>
Net income attributable to non-controlling interests	<b>D.32.</b>	91	101	119
<b>Net income attributable to equity holders of Sanofi</b>		<b>4,709</b>	<b>4,287</b>	<b>4,390</b>
Average number of shares outstanding (million)	<b>D.15.9.</b>	1,286.6	1,306.2	1,315.8
Average number of shares outstanding after dilution (million)	<b>D.15.9.</b>	1,296.0	1,320.7	1,331.1
Basic earnings per share (in euros)		3.66	3.28	3.34
Basic earnings per share excluding the held-for-exchange Animal Health business (in euros)		3.42	3.38	3.25
Diluted earnings per share (in euros)		3.63	3.25	3.30
Diluted earnings per share excluding the held-for-exchange Animal Health business (in euros)		3.39	3.34	3.21

(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.2. and D.36.

(b) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards (see Notes A.5. and B.14.). The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).

**Table of Contents****CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**

<i>( million)</i>	Note	2016	2015	2014
<b>Net income</b>		<b>4,800</b>	<b>4,388</b>	<b>4,509</b>
<i>Attributable to equity holders of Sanofi</i>		4,709	4,287	4,390
<i>Attributable to non-controlling interests</i>		91	101	119
<b>Other comprehensive income:</b>				
· Actuarial gains/(losses)	D.15.7.	(106)	652	(869)
· Tax effects	D.15.7.	(22)	(187)	303
<b>Sub-total: items not subsequently reclassifiable to profit or loss (a)</b>		<b>(128)</b>	<b>465</b>	<b>(566)</b>
· Available-for-sale financial assets	D.15.7.	(105)	(37)	(2,760)
· Cash flow hedges	D.15.7.	31	(3)	
· Change in currency translation differences	D.15.7.	1,090	1,915	2,506
· Tax effects	D.15.7.	40	20	250
<b>Sub-total: items subsequently reclassifiable to profit or loss (b)</b>		<b>1,056</b>	<b>1,895</b>	<b>(4)</b>
<b>Other comprehensive income for the period, net of taxes (a+b)</b>		<b>928</b>	<b>2,360</b>	<b>(570)</b>
<b>Comprehensive income</b>		<b>5,728</b>	<b>6,748</b>	<b>3,939</b>
<i>Attributable to equity holders of Sanofi</i>		5,634	6,641	3,810
<i>Attributable to non-controlling interests</i>		94	107	129

F- 7

**Table of Contents****CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

( million)	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share- based payment	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
<b>Balance at January 1, 2014</b>	<b>2,649</b>	<b>53,072</b>	<b>(244)</b>	<b>2,390</b>	<b>(963)</b>	<b>56,904</b>	<b>129</b>	<b>57,033</b>
Other comprehensive income for the period	-	(566)	-	-	(14)	(580)	10	(570)
Net income for the period	-	4,390	-	-	-	4,390	119	4,509
<b>Comprehensive income for the period</b>	<b>-</b>	<b>3,824</b>	<b>-</b>	<b>-</b>	<b>(14)</b>	<b>3,810</b>	<b>129</b>	<b>3,939</b>
Dividend paid out of 2013 earnings ( 2.80 per share)	-	(3,676)	-	-	-	(3,676)	-	(3,676)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(125)	(125)
Share repurchase program <sup>(a)</sup>	-	-	(1,801)	-	-	(1,801)	-	(1,801)
Reduction in share capital <sup>(a)</sup>	(36)	(1,314)	1,350	-	-	-	-	-
Share-based payment plans:								
· Exercise of stock options <sup>(a)</sup>	22	658	-	-	-	680	-	680
· Issuance of restricted shares <sup>(a)</sup>	4	(4)	-	-	-	-	-	-
· Proceeds from sale of treasury shares on exercise of stock options	-	-	1	-	-	1	-	1
· Value of services obtained from employees	-	-	-	202	-	202	-	202
· Tax effects of the exercise of stock options	-	-	-	7	-	7	-	7
Change in non-controlling interests without loss of control	-	(7)	-	-	-	(7)	15	8
<b>Balance at December 31, 2014</b>	<b>2,639</b>	<b>52,553</b>	<b>(694)</b>	<b>2,599</b>	<b>(977)</b>	<b>56,120</b>	<b>148</b>	<b>56,268</b>
Other comprehensive income for the period	-	465	-	-	1,889	2,354	6	2,360
Net income for the period	-	4,287	-	-	-	4,287	101	4,388
<b>Comprehensive income for the period</b>	<b>-</b>	<b>4,752</b>	<b>-</b>	<b>-</b>	<b>1,889</b>	<b>6,641</b>	<b>107</b>	<b>6,748</b>
Dividend paid out of 2014 earnings ( 2.85 per share)	-	(3,694)	-	-	-	(3,694)	-	(3,694)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(110)	(110)
Share repurchase program <sup>(a)</sup>	-	-	(1,781)	-	-	(1,781)	-	(1,781)
Reduction in share capital <sup>(a)</sup>	(52)	(2,124)	2,176	-	-	-	-	-
Share-based payment plans:								
· Exercise of stock options <sup>(a)</sup>	18	555	-	-	-	573	-	573
· Issuance of restricted shares <sup>(a)</sup>	6	(6)	-	-	-	-	-	-
· Proceeds from sale of treasury shares on exercise of stock options	-	-	1	-	-	1	-	1
· Value of services obtained from employees	-	-	-	205	-	205	-	205
· Tax effects of the exercise of stock options	-	-	-	10	-	10	-	10
Change in non-controlling interests without loss of control	-	(26)	-	-	-	(26)	16	(10)
<b>Balance at December 31, 2015</b>	<b>2,611</b>	<b>52,010</b>	<b>(298)</b>	<b>2,814</b>	<b>912</b>	<b>58,049</b>	<b>161</b>	<b>58,210</b>

F- 8

**Table of Contents**

<i>( million)</i>	Share capital	Additional paid-in capital and retained earnings	Treasury shares	Stock options and other share-based payment	Other comprehensive income	Attributable to equity holders of Sanofi	Attributable to non-controlling interests	Total equity
<b>Balance at December 31, 2015</b>	<b>2,611</b>	<b>52,010</b>	<b>(298)</b>	<b>2,814</b>	<b>912</b>	<b>58,049</b>	<b>161</b>	<b>58,210</b>
Other comprehensive income for the period	-	(127)	-	-	1,052	925	3	928
Net income for the period	-	4,709	-	-	-	4,709	91	4,800
<b>Comprehensive income for the period</b>	<b>-</b>	<b>4,582</b>	<b>-</b>	<b>-</b>	<b>1,052</b>	<b>5,634</b>	<b>94</b>	<b>5,728</b>
Dividend paid out of 2015 earnings ( 2.93 per share)	-	(3,759)	-	-	-	(3,759)	-	(3,759)
Payment of dividends to non-controlling interests	-	-	-	-	-	-	(110)	(110)
Share repurchase program <sup>(a)</sup>	-	-	(2,905)	-	-	(2,905)	-	(2,905)
Reduction in share capital <sup>(a)</sup>	(45)	(1,655)	1,700	-	-	-	-	-
Share-based payment plans:								
· Exercise of stock options <sup>(a)</sup>	7	212	-	-	-	219	-	219
· Issuance of restricted shares <sup>(a)</sup>	7	(7)	-	-	-	-	-	-
· Employee share ownership plans <sup>(a)</sup>	4	96	-	-	-	100	-	100
· Proceeds from sale of treasury shares on exercise of stock options	-	-	-	-	-	-	-	-
· Value of services obtained from employees	-	-	-	227	-	227	-	227
· Tax effects of the exercise of stock options	-	-	-	(9)	-	(9)	-	(9)
Change in non-controlling interests without loss of control	-	(2)	-	-	-	(2)	27	25
Change in non-controlling interests arising from divestment	-	-	-	-	-	-	(2)	(2)
<b>Balance at December 31, 2016</b>	<b>2,584</b>	<b>51,477</b>	<b>(1,503)</b>	<b>3,032</b>	<b>1,964</b>	<b>57,554</b>	<b>170</b>	<b>57,724</b>

(a) See Notes D.15.1., D.15.3., D.15.4. and D.15.5.

**Table of Contents****CONSOLIDATED STATEMENTS OF CASH FLOWS**

<i>( million)</i>	Note	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
<b>Net income attributable to equity holders of Sanofi</b>		<b>4,709</b>	<b>4,287</b>	<b>4,390</b>
Net (income)/loss of the held-for-exchange Animal Health business		(314)	124	(117)
Non-controlling interests, excluding BMS <sup>(b)</sup>	<b>D.32.</b>	5	7	10
Share of undistributed earnings of associates and joint ventures		(83)	115	142
Depreciation, amortization and impairment of property, plant and equipment and intangible assets <sup>(c)</sup>		3,301	4,276	3,280
Gains and losses on disposals of non-current assets, net of tax <sup>(d)</sup>		(244)	(136)	(249)
Net change in deferred taxes		(542)	(1,253)	(1,151)
Net change in provisions <sup>(e)</sup>		20	(13)	(374)
Cost of employee benefits (stock options and other share-based payments)	<b>D.15.2. - D.15.3. - D.15.8.</b>	241	193	192
Impact of the workdown of acquired inventories remeasured at fair value	<b>D.35.1.</b>	-	-	-
Unrealized (gains)/losses recognized in income		(83)	(365)	134
<b>Operating cash flow before changes in working capital and excluding the held-for-exchange Animal Health business</b>		<b>7,010</b>	<b>7,235</b>	<b>6,257</b>
(Increase)/decrease in inventories		(323)	(466)	(8)
(Increase)/decrease in accounts receivable		168	(493)	(20)
Increase/(decrease) in accounts payable		447	241	459
Net change in other current assets and other current liabilities		536	1,773	477
<b>Net cash provided by/(used in) operating activities excluding the held-for-exchange Animal Health business<sup>(f)</sup></b>		<b>7,838</b>	<b>8,290</b>	<b>7,165</b>
<b>Net cash provided by/(used in) operating activities of the held-for-exchange Animal Health business</b>		<b>346</b>	<b>630</b>	<b>525</b>
Acquisitions of property, plant and equipment and intangible assets	<b>D.3. D.4.</b>	(2,083)	(2,772)	(1,453)
Acquisitions of investments in consolidated undertakings, net of cash acquired <sup>(g)</sup>	<b>D.1.- D.18.</b>	(426)	(220)	(1,723)
Acquisitions of available-for-sale financial assets	<b>D.7.</b>	(208)	(142)	(571)
Proceeds from disposals of property, plant and equipment, intangible assets and other non-current assets, net of tax <sup>(h)</sup>		209	211	262
Net change in loans and other financial assets		(3)	(88)	128
<b>Net cash provided by/(used in) investing activities excluding the held-for-exchange Animal Health business</b>		<b>(2,511)</b>	<b>(3,011)</b>	<b>(3,357)</b>
<b>Net cash provided by/(used in) investing activities of the held-for-exchange Animal Health business</b>		<b>(126)</b>	<b>(246)</b>	<b>(103)</b>

F- 10

**Table of Contents**

( million)	Note	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
Issuance of Sanofi shares	D.15.1.	305	573	680
Dividends paid:				
to shareholders of Sanofi		(3,759)	(3,694)	(3,676)
to non-controlling interests, excluding BMS <sup>(b)</sup>		(21)	(12)	(10)
Transaction with non-controlling interests, other than dividends		(11)	(8)	2
Addition of long-term debt contracted	D.17.	4,773	2,253	2,980
Repayments of long-term debt	D.17.	(2,576)	(708)	(3,032)
Net change in short-term debt		96	(199)	(338)
Acquisition of treasury shares	D.15.4.	(2,908)	(1,784)	(1,801)
Disposals of treasury shares, net of tax	D.15.	-	1	1
<b>Net cash provided by/(used in) financing activities excluding the held-for-exchange Animal Health business</b>		<b>(4,101)</b>	<b>(3,578)</b>	<b>(5,194)</b>
<b>Net cash provided by/(used in) financing activities of the held-for-exchange Animal Health business</b>		<b>111</b>	<b>(23)</b>	<b>14</b>
<b>Impact of exchange rates on cash and cash equivalents</b>		<b>(101)</b>	<b>(232)</b>	<b>34</b>
<b>Impact on cash and cash equivalents of the reclassification of the Animal Health business to Assets held for sale or exchange<sup>(c)</sup></b>	D.36.	-	(23)	-
<b>Net change in cash and cash equivalents</b>		<b>1,125</b>	<b>1,807</b>	<b>(916)</b>
<b>Cash and cash equivalents, beginning of period</b>		<b>9,148</b>	<b>7,341</b>	<b>8,257</b>
<b>Cash and cash equivalents, end of period</b>	D.13.	<b>10,273</b>	<b>9,148</b>	<b>7,341</b>
<b>Net change in cash and cash equivalents excluding the Animal Health business (2014 and 2015)</b>		<b>-</b>	<b>1,469</b>	<b>(1,352)</b>
<b>Net change in cash and cash equivalents of the Animal Health business (2014 and 2015)</b>		<b>-</b>	<b>361</b>	<b>436</b>

(a) Cash flows of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations).

(b) See Note C.2. to the financial statements for the year ended December 31, 2016.

(c) In 2014, this line item includes 356 million for the partial reversal of the impairment loss taken against Lemtrada<sup>®</sup> in 2013 (see Note D.5.).

(d) Includes available-for-sale financial assets.

(e) This line item includes contributions paid to pension funds (see Note D.19.1.).

(f) Including:

	2016	2015	2014
Income tax paid	(2,096)	(1,706)	(2,607)
Interest paid (excluding cash flows on derivative instruments used to hedge debt)	(401)	(404)	(443)
Interest received (excluding cash flows on derivative instruments used to hedge debt)	56	57	68
Dividends received from non-consolidated entities	9	9	5

(g) This line item includes payments made in respect of contingent consideration identified and recognized as a liability in business combinations.

(h) This line item includes proceeds from disposals of investments in consolidated entities and of other non-current financial assets.

Edgar Filing: Sanofi - Form 20-F

(i) *Cash and cash equivalents of the Animal Health business are presented within the line item **Cash and cash equivalents** for 2014, and within the line item **Assets held for sale or exchange** for 2015 and 2016.*

**F- 11**

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS**

**YEAR ENDED DECEMBER 31, 2016**

Sanofi, together with its subsidiaries (collectively "Sanofi"), is a global healthcare leader engaged in the research, development and marketing of therapeutic solutions focused on patient needs.

Sanofi is listed in Paris (Euronext: SAN) and New York (NYSE: SNY).

The consolidated financial statements for the year ended December 31, 2016, and the notes thereto, were signed off by the Sanofi Board of Directors on February 7, 2017.

**A/ Basis of preparation**

**A.1. INTERNATIONAL FINANCIAL REPORTING STANDARDS (IFRS)**

The consolidated financial statements cover the twelve-month periods ended December 31, 2016, 2015 and 2014.

In accordance with Regulation No. 1606/2002 of the European Parliament and Council of July 19, 2002 on the application of international accounting standards, Sanofi has presented its consolidated financial statements in accordance with IFRS since January 1, 2005. The term "IFRS" refers collectively to international accounting and financial reporting standards (IASs and IFRSs) and to interpretations of the interpretations committees (SIC and IFRIC) with mandatory application as of December 31, 2016.

The consolidated financial statements of Sanofi as of December 31, 2016 have been prepared in compliance with IFRS as issued by the International Accounting Standards Board (IASB) and with IFRS as endorsed by the European Union as of December 31, 2016.

IFRS as endorsed by the European Union as of December 31, 2016 are available under the heading "IFRS Financial Statements" via the following web link:

[http://ec.europa.eu/finance/company-reporting/ifrs-financial-statements/index\\_en.htm](http://ec.europa.eu/finance/company-reporting/ifrs-financial-statements/index_en.htm)

The consolidated financial statements have been prepared in accordance with the IFRS general principles of fair presentation, going concern, accrual basis of accounting, consistency of presentation, materiality, and aggregation.

**A.2. NEW STANDARDS, AMENDMENTS AND INTERPRETATIONS APPLICABLE IN 2016**

The new standards, amendments to standards, and interpretations that are mandatorily applicable with effect from the 2016 financial year have no material impact on the financial statements, or on their presentation.

For standards, amendments and interpretations issued by the IASB that apply from 2017 onwards, refer to Note B.28.

**A.3. USE OF ESTIMATES AND JUDGMENTS**

The preparation of financial statements requires management to make reasonable estimates and assumptions based on information available at the date of the finalization of the financial statements. Those estimates and assumptions may affect the reported amounts of assets, liabilities, revenues and expenses in the financial statements, and disclosures of contingent assets and contingent liabilities as of the date of the review of the financial statements. Examples of estimates and assumptions include:

- amounts deducted from sales for projected sales returns, chargeback incentives, rebates and price reductions (see Notes B.13. and D.23.);
  - impairment of property, plant and equipment, intangible assets, and investments in associates and joint ventures (see Notes B.6. and D.5.);
  - the valuation of goodwill and the valuation and useful life of acquired intangible assets (see Notes B.3.2., B.4.3., D.4. and D.5.);
  - the measurement of contingent consideration receivable in connection with asset divestments (see Notes B.8.6. and D.7.);
  - the amount of post-employment benefit obligations (see Notes B.23. and D.19.1.);
  - the amount of provisions for restructuring, litigation, tax risks and environmental risks (see Notes B.12., B.20., B.22., D.19. and D.22.);
  - the amount of deferred tax assets resulting from tax losses available for carry-forward and deductible temporary differences (see Notes B.22. and D.14.);
  - the measurement of contingent consideration liabilities (see Notes B.3. and D.18.); and
  - which exchange rate to use at the end of the reporting period for the translation of accounts denominated in foreign currencies, and of financial statements of foreign subsidiaries, in cases where more than one exchange rate exists for a given currency (see Note A.4.).
- Actual results could differ from these estimates.

Management is also required to exercise judgment in assessing whether the criteria specified in IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations) are met, and hence whether a non-current asset or asset group should be classified as held for sale or exchange and whether a discontinued operation should be reported separately. Such assessments are reviewed at each reporting dated based on the facts and circumstances.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****A.4. CONSOLIDATION AND FOREIGN CURRENCY TRANSLATION OF THE FINANCIAL STATEMENTS OF VENEZUELAN SUBSIDIARIES**

Sanofi continues to account for subsidiaries based in Venezuela using the full consolidation method, on the basis that the criteria for control as specified in IFRS 10 (Consolidated Financial Statements) are still met.

Until the start of 2016, the Venezuelan foreign exchange system consisted of three exchange rates: (i) the CENCOEX rate, set at a fixed rate of 6.3 bolivars per US dollar and restricted to essential goods; (ii) an administered exchange rate (the SICAD rate), which was 13.5 bolivars per US dollar as of December 31, 2015 and applied to certain specific business sectors; and (iii) the SIMADI rate, of approximately 200 bolivars per US dollar, applied to specified transactions. In preparing the consolidated financial statements, the financial statements of the Venezuelan subsidiaries were translated into euros using the SICAD official exchange rate, which was the estimated rate at which the profits generated by the operations of those subsidiaries would be remitted to the parent.

In February 2016, the Venezuelan government announced a further reform to the foreign exchange system, which now consists of two categories:

- a first category for essential goods to which is applied the DIPRO rate, set at a fixed exchange rate of 10 bolivars per US dollar;
  - a second category to which is applied the DICOM rate, which is a floating exchange rate against the US dollar that initially stood at 206 bolivars per US dollar and was approximately 674 bolivars per US dollar as of December 31, 2016.
- In light of these changes to the foreign exchange system, recent economic and political developments and the scarcity of US dollar cash in Venezuela, Sanofi has changed the exchange rate used to translate its Venezuelan operations and now applies the DICOM rate. This change led to the recognition of a foreign exchange loss of 102 million. Following the adoption of this new rate, the Venezuelan subsidiaries contributed 18 million to consolidated net sales in 2016 ( 455 million in 2015) and had a cash position of 6 million as of December 31, 2016 ( 90 million as of December 31, 2015). The net assets of the Venezuelan subsidiaries were not material as of December 31, 2016.

**A.5. VAXSERVE REVENUES**

VaxServe is a Vaccines segment entity whose operations include the distribution within the United States of vaccines and other products manufactured by third parties.

In order to improve the clarity of the financial information published by Sanofi, with effect from January 1, 2016 some sales recorded by VaxServe are presented within the line

item *Other revenues* because they are not derived from the sale of products manufactured by Sanofi. Previously, all VaxServe sales were recognized within *Net sales*.

VaxServe sales presented within *Other revenues* totaled 581 million in 2016. The impact of this change in presentation on comparative periods is a reclassification from *Net sales* to *Other revenues* of 482 million in 2015 and 314 million in 2014.

**B/ Summary of significant accounting policies**

## **B.1. BASIS OF CONSOLIDATION**

In accordance with IFRS 10 (Consolidated Financial Statements), the consolidated financial statements of Sanofi include the financial statements of entities that Sanofi controls directly or indirectly, regardless of the level of the equity interest in those entities. An entity is controlled when Sanofi has power over the entity, exposure or rights to variable returns from its involvement with the entity, and the ability to affect those returns through its power over the entity. In determining whether control exists, potential voting rights must be taken into account if those rights are substantive, in other words they can be exercised on a timely basis when decisions about the relevant activities of the entity are to be taken.

Entities consolidated by Sanofi are referred to as subsidiaries. Entities that Sanofi controls by means other than voting rights are referred to as consolidated structured entities.

In accordance with IFRS 11 (Joint Arrangements), Sanofi classifies its joint arrangements (i.e. arrangements in which Sanofi exercises joint control with one or more other parties) either as a joint operation or a joint venture. In the case of a joint operation, Sanofi recognizes the assets and liabilities of the operation in proportion to its rights and obligations relating to those assets and liabilities. Joint ventures are accounted for by the equity method.

Sanofi exercises joint control over a joint arrangement when decisions relating to the relevant activities of the arrangement require the unanimous consent of Sanofi and the other parties with whom control is shared.

Sanofi exercises significant influence over an entity when it has the power to participate in the financial and operating policy decisions of that entity, but does not have the power to exercise control or joint control over those policies.

In accordance with IAS 28 (Investments in Associates and Joint Ventures), the equity method is used to account for joint ventures (i.e. entities over which Sanofi exercises joint control) and for associates (i.e. entities over which Sanofi exercises significant influence).

Under the equity method, the investment is initially recognized at cost, and subsequently adjusted to reflect

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

changes in the net assets of the associate or joint venture. IAS 28 does not specify the treatment to be adopted on first-time application of the equity method to an investee following a step acquisition. Consequently, by reference to paragraph 10 of IAS 28, Sanofi has opted to apply the cost method, whereby the carrying amount of the investment represents the sum of the historical cost amounts for each step in the acquisition. As of the date on which the equity method is first applied, goodwill (which is included in the carrying amount of the investment) is determined for each acquisition step. The same applies to subsequent increases in the percentage interest in the associate or joint venture.

When the criteria of IFRS 5 are met, Sanofi recognizes the equity interest within the balance sheet line item *Assets held for sale or exchange*. The equity method is not applied to equity interests that are classified as held-for-sale assets.

Transactions between consolidated companies are eliminated, as are intragroup profits.

A list of the principal companies included in the consolidation during the year ended December 31, 2016 is presented in Note F.

**B.2. FOREIGN CURRENCY TRANSLATION****B.2.1. Accounting for foreign currency transactions in the financial statements of consolidated entities**

Non-current assets (other than receivables) and inventories acquired in foreign currencies are translated into the functional currency using the exchange rate prevailing at the acquisition date.

Monetary assets and liabilities denominated in foreign currencies are translated using the exchange rate prevailing at the end of the reporting period. The gains and losses resulting from foreign currency translation are recorded in the income statement. However, foreign exchange gains and losses arising from the translation of advances between consolidated subsidiaries for which settlement is neither planned nor likely to occur in the foreseeable future are recognized in equity, in the line item *Change in currency translation differences*.

**B.2.2. Foreign currency translation of the financial statements of foreign entities**

Sanofi presents its consolidated financial statements in euros (€). In accordance with IAS 21 (The Effects of Changes in Foreign Exchange Rates), each subsidiary accounts for its transactions in the currency that is most representative of its economic environment (the functional currency).

All assets and liabilities are translated into euros using the exchange rate of the subsidiary's functional currency prevailing at the end of the reporting period. Income

statements are translated using a weighted average exchange rate for the period, except in the case of foreign subsidiaries in a hyperinflationary economy. The resulting currency translation difference is recognized as a separate component of equity in the consolidated statement of comprehensive income, and is recognized in the income statement only when the subsidiary is sold or is wholly or partially liquidated.

**B.3. BUSINESS COMBINATIONS AND TRANSACTIONS WITH NON-CONTROLLING INTERESTS**

**B.3.1. Accounting for business combinations, transactions with non-controlling interests and loss of control**

Business combinations are accounted for in accordance with IFRS 3 (Business Combinations) and IFRS 10 (Consolidated Financial Statements).

Business combinations are accounted for using the acquisition method. Under this method, the acquirer's identifiable assets and liabilities that satisfy the recognition criteria of IFRS 3 (Business Combinations) are measured initially at their fair values as at the date of acquisition, except for (i) non-current assets classified as held for sale (which are measured at fair value less costs to sell) and (ii) assets and liabilities that fall within the scope of IAS 12 (Income Taxes) and IAS 19 (Employee Benefits). Restructuring liabilities are recognized as a liability of the acquiree only if the acquiree has an obligation as of the acquisition date to carry out the restructuring.

The principal accounting rules applicable to business combinations and transactions with non-controlling interests include:

- Acquisition-related costs are recognized as an expense on the acquisition date, as a component of *Operating income*.
- Contingent consideration is recognized in equity if the contingent payment is settled by delivery of a fixed number of the acquirer's equity instruments; otherwise, it is recognized in *Liabilities related to business combinations*. Contingent consideration is recognized at fair value at the acquisition date irrespective of the probability of payment. If the contingent consideration was originally recognized as a financial liability, subsequent adjustments to the liability are recognized in profit or loss in the line item *Fair value remeasurement of contingent consideration liabilities*, unless the adjustment is made within the twelve months following the acquisition date and relates to facts and circumstances existing as of that date. Subsequent contingent consideration adjustments in respect of business combinations completed before January 1, 2010 continue to be accounted for in accordance with the pre-revision IFRS 3 (i.e. through goodwill).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

- In the case of a step acquisition, the previously-held equity interest is remeasured at its acquisition-date fair value. The difference between this fair value and the carrying amount is recorded in profit or loss, along with any gains or losses relating to the previously-held interest that were recognized in other comprehensive income and are reclassifiable to profit or loss.
  - Goodwill may be calculated on the basis of either (i) the entire fair value of the acquiree, or (ii) a share of the fair value of the acquiree proportionate to the interest acquired. This option may be elected for each acquisition individually.
  - The effects of (i) a buyout of non-controlling interests in a subsidiary already controlled by Sanofi, and (ii) a disposal of a percentage interest without loss of control, are recognized in equity.
  - In a partial disposal resulting in loss of control, the retained equity interest is remeasured at fair value at the date of loss of control. The gain or loss recognized on the disposal includes the effect of that remeasurement, and items that were initially recognized in equity and are required to be reclassified to profit or loss.
  - Adjustments to the values of assets and liabilities initially determined provisionally (pending the results of independent valuations or further analysis) are recognized as a retrospective adjustment to goodwill if they are made within twelve months of the acquisition date. Once this twelve-month period has elapsed, the effects of any adjustments are recognized directly in profit or loss, unless they qualify as an error correction.
- Purchase price allocations are performed under the responsibility of management, with assistance from an independent valuer in the case of major acquisitions. The revised IFRS 3 does not specify an accounting treatment for contingent consideration arising from a business combination made by an entity prior to the acquisition of control in that entity and carried as a liability in the acquired entity's balance sheet. The accounting treatment applied by Sanofi to such a liability is to measure it at fair value as of the acquisition date and to report it in the line item ***Liabilities related to business combinations and to non-controlling interests***, with subsequent remeasurements recognized in profit or loss. This treatment is consistent with the accounting applied to contingent consideration in the books of the acquirer.

**B.3.2. Goodwill**

The excess of the cost of an acquisition over Sanofi's interest in the fair value of the identifiable assets and liabilities of the acquiree is recognized as goodwill at the date of the business combination.

Goodwill arising on the acquisition of subsidiaries is shown in a separate balance sheet line item, whereas goodwill arising on the acquisition of associates and joint ventures is recorded in ***Investments in associates and joint ventures***.

Goodwill arising on foreign operations is expressed in the functional currency of the country concerned and translated into euros using the exchange rate prevailing at the end of the reporting period.

In accordance with IAS 36 (Impairment of Assets), goodwill is carried at cost less accumulated impairment (see Note B.6.).

Goodwill is tested for impairment annually and whenever events or circumstances indicate that impairment might exist. Such events or circumstances include significant changes more likely than not to have an other-than-temporary impact on the substance of the original investment.

#### **B.4. OTHER INTANGIBLE ASSETS**

Other intangible assets are initially measured at acquisition cost or production cost, including any directly attributable costs of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. Intangible assets are amortized on a straight line basis over their useful lives.

The useful lives of other intangible assets are reviewed at the end of each reporting period. The effect of any adjustment to useful lives is recognized prospectively as a change in accounting estimate.

Amortization of other intangible assets is recognized in the income statement within *Amortization of intangible assets* except for amortization charged against (i) acquired or internally-developed software and (ii) other rights of an industrial or operational nature, which is recognized in the relevant classification of expense by function.

Sanofi does not own any other intangible assets with an indefinite useful life.

Intangible assets (other than goodwill) are carried at cost less accumulated amortization and accumulated impairment, if any, in accordance with IAS 36 (see Note B.6.).

##### **B.4.1. Research and development not acquired in a business combination**

#### **Internally generated research and development**

Under IAS 38, research expenses are recognized in profit or loss when incurred.

Internally generated development expenses are recognized as an intangible asset if, and only if, all the following six criteria can be demonstrated: (a) the technical feasibility of

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

completing the development project; (b) Sanofi's intention to complete the project; (c) Sanofi's ability to use the project; (d) the probability that the project will generate future economic benefits; (e) the availability of adequate technical, financial and other resources to complete the project; and (f) the ability to measure the development expenditure reliably.

Due to the risks and uncertainties relating to regulatory approval and to the research and development process, the six criteria for capitalization are usually considered not to have been met until the product has obtained marketing approval from the regulatory authorities. Consequently, internally generated development expenses arising before marketing approval has been obtained, mainly the cost of clinical trials, are generally expensed as incurred within *Research and development expenses*.

Some industrial development expenses (such as those incurred in developing a second-generation synthesis process) are incurred after marketing approval has been obtained, in order to improve the industrial process for an active ingredient. To the extent that the six IAS 38 criteria are considered as having been met, such expenses are recognized as an asset in the balance sheet within *Other intangible assets* as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the six capitalization criteria under IAS 38, in which case the related expenses are recognized as an asset in the balance sheet within *Other intangible assets*.

**Separately acquired research and development**

Payments for separately acquired research and development are capitalized within *Other intangible assets* provided that they meet the definition of an intangible asset: a resource that is (i) controlled by Sanofi, (ii) expected to provide future economic benefits for Sanofi, and (iii) identifiable (i.e. it is either separable or arises from contractual or legal rights). Under paragraph 25 of IAS 38, the first condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. Consequently, upfront and milestone payments to third parties related to pharmaceutical products for which marketing approval has not yet been obtained are recognized as intangible assets, and amortized on a straight line basis over their useful lives beginning when marketing approval is obtained.

Payments under research and development arrangements relating to access to technology or to databases and payments made to purchase generics dossiers are also capitalized, and amortized over the useful life of the intangible asset.

Subcontracting arrangements, payments for research and development services, and continuous payments under

research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term.

**B.4.2. Other intangible assets not acquired in a business combination**

Licenses other than those related to pharmaceutical products and research projects, in particular software licenses, are capitalized at acquisition cost, including any directly attributable cost of preparing the software for its intended use. Software licenses are amortized on a straight line basis over their useful lives for Sanofi (three to five years).

Internally generated costs incurred to develop or upgrade software are capitalized if the IAS 38 recognition criteria are satisfied, and amortized on a straight line basis over the useful life of the software from the date on which the software is ready for use.

**B.4.3. Other intangible assets acquired in a business combination**

Other intangible assets acquired in a business combination which relate to in-process research and development and currently marketed products and are reliably measurable are identified separately from goodwill, measured at fair value and capitalized within *Other intangible assets* in accordance with IFRS 3 (Business Combinations) and IAS 38 (Intangible Assets). The related deferred tax liability is also recognized if a deductible or taxable temporary difference exists.

In-process research and development acquired in a business combination is amortized on a straight line basis over its useful life from the date of receipt of marketing approval.

Rights to products currently marketed by Sanofi are amortized on a straight line basis over their useful lives, determined on the basis of cash flow forecasts which take into account the patent protection period of the marketed product.

**B.5. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment is initially measured and recognized at acquisition cost, including any directly attributable cost of preparing the asset for its intended use, or (in the case of assets acquired in a business combination) at fair value as of the date of the business combination. The component-based approach to accounting for property, plant and equipment is applied. Under this approach, each component of an item of property, plant and equipment with a cost which is significant in relation to the total cost of the item and which has a different useful life from the other components must be depreciated separately.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

After initial measurement, property, plant and equipment is carried at cost less accumulated depreciation and impairment, except for land which is carried at cost less impairment.

Subsequent costs are not recognized as assets unless (i) it is probable that future economic benefits associated with those costs will flow to Sanofi and (ii) the costs can be measured reliably.

Day-to-day maintenance costs of property, plant and equipment are expensed as incurred.

Borrowing costs attributable to the financing of items of property, plant and equipment, and incurred during the construction period, are capitalized as part of the acquisition cost of the item.

Government grants relating to property, plant and equipment are deducted from the acquisition cost of the asset to which they relate.

In accordance with IAS 17 (Leases), items of property, plant and equipment leased by Sanofi as lessee under finance leases are recognized as an asset in the balance sheet, with the related lease obligation recognized as a liability. A lease qualifies as a finance lease if it transfers substantially all of the risks and rewards of ownership of the asset to Sanofi. Assets held under finance leases are carried at the lower of the fair value of the leased asset or the present value of the minimum lease payments, and are depreciated over the shorter of the useful life of the asset or the term of the lease.

The depreciable amount of items of property, plant and equipment, net of any residual value, is depreciated on a straight line basis over the useful life of the asset. The useful life of an asset is usually equivalent to its economic life.

The useful lives of property, plant and equipment are as follows:

Buildings	15 to 40 years
Fixtures	10 to 20 years
Plant and equipment	5 to 15 years
Other property, plant and equipment	3 to 15 years

Useful lives and residual values of property, plant and equipment are reviewed annually. The effect of any adjustment to useful lives or residual values is recognized prospectively as a change in accounting estimate.

Depreciation of property, plant and equipment is recognized as an expense in the income statement, in the relevant classification of expense by function.

## **B.6. IMPAIRMENT OF PROPERTY, PLANT AND EQUIPMENT, INTANGIBLE ASSETS, AND INVESTMENTS IN ASSOCIATES AND JOINT VENTURES**

### **B.6.1. Impairment of property, plant and equipment and intangible assets**

## Edgar Filing: Sanofi - Form 20-F

In accordance with IAS 36 (Impairment of Assets), assets that generate separate cash flows and assets included in cash-generating units (CGUs) are assessed for impairment when events or changes in circumstances indicate that the asset or CGU may be impaired. A CGU is the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets.

Under IAS 36, each CGU to which goodwill is allocated must (i) represent the lowest level within the entity at which the goodwill is monitored for internal management purposes, and (ii) not be larger than an operating segment determined in accordance with IFRS 8 (Operating Segments), before application of the IFRS 8 aggregation criteria (see Note B.26).

Quantitative and qualitative indications of impairment (primarily relating to the status of the research and development portfolio, pharmacovigilance, patent litigation, and the launch of competing products) are reviewed at the end of each reporting period. If there is any internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset or CGU.

Other intangible assets not yet available for use (such as capitalized in-process research and development), and CGUs that include goodwill, are tested for impairment annually whether or not there is any indication of impairment, and more frequently if any event or circumstance indicates that they might be impaired. Such assets are not amortized.

When there is an internal or external indication of impairment, Sanofi estimates the recoverable amount of the asset and recognizes an impairment loss if the carrying amount of the asset exceeds its recoverable amount. The recoverable amount of the asset is the higher of its fair value less costs to sell or its value in use. To determine value in use, Sanofi uses estimates of future cash flows generated by the asset or CGU, prepared using the same methods as those used in the initial measurement of the asset or CGU on the basis of medium-term strategic plans.

In the case of goodwill, estimates of future cash flows are based on a medium-term strategic plan, an extrapolation of the cash flows beyond that plan, and a terminal value. In the case of other intangible assets, the period used is based on the economic life of the asset.

Estimated cash flows are discounted at long-term market interest rates that reflect the best estimate by Sanofi of the time value of money, the risks specific to the asset or CGU,

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and economic conditions in the geographical regions in which the business activity associated with the asset or CGU is located.

Certain assets and liabilities that are not directly attributable to a specific CGU are allocated between CGUs on a basis that is reasonable, and consistent with the allocation of the corresponding goodwill.

Impairment losses arising on property, plant and equipment, on software and on certain rights are recognized in the relevant classification of expense by function.

Impairment losses arising on other intangible assets are recognized within *Impairment of intangible assets* in the income statement.

**B.6.2. Impairment of investments in associates and joint ventures**

In accordance with IAS 28 (Investments in Associates), Sanofi applies the criteria specified in IAS 39 (Financial Instruments: Recognition and Measurement) to determine whether an investment in an associate or joint venture may be impaired (see Note B.8.2.). If an investment is impaired, the amount of the impairment loss is determined by applying IAS 36 (see Note B.6.1.) and recognized in *Share of profit/(loss) of associates and joint ventures*.

**B.6.3. Reversals of impairment losses charged against property, plant and equipment, intangible assets, and investments in associates and joint ventures**

At the end of each reporting period, Sanofi assesses whether events or changes in circumstances indicate that an impairment loss recognized in a prior period in respect of an asset (other than goodwill) or an investment in an associate or joint venture can be reversed. If this is the case, and the recoverable amount as determined based on the revised estimates exceeds the carrying amount of the asset, Sanofi reverses the impairment loss only to the extent of the carrying amount that would have been determined had no impairment loss been recognized for the asset.

Reversals of impairment losses in respect of other intangible assets are recognized within the income statement line item *Impairment of intangible assets*, while reversals of impairment losses in respect of investments in associates and joint ventures are recognized within the income statement line item *Share of profit/(loss) of associates and joint ventures*. Impairment losses taken against goodwill are never reversed, unless the goodwill is part of the carrying amount of an investment in an associate or joint venture.

**B.7. ASSETS HELD FOR SALE OR EXCHANGE AND LIABILITIES RELATED TO ASSETS HELD FOR SALE OR EXCHANGE**

In accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations), non-current assets and groups of assets are classified as held for sale in the balance sheet if their carrying amount will be recovered principally through a sale transaction rather than through continuing use. Within the meaning of IFRS 5, the term *sale* also includes exchanges for other assets.

Non-current assets or asset groups held for sale must be available for immediate sale in their present condition, subject only to terms that are usual and customary for sales of such assets, and a sale must be highly probable. Criteria used to determine whether a sale is highly probable include:

- the appropriate level of management must be committed to a plan to sell;
- an active program to locate a buyer and complete the plan must have been initiated;
- the asset must be actively marketed for sale at a price that is reasonable in relation to its current fair value;
- completion of the sale should be foreseeable within the twelve months following the date of reclassification to *Assets held for sale or exchange*; and
- actions required to complete the plan should indicate that it is unlikely that significant changes to the plan will be made or that the plan will be withdrawn.

Before initial reclassification of the non-current asset (or asset group) to *Assets held for sale or exchange*, the carrying amounts of the asset (or of all the assets and liabilities in the asset group) must be measured in accordance with the applicable standards.

Subsequent to reclassification to *Assets held for sale or exchange*, the non-current asset (or asset group) is measured at the lower of carrying amount or fair value less costs to sell, with any write-down recognized by means of an impairment loss. Once a non-current asset has been reclassified as held for sale or exchange, it is no longer depreciated or amortized.

In a disposal of an equity interest leading to loss of control, all the assets and liabilities of the entity involved are classified as held-for-sale assets or liabilities within the balance sheet line items *Assets held for sale or exchange* or *Liabilities related to assets held for sale or exchange*, provided that the disposal satisfies the IFRS 5 classification criteria.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The profit or loss generated by a held-for-sale asset group is reported in a separate line item in the income statement for the current period and for the comparative periods presented, provided that the asset group:

- represents a separate major line of business or geographical area of operations; or,
  - is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations; or,
  - is a subsidiary acquired exclusively with a view to resale.
- In accordance with IFRS 10, transactions between companies that are held for sale or treated as discontinued operations and other consolidated companies are eliminated.

Events or circumstances beyond Sanofi's control may extend the period to complete the sale or exchange beyond one year without precluding classification of the asset (or disposal group) in *Assets held for sale or exchange* provided that there is sufficient evidence that Sanofi remains committed to the planned sale or exchange.

Finally, in the event of changes to a plan of sale that require an asset no longer to be classified as held for sale, IFRS 5 specifies the following treatment:

- The assets and liabilities previously classified as held for sale are reclassified to the appropriate balance sheet line items, with no restatement of comparative periods.
- Each asset is measured at the lower of (a) its carrying amount before the asset was reclassified as held for sale, adjusted for any depreciation, amortization or revaluation that would have been recognized if the asset had not been reclassified as held for sale, or (b) its recoverable amount at the date of reclassification.
- The backlog of depreciation, amortization and impairment not recognized while non-current assets were classified as held for sale must be reported in the same income statement line item that was used to report impairment losses arising on initial reclassification of assets as held for sale and gains or losses arising on the sale of such assets. In the consolidated income statement, those impacts are reported within the line item *Other gains and losses, and litigation*.
- The net income of a business previously classified as discontinued or, as held for sale or exchange and reported on a separate line in the income statement must be reclassified and included in net income from continuing operations, for all periods presented.
- In addition, segment information relating to the income statement and the statement of cash flows (acquisitions of non-current assets) must be disclosed in the notes to the financial statements in accordance with IFRS 8 (Operating Segments), and must also be restated for all prior

periods presented.

## **B.8. FINANCIAL INSTRUMENTS**

### **B.8.1. Non-derivative financial assets**

In accordance with IAS 39 (Financial Instruments: Recognition and Measurement) and IAS 32 (Financial Instruments: Presentation), Sanofi has adopted the following classification for non-derivative financial assets, based on the type of asset and on management intention at the date of initial recognition. The designation and classification of such financial assets are subsequently reassessed at the end of each reporting period.

Non-derivative financial assets are recognized on the date when Sanofi becomes party to the contractual terms of the asset. On initial recognition, financial assets are measured at fair value, plus direct transaction costs in the case of financial assets not classified as fair value through profit or loss.

Classification, presentation and subsequent measurement of non-derivative financial assets are as follows:

#### **Financial assets at fair value through profit or loss**

These assets are classified in the balance sheet within the line items *Other non-current assets*, *Other current assets* and *Cash and cash equivalents*.

Financial assets at fair value through profit or loss comprise assets held for trading (financial assets acquired principally for the purpose of reselling them in the near term, usually within less than 12 months), and financial instruments designated at fair value through profit and loss on initial recognition in accordance with the conditions for application of the fair value option.

Such financial assets are carried at fair value, without any deduction for transaction costs that may be incurred on sale. Realized and unrealized gains and losses resulting from changes in the fair value of these assets are recognized in the income statement, in *Financial income* or *Financial expenses*.

Realized and unrealized foreign exchange gains and losses on financial assets in currencies other than the euro are recognized in the income statement in *Financial income* or *Financial expenses*.

#### **Available-for-sale financial assets**

Available-for-sale financial assets are non-derivative financial assets that are (i) designated by management as available-for-sale or (ii) not classified as Financial assets at fair value through profit or loss Held-to-maturity investments or Loans and receivables . This category includes equity interests in quoted or unquoted companies other than investments in associates and joint ventures. Available-for-sale financial assets are classified in *Other non-current assets*.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Available-for-sale financial assets are measured at fair value, without any deduction for transaction costs that may be incurred on sale. Gains and losses arising from changes in the fair value of these assets, including unrealized foreign exchange gains and losses, are recognized directly in equity in the consolidated statement of comprehensive income in the period in which they occur, except for impairment losses and foreign exchange gains and losses on debt instruments. On derecognition of an available-for-sale financial asset, or on recognition of an impairment loss on such an asset, the cumulative gains and losses previously recognized in equity are recognized in the income statement for the period within *Financial income* or *Financial expenses*.

Interest income and dividends on equity instruments are recognized in the income statement within *Financial income* when Sanofi is entitled to receive payment.

Available-for-sale financial assets in the form of equity interests in companies not quoted in an active market are measured at cost if their fair value cannot be measured reliably; an impairment loss is recognized when there is objective evidence that such an asset is impaired.

Contingent consideration receivable in connection with divestments is recognized as an available-for-sale financial asset at fair value (plus any transaction costs), provided that it represents an unconditional right to receive cash as of the date of the divestment. Fair value is initially measured on the basis of estimated future cash flows.

Subsequent adjustments to fair value arising from revisions to those estimates are recognized immediately in profit or loss. Interest income generated on such assets is calculated using the effective interest method, and recognized in profit or loss on an accruals basis. An impairment loss is taken against contingent consideration arising on divestments where counterparty credit risk suggests its value may have become impaired.

Other adjustments to fair value, such as those arising from a change in the discount rate, are recognized in equity within the statement of comprehensive income in the period in which they occur.

**Held-to-maturity investments**

Held-to-maturity investments are non-derivative financial assets with fixed or determinable payments and fixed maturities that Sanofi has the positive intention and ability to hold to maturity.

Such investments are measured at amortized cost using the effective interest method.

Sanofi did not hold any such investments during the years ended December 31, 2016, 2015 or 2014.

**Loans and receivables**

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are presented within *Other current assets*, *Accounts receivable* and *Cash and cash equivalents*. Loans with a maturity of more than 12 months are presented in Long-term loans and advances within *Other non-current assets*. Those financial assets are measured at amortized cost using the effective interest method.

**B.8.2. Impairment of non-derivative financial assets**

## Edgar Filing: Sanofi - Form 20-F

Indicators of impairment are reviewed for all non-derivative financial assets at the end of each reporting period. Such indicators include default in contractual payments, significant financial difficulties of the issuer or debtor, probability of bankruptcy, or a prolonged or significant decline in quoted market price. An impairment loss is recognized in the income statement if there is objective evidence of impairment resulting from one or more events after the initial recognition of the asset (a loss event) and that loss event has a reliably measurable impact on the estimated future cash flows of the financial asset (or group of financial assets).

The impairment loss on loans and receivables, which are measured at amortized cost, is the difference between the carrying amount of the asset and the present value of estimated future cash flows discounted at the financial asset's original effective interest rate.

When an impairment loss is identified on an available-for-sale financial asset, the cumulative losses previously recognized directly in equity are recorded in the income statement. The loss recognized in the income statement is the difference between the acquisition cost (net of principal repayments and amortization) and the fair value at the time of impairment, less any impairment loss previously recognized in the income statement.

The impairment loss on investments in companies not quoted in an active market and measured at cost is the difference between the carrying amount of the investment and the present value of its estimated future cash flows, discounted at the current market interest rate for similar financial assets.

Impairment losses in respect of loans are recognized within *Financial expenses* in the income statement.

Impairment losses in respect of trade receivables are recognized within *Selling and general expenses* in the income statement.

Impairment losses on equity instruments classified as available-for-sale financial assets cannot be reversed through the income statement.

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****B.8.3. Derivative instruments**

Derivative instruments that do not qualify for hedge accounting are initially and subsequently measured at fair value, with changes in fair value recognized in the income statement in *Other operating income* or in *Financial income* or *Financial expenses*, depending on the nature of the underlying economic item which is hedged.

Derivative instruments that qualify for hedge accounting are measured in accordance with the hedge accounting requirements of IAS 39 (see Note B.8.4.).

IFRS 13 (Fair Value Measurement) requires counterparty credit risk to be taken into account when measuring the fair value of financial instruments. This risk is estimated on the basis of observable, publicly-available statistical data.

**Policy on offsetting**

In order for a financial asset and a financial liability to be presented as a net amount in the balance sheet under IAS 32, there must be (a) a legally enforceable right to offset and (b) the intention either to settle on a net basis, or to realize the asset and settle the liability simultaneously.

In addition, IFRS 7 (Financial Instruments: Disclosures) requires the notes to the financial statements to include a schedule showing a list of any offsets recognized under IAS 32 and of transactions for which only criterion (a) is met, i.e. potential offsets such as those specified in close out netting agreements (positions offset only in the event of default, as specified in the International Swaps and Derivatives Association (ISDA) standard).

**B.8.4. Hedging**

Hedging involves the use of derivative financial instruments. Changes in the fair value of such instruments are intended to offset the exposure of the hedged items to changes in fair value.

As part of its overall interest rate risk and foreign exchange risk management policy, Sanofi enters into various transactions involving derivative instruments. Derivative instruments used in connection with Sanofi's hedging policy may include forward exchange contracts, currency options, interest rate swaps and interest rate options.

Derivative financial instruments qualify as hedging instruments for hedge accounting purposes when (a) at the inception of the hedge there is formal designation and documentation of the hedging relationship and of the risk management strategy and objective; (b) the hedge is expected by management to be highly effective in offsetting the risk; (c) the forecast transaction being hedged is highly probable and presents an exposure to variations in cash flows that could ultimately affect profit or loss; (d) the effectiveness of the hedge can be reliably measured; and

(e) the effectiveness of the hedge is assessed on an ongoing basis and the hedge is determined actually to have been highly effective throughout the reporting periods for which the hedge was designated.

The above criteria are applied when Sanofi uses derivative instruments designated as a fair value hedge, a cash flow hedge or a hedge of a net investment in a foreign operation.

### **Fair value hedge**

A fair value hedge is a hedge of the exposure to changes in fair value of a recognized asset or liability or unrecognized firm commitment that could affect profit or loss.

Changes in fair value of the hedging instrument and changes in fair value of the hedged item attributable to the hedged risk are recognized in the income statement, within *Other operating income* for hedges related to operating activities, or within *Financial income* or *Financial expenses* for hedges related to investing or financing activities.

### **Cash flow hedge**

A cash flow hedge is a hedge of the exposure to variability in cash flows attributable to a particular risk associated with a recognized asset or liability, or a highly probable forecast transaction, which could affect profit or loss.

Changes in fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within *Other operating income* for hedges related to operating activities, or within *Financial income* or *Financial expenses* for hedges related to investing or financing activities.

Cumulative changes in fair value of the hedging instrument previously recognized in equity are reclassified to the income statement when the hedged transaction affects profit or loss. These transferred gains and losses are recorded within *Other operating income* for hedges of operating activities, and within *Financial income* or *Financial expenses* for hedges of investing or financing activities.

When a forecast transaction results in the recognition of a non-financial asset or liability, cumulative changes in the fair value of the hedging instrument previously recognized in equity are included in the initial measurement of that asset or liability.

When the hedging instrument expires or is sold, terminated or exercised, the cumulative gain or loss previously recognized in equity remains separately recognized in equity and is not reclassified to the income statement until the forecast transaction occurs. However, if Sanofi no longer expects the forecast transaction to occur, the cumulative gain or loss previously recognized in equity is recognized immediately in profit or loss.

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Hedge of a net investment in a foreign operation**

In a hedge of a net investment in a foreign operation, changes in the fair value of the hedging instrument attributable to the effective portion of the hedge are recognized directly in equity in the consolidated statement of comprehensive income. Changes in fair value attributable to the ineffective portion of the hedge are recognized in the income statement within *Financial income* or *Financial expenses*. When the investment in the foreign operation is sold, the changes in the fair value of the hedging instrument previously recognized in equity are reclassified to the income statement within *Financial income* or *Financial expenses*.

**Discontinuation of hedge accounting**

Hedge accounting is discontinued when (a) the hedging instrument expires or is sold, terminated or exercised, or (b) the hedge no longer meets the criteria for hedge accounting, or (c) Sanofi revokes the hedge designation, or (d) management no longer expects the forecast transaction to occur.

**B.8.5. Non-derivative financial liabilities****Borrowings and debt**

Bank borrowings and debt instruments are initially measured at fair value of the consideration received, net of directly attributable transaction costs.

Subsequently, they are measured at amortized cost using the effective interest method. All costs related to the issuance of borrowings or debt instruments, and all differences between the issue proceeds net of transaction costs and the value on redemption, are recognized within

*Financial expenses* in the income statement over the term of the debt using the effective interest method.

**Liabilities related to business combinations and to non-controlling interests**

Liabilities related to business combinations and to non-controlling interests are classified into a current portion and a non-current portion. These line items record the fair value of (i) contingent consideration payable in connection with business combinations (see Note B.3.1. for a description of the relevant accounting policy), and (ii) commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests.

Adjustments to the fair value of commitments to buy out equity holders of subsidiaries, including put options granted to non-controlling interests, are recognized in equity.

**Other non-derivative financial liabilities**

Other non-derivative financial liabilities include trade accounts payable, which are measured at fair value (which in most cases equates to face value) on initial recognition, and subsequently at amortized cost.

**B.8.6. Fair value of financial instruments**

The disclosures required under IFRS 13 relating to the fair value of the principal financial assets and liabilities reported in the consolidated balance sheet and in the notes to consolidated financial statements, and to the level of those instruments in the fair value hierarchy, are presented in Note D.12. The disclosures required under IFRS 13 relating to the sensitivity of level 3 fair value measurements are presented in Note D.18.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows the disclosures required under IFRS 7 relating to the measurement principles applied to financial instruments.

<b>Note</b>	<b>Type of financial instrument</b>	<b>Measurement principle</b>	<b>Valuation model</b>	<b>Market data Exchange rate</b>	<b>Interest rate</b>	<b>Volatility</b>
D.7.	Available-for-sale financial assets (quoted equity securities)	Fair value	Quoted market price		N/A	
D.7.	Available-for-sale financial assets (quoted debt securities)	Fair value	Quoted market price		N/A	
D.7.	Available-for-sale financial assets (contingent consideration receivable):	Fair value	Under IAS 39, contingent consideration receivable on a divestment is a financial asset. The fair value of such assets is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.7.			
D.7.	Long-term loans and advances and other non-current receivables	Amortized cost	The amortized cost of long-term loans and advances and other non-current receivables at the end of the reporting period is not materially different from their fair value.			
D.7.	Financial assets recognized under the fair value option <sup>(a)</sup>	Fair value	Market value (net asset value)		N/A	
D.20.	Forward currency contracts	Fair value	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	N/A
D.20.	Interest rate swaps	Fair value	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	N/A
D.20.	Cross-currency swaps	Fair value	Present value of future cash flows	Mid Market Spot	< 1 year: Mid Money Market > 1 year: Mid Zero Coupon	N/A
D.13.	Investments in mutual funds	Fair value	Market value (net asset value)		N/A	
D.13.	Negotiable debt instruments, commercial paper, instant access deposits and term deposits	Amortized cost	Because these instruments have a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as disclosed in the notes to the consolidated financial statements. In the case of debt with a maturity of less than 3 months, amortized cost is regarded as an acceptable approximation of fair value as reported in the notes to the consolidated financial statements.			
D.17.	Debt	Amortized cost <sup>(b)</sup>	For debt with a maturity of more than 3 months, fair value as reported in the notes to the consolidated financial statements is determined either by reference to quoted market prices at the end of the reporting period (quoted instruments) or by discounting the future cash flows based on observable market data at the end of the reporting period (unquoted instruments).			
D.18.	Liabilities related to business combinations and to non-controlling interests (CVRs)	Fair value	Quoted market price		N/A	
D.18.	Liabilities related to business combinations and to non-controlling interests (other than CVRs)	Fair value <sup>(c)</sup>	Under IAS 32, contingent consideration payable in a business combination is a financial liability. The fair value of such liabilities is determined by adjusting the contingent consideration at the end of the reporting period using the method described in Note D.18.			

- (a) *These assets are held to fund a deferred compensation plan offered to certain employees.*
  
- (b) *In the case of debt designated as a hedged item in a fair value hedging relationship, the carrying amount in the consolidated balance sheet includes changes in fair value attributable to the hedged risk(s).*
  
- (c) *For business combinations completed prior to application of the revised IFRS 3, contingent consideration is recognized when payment becomes probable (see Note B.3.1.).*

**F- 23**

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The other financial assets and liabilities included in the consolidated balance sheet are:

- Non-derivative current financial assets and liabilities: because these items have a maturity close to the end of the reporting period, Sanofi regards their carrying amount (i.e. historical cost less any credit risk allowance) as a reasonable approximation of their fair value.
- Equity interests in companies not quoted in an active market and the fair value of which cannot be measured reliably, which are measured at amortized cost in accordance with IAS 39.

**B.8.7. Derecognition of financial instruments**

Financial assets are derecognized when the contractual rights to cash flows from the asset have ended or have been transferred and when Sanofi has transferred substantially all risks and rewards of ownership of the asset. If Sanofi has neither transferred nor retained substantially all the risks and rewards of ownership of a financial asset, it is derecognized if Sanofi does not retain control of the asset.

A financial liability is derecognized when Sanofi's contractual obligations in respect of the liability are discharged, cancelled or extinguished.

**B.8.8. Risks relating to financial instruments**

Market risks in respect of non-current financial assets, cash equivalents, derivative instruments and debt are described in the discussions of risk factors presented in Item 3.D. and Item 11.

Credit risk is the risk that customers may fail to pay their debts. This risk also arises as a result of the concentration of Sanofi's sales with its largest customers, in particular certain wholesalers in the United States. Customer credit risk is described in Item 3.D. Risk Factors We are subject to the risk of non-payment by our customers .

**B.9. INVENTORIES**

Inventories are measured at the lower of cost or net realizable value. Cost is calculated using the weighted average cost method or the first-in, first-out method, depending on the nature of the inventory.

The cost of finished goods inventories includes costs of purchase, costs of conversion and other costs incurred in bringing the inventories to their present location and condition.

Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated costs necessary to make the sale.

During the launch phase of a new product, any inventories of that product are written down to zero pending regulatory approval. The write-down is reversed once it becomes highly probable that marketing approval will be obtained.

#### **B.10. CASH AND CASH EQUIVALENTS**

Cash and cash equivalents as shown in the consolidated balance sheet and statement of cash flows comprise cash, plus liquid short-term investments that are readily convertible into cash and are subject to an insignificant risk of changes in value in the event of movements in interest rates.

#### **B.11. TREASURY SHARES**

In accordance with IAS 32, Sanofi treasury shares are deducted from equity, irrespective of the purpose for which they are held. No gain or loss is recognized in the income statement on the purchase, sale, impairment or cancellation of treasury shares.

#### **B.12. PROVISIONS FOR RISKS**

In accordance with IAS 37 (Provisions, Contingent Liabilities and Contingent Assets), Sanofi records a provision when it has a present obligation, whether legal or constructive, as a result of a past event; it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation; and a reliable estimate can be made of the amount of the outflow of resources.

If the obligation is expected to be settled more than twelve months after the end of the reporting period, or has no definite settlement date, the provision is recorded within *Provisions and other non-current liabilities*.

Provisions relating to the insurance programs in which Sanofi's captive insurance company participates are based on risk exposure estimates calculated by management, with assistance from independent actuaries, using IBNR (Incurred But Not Reported) techniques. Those techniques use past claims experience, within Sanofi and in the market, to estimate future trends in the cost of claims.

Contingent liabilities are not recognized, but are disclosed in the notes to the financial statements unless the possibility of an outflow of economic resources is remote.

Sanofi estimates provisions on the basis of events and circumstances related to present obligations at the end of the reporting period and of past experience, and to the best of management's knowledge at the date of preparation of the financial statements.

Reimbursements offsetting the probable outflow of resources are recognized as assets only if it is virtually certain that they will be received. Contingent assets are not recognized.

Restructuring provisions are recognized if Sanofi has a detailed, formal restructuring plan at the end of the reporting period and has announced its intention to implement this plan to those affected by it.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

No provisions are recorded for future operating losses.

Sanofi records non-current provisions for certain obligations, such as legal or constructive environmental obligations and litigation, where an outflow of resources is probable and the amount of the outflow can be reliably estimated. Where the effect of the time value of money is material, those provisions are measured at the present value of the expenditures expected to be required to settle the obligation, calculated using a discount rate that reflects an estimate of the time value of money and the risks specific to the obligation.

Increases in provisions to reflect the effects of the passage of time are recognized within *Financial expenses*.

**B.13. REVENUE RECOGNITION**

Revenue arising from the sale of goods is presented in the income statement within *Net sales*. Net sales comprise revenue from sales of pharmaceutical products, active ingredients and vaccines, net of sales returns, of customer incentives and discounts, and of certain sales-based payments paid or payable to the healthcare authorities.

Revenue is recognized when all of the following conditions have been met: the risks and rewards of ownership have been transferred to the customer; Sanofi no longer has effective control over the goods sold; the amount of revenue and costs associated with the transaction can be measured reliably; and it is probable that the economic benefits associated with the transaction will flow to Sanofi, in accordance with IAS 18 (Revenue). In particular, the contracts between Sanofi Pasteur and government agencies specify conditions for the supply and acceptance of batches of vaccine; revenue is recognized when those conditions are met.

Sanofi offers various types of price reductions on its products. In particular, products sold in the United States are covered by various governmental programs (such as Medicare and Medicaid) under which products are sold at a discount. Rebates are granted to healthcare authorities, and under contractual arrangements with certain customers. Some wholesalers are entitled to chargeback incentives based on the selling price to the end customer, under specific contractual arrangements. Cash discounts may also be granted for prompt payment.

Returns, discounts, incentives and rebates, as described above, are recognized in the period in which the underlying sales are recognized as a reduction of sales revenue.

These amounts are calculated as follows:

- Provisions for chargeback incentives are estimated on the basis of the relevant subsidiary's standard sales terms and conditions, and in certain cases on the basis of specific contractual arrangements with the customer. They represent management's best estimate of the amount of chargeback incentives that will ultimately be claimed by the customer.
- Provisions for rebates based on attainment of sales targets are estimated and accrued as each of the underlying sales transactions is recognized.
- Provisions for price reductions under Government and State programs, largely in the United States, are estimated on the basis of the specific terms of the relevant regulations or agreements, and accrued as each of the underlying sales transactions is recognized.

## Edgar Filing: Sanofi - Form 20-F

Provisions for sales returns are calculated on the basis of management's best estimate of the amount of product that will ultimately be returned by customers. In countries where product returns are possible, Sanofi operates a returns policy that allows the customer to return products within a certain period either side of the expiry date (usually 6 months before and 12 months after the expiry date). The provision is estimated on the basis of past experience of sales returns.

Sanofi also takes into account factors such as levels of inventory in its various distribution channels, product expiry dates, information about potential discontinuation of products, the entry of competing generics into the market, and the launch of over-the-counter medicines.

In each case, the provisions are subject to continuous review and adjustment as appropriate based on the most recent data available to management.

Sanofi believes that it has the ability to measure each of the above provisions reliably, using the following factors in developing its estimates:

- the nature and patient profile of the underlying product;
- the applicable regulations or the specific terms and conditions of contracts with governmental authorities, wholesalers and other customers;
- historical data relating to similar contracts, in the case of qualitative and quantitative rebates and chargeback incentives;
- past experience and sales growth trends for the same or similar products;
- actual inventory levels in distribution channels, monitored by Sanofi using internal sales data and externally provided data;
- the shelf life of Sanofi products; and
- market trends including competition, pricing and demand.

### **B.14. OTHER REVENUES**

Other revenues mainly comprise royalties under licensing agreements (see Note C.) and VaxServe sales of products sourced from third-party manufacturers (see Note A.5.).

---

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****B.15. COST OF SALES**

*Cost of sales* consists primarily of the industrial cost of goods sold, payments made under licensing agreements, and distribution costs. The industrial cost of goods sold includes the cost of materials, depreciation of property, plant and equipment and software, personnel costs, and other expenses attributable to production.

**B.16. RESEARCH AND DEVELOPMENT**

Note B.4.1. Research and development not acquired in a business combination and Note B.4.3. Other intangible assets acquired in a business combination describe the principles applied to the recognition of research and development costs.

Contributions or reimbursements received from alliance partners are recorded as a reduction of *Research and development expenses*.

**B.17. OTHER OPERATING INCOME AND EXPENSES****B.17.1. Other operating income**

*Other operating income* includes the share of profits that Sanofi is entitled to receive from alliance partners in respect of product marketing agreements. It also includes revenues generated under certain complex agreements, which may include partnership and co-promotion arrangements.

Upfront payments received are deferred until the service obligation is met. Milestone payments are assessed on a case by case basis, and recognized in the income statement on delivery of the products and/or upon the service obligation being met. Revenue generated in connection with these services is recognized on the basis of delivery of the goods or provision of the services to the other contracting party.

This line item also includes realized and unrealized foreign exchange gains and losses on operating activities (see Note B.8.4.), and operating gains on disposals not regarded as major disposals (see Note B.20.).

**B.17.2. Other operating expenses**

*Other operating expenses* mainly comprise the share of profits that alliance partners are entitled to receive from Sanofi under product marketing agreements.

**B.18. AMORTIZATION AND IMPAIRMENT OF INTANGIBLE ASSETS****B.18.1. Amortization of intangible assets**

The expenses recorded in this line item comprise amortization of product rights (see Note D.4.), given that the benefit of those rights to Sanofi's commercial, industrial and development functions cannot be separately identified.

Amortization of software, and of other rights of an industrial or operational nature, is recognized as an expense in the income statement, in the relevant line items of expense by function.

#### **B.18.2. Impairment of intangible assets**

This line item records impairment losses (other than those associated with restructuring) recognized against intangible assets (including goodwill, but excluding software and other rights of an industrial or operational nature), and any reversals of such impairment losses.

#### **B.19. FAIR VALUE REMEASUREMENT OF CONTINGENT CONSIDERATION LIABILITIES**

Changes in the fair value of contingent consideration that was (i) already carried in the books of an acquired entity, or (ii) granted in connection with a business combination and initially recognized as a liability in accordance with the revised IFRS 3, are reported in profit or loss in accordance with the principles described in Note B.3.1. Such adjustments are reported separately in the income statement, in the line item *Fair value remeasurement of contingent consideration liabilities*. This line item also includes the effect of the unwinding of discount, and of exchange rate movements where the liability is expressed in a currency other than the functional currency of the reporting entity.

#### **B.20. RESTRUCTURING COSTS AND OTHER GAINS AND LOSSES, AND LITIGATION**

##### **B.20.1. Restructuring costs and similar items**

Restructuring costs are expenses incurred in connection with the transformation or reorganization of Sanofi's operations or support functions. Such costs include collective redundancy plans, compensation to third parties for early termination of contracts, and commitments made in connection with transformation or reorganization decisions. They also include accelerated depreciation charges arising from site closures and losses on asset disposals resulting from such decisions.

In addition, this line item includes expenses incurred in connection with programs implemented as part of the transformation strategy announced in November 2015 intended to deliver a global information systems solution, to standardize and consolidate processes, and to transition towards a worldwide services platform.

##### **B.20.2. Other gains and losses, and litigation**

The line item *Other gains and losses, and litigation* includes the impact of material transactions of an unusual nature or amount which Sanofi believes it necessary to report separately in the income statement in order to improve the relevance of the financial statements, such as:

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

- gains and losses on major disposals of property, plant and equipment, of intangible assets, of assets (or groups of assets and liabilities) held for sale, or of a business within the meaning of the revised IFRS 3, other than those considered to be restructuring costs;
- impairment losses and reversals of impairment losses on assets (or groups of assets and liabilities) held for sale, other than those considered to be restructuring costs;
- gains on bargain purchases; and
- costs and provisions relating to major litigation.

**B.21. FINANCIAL EXPENSES AND INCOME**

**B.21.1. Financial expenses**

*Financial expenses* mainly comprise interest charges on debt financing; negative changes in the fair value of financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange losses on financing and investing activities; impairment losses on financial instruments; and any reversals of impairment losses on financial instruments.

*Financial expenses* also include expenses arising from the unwinding of discount on long-term provisions, and the net interest cost related to employee benefits. This line item does not include commercial cash discounts, which are deducted from net sales.

**B.21.2. Financial income**

*Financial income* includes interest and dividend income; positive changes in the fair value of financial instruments (where changes in fair value are recognized in profit or loss); realized and unrealized foreign exchange gains on financing and investing activities; and gains or losses on disposals of financial assets.

**B.22. INCOME TAX EXPENSE**

*Income tax expense* includes all current and deferred taxes of consolidated companies.

Sanofi accounts for deferred taxes in accordance with IAS 12 (Income Taxes), using the methods described below:

## Edgar Filing: Sanofi - Form 20-F

Deferred tax assets and liabilities are recognized on taxable and deductible temporary differences, and on tax loss carry-forwards. Temporary differences are differences between the carrying amount of an asset or liability in the balance sheet and its tax base.

Reforms to French business taxes came into force on January 1, 2010, introducing a new tax known as the CET (*Contribution Economique Territoriale*). This tax has two components: the CFE (*Cotisation Foncière des Entreprises*) and the CVAE (*Cotisation sur la Valeur Ajoutée des Entreprises*). The second of those components is determined by applying a rate to the amount of value added generated by the business during the year. Given that (i) the CVAE component is calculated as the amount by which certain revenues exceed certain expenses and (ii) this tax will be borne primarily by companies that own intellectual property rights on income derived from those rights (royalties, and margin on sales to third parties and to Sanofi entities), the CVAE component is regarded as meeting the definition of income taxes specified in IAS 12, paragraph 2 (taxes which are based on taxable profits).

Deferred tax assets and liabilities are calculated using the tax rate expected to apply in the period when the corresponding temporary differences are expected to reverse, based on tax rates enacted or substantively enacted at the end of the reporting period.

Deferred tax assets are recognized in respect of deductible temporary differences, tax losses available for carry-forward and unused tax credits to the extent that future recovery is regarded as probable. The recoverability of deferred tax assets is assessed on a case-by-case basis, taking into account the profit forecasts contained in Sanofi's medium-term business plan.

A deferred tax liability is recognized for temporary differences relating to interests in subsidiaries, associates and joint ventures, except in cases where Sanofi is able to control the timing of the reversal of the temporary differences. This applies in particular when Sanofi is able to control dividend policy and it is probable that the temporary differences will not reverse in the foreseeable future.

No deferred tax is recognized on eliminations of intragroup transfers of interests in subsidiaries, associates or joint ventures.

Each tax entity calculates its own net deferred tax position. All net deferred tax asset and liability positions are then aggregated and shown in separate line items on the relevant side of the consolidated balance sheet. Deferred tax assets and liabilities are offset only if (i) Sanofi has a legally enforceable right to offset current tax assets and current tax liabilities, and (ii) the deferred tax assets and deferred tax liabilities relate to income taxes levied by the same taxation authority.

Deferred taxes are not discounted, except implicitly in the case of deferred taxes on assets and liabilities which are already impacted by discounting.

Withholding taxes on intragroup royalties and dividends, and on royalties and dividends collected from third parties, are accounted for as current income taxes.

In accounting for business combinations, Sanofi complies with the revised IFRS 3 in regards to the recognition of

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

deferred tax assets after the initial accounting period. Consequently, any deferred tax assets recognized by the acquiree after the end of this period in respect of temporary differences or tax loss carry-forwards existing at the acquisition date are recognized in profit or loss.

The positions adopted by Sanofi in tax matters are based on its interpretation of tax laws and regulations. Some of those positions may be subject to uncertainty. In such cases, Sanofi assesses the amount of the tax liability on the basis of the following assumptions: that its position will be examined by one or more tax authorities on the basis of all relevant information; that a technical assessment is carried out with reference to legislation, case law, regulations, and established practice; and that each position is assessed individually, with no offset or aggregation between positions. Those assumptions are assessed on the basis of facts and circumstances existing at the end of the reporting period. When an uncertain tax position is considered probable, a tax liability is recognized (or a deferred tax asset is not recognized) measured using Sanofi's best estimate. The amount of the liability includes any penalties and late payment interest. The line item *Income tax expense* includes the effects of tax disputes, and any penalties and late payment interest arising from such disputes.

**B.23. EMPLOYEE BENEFIT OBLIGATIONS**

Sanofi offers retirement benefits to employees and retirees. Such benefits are accounted for in accordance with IAS 19 (Employee Benefits), the revised version of which was mandatorily applicable for the first time in 2013.

Benefits are provided in the form of either defined contribution plans or defined benefit plans. In the case of defined contribution plans, the cost is recognized immediately in the period in which it is incurred, and equates to the amount of the contributions paid by Sanofi. For defined benefit plans, Sanofi generally recognizes its obligations to pay pensions and similar benefits to employees as a liability, based on an actuarial estimate of the rights vested or currently vesting in employees and retirees, using the projected unit credit method. Estimates are performed at least once a year, and rely on financial assumptions (such as discount rates) and demographic assumptions (such as life expectancy, retirement age, employee turnover, and the rate of salary increases).

Obligations relating to other post-employment benefits (healthcare and life insurance) offered by Sanofi companies to employees are also recognized as a liability based on an actuarial estimate of the rights vested or currently vesting in employees and retirees at the end of the reporting period.

Such liabilities are recognized net of the fair value of plan assets.

In the case of multi-employer defined benefit plans where plan assets cannot be allocated to each participating

employer with sufficient reliability, the plan is accounted for as a defined contribution plan, in accordance with paragraph 34 of IAS 19.

The benefit cost for the period consists primarily of current service cost, past service cost, net interest cost, gains or losses arising from plan settlements not specified in the terms of the plan, and actuarial gains or losses arising from plan curtailments. Net interest cost for the period is determined by applying the discount rate specified in IAS 19 to the net liability (i.e. the amount of the obligation, net of plan assets) recognized in respect of defined benefit plans. Past service cost is recognized immediately in profit or loss in the period in which it is incurred, regardless of whether or not the rights have vested at the time of adoption (in the case of a new plan) or of amendment (in the case of an existing plan).

Actuarial gains and losses on defined benefit plans (pensions and other post-employment benefits), also referred to as Remeasurements of the net defined benefit liability (asset), arise as a result of changes in financial and demographic assumptions, experience adjustments, and the difference between the actual return and interest cost on plan assets. The impacts of those remeasurements are recognized in *Other comprehensive income*, net of deferred taxes; they are not subsequently reclassifiable to profit or loss.

**B.24. SHARE-BASED PAYMENT**

## Edgar Filing: Sanofi - Form 20-F

Share-based payment expense is recognized as a component of *Operating income*, in the relevant classification of expense by function. In measuring the expense, the level of attainment of any performance conditions is taken into account.

### **B.24.1. Stock option plans**

Sanofi has granted a number of equity-settled share-based payment plans (stock option plans) to some of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2 (Share-Based Payment), services received from employees as consideration for stock options are recognized as an expense in the income statement, with the opposite entry recognized in equity. The expense corresponds to the fair value of the stock option plans, and is charged to income on a straight-line basis over the four-year vesting period of the plan.

The fair value of stock option plans is measured at the date of grant using the Black-Scholes valuation model, taking into account the expected life of the options. The resulting expense also takes into account the expected cancellation rate of the options. The expense is adjusted over the vesting period to reflect actual cancellation rates resulting from option-holders ceasing to be employed by Sanofi.

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**B.24.2. Employee share ownership plans**

Sanofi may offer its employees the opportunity to subscribe to reserved share issues at a discount to the reference market price. Shares awarded to employees under such plans fall within the scope of IFRS 2. Consequently, an expense is recognized at the subscription date, based on the value of the discount offered to employees.

**B.24.3. Restricted share plans**

Sanofi may award restricted share plans to certain of its employees. The terms of those plans may make the award contingent on the attainment of performance criteria for some of the grantees.

In accordance with IFRS 2, an expense equivalent to the fair value of such plans is recognized on a straight line basis over the vesting period of the plan, with the opposite entry recognized in equity. Depending on the country, the vesting period of such plans is either three or four years. Plans with a two-year or three-year vesting period are subject to a two-year lock-up period.

The fair value of stock option plans is based on the fair value of the equity instruments granted, representing the fair value of the services received during the vesting period. The fair value of an equity instrument granted under a plan is the market price of the share at the grant date, adjusted for expected dividends during the vesting period.

**B.25. EARNINGS PER SHARE**

Basic earnings per share is calculated using the weighted average number of shares outstanding during the reporting period, adjusted on a time-weighted basis from the acquisition date to reflect the number of own shares held by Sanofi. Diluted earnings per share is calculated on the basis of the weighted average number of ordinary shares, computed using the treasury stock method.

This method assumes that (a) all outstanding dilutive options and warrants are exercised, and (b) Sanofi acquires its own shares at the quoted market price for an amount equivalent to the cash received as consideration for the exercise of the options or warrants, plus the expense arising on unamortized stock options.

**B.26. SEGMENT INFORMATION**

In accordance with IFRS 8 (Operating Segments), the segment information reported by Sanofi is prepared on the basis of internal management data provided to the Chief Executive Officer, who is the chief operating decision maker.

The segments reported by Sanofi correspond to its operating segments, with no aggregation. Sanofi has two operating segments: Pharmaceuticals and Human Vaccines (Vaccines).

The Pharmaceuticals segment comprises:

## Edgar Filing: Sanofi - Form 20-F

the commercial operations of the following franchises: Specialty Care (Rare Diseases, Multiple Sclerosis, Oncology), Diabetes & Cardiovascular, Established Prescription Products, Consumer Healthcare and Generics; and

dedicated research and development, production and marketing activities for all of Sanofi's pharmaceuticals operations. The Vaccines segment comprises:

the commercial operations of Sanofi Pasteur; and

dedicated research and development, production and marketing activities for Sanofi's vaccines operations. Each segment includes global support function costs as allocated for internal reporting purposes within Sanofi.

The Other segment includes all activities that do not qualify as reportable segments under IFRS 8.

Those segments reflect the internal organizational structure. The reporting segments are consistent with the internal reporting regularly provided to the chief operating decision maker and used to assess performance and make resource allocation decisions.

Information on operating segments is provided in Note D.35.

In 2016, Sanofi reviewed the definition of its operating segments following the signature of an agreement to exchange its Animal Health business for Boehringer Ingelheim's Consumer Healthcare business.

The Animal Health business no longer qualifies as an operating segment, given that (i) the exchange transaction closed on January 1, 2017 and (ii) Sanofi no longer prospectively monitors the performance of the business. In the consolidated income statement, the Animal Health business (Merial) is presented in a separate line item, *Net income/(loss) of the held-for-exchange Animal Health business*, in accordance with IFRS 5 (see Notes D.2. and D.36. to the consolidated financial statements).

### **B.27. MANAGEMENT OF CAPITAL**

In order to maintain or adjust the capital structure, Sanofi can adjust the amount of dividends paid to shareholders, repurchase its own shares, issue new shares, or issue securities giving access to its capital.

The following objectives are defined under the terms of Sanofi's share repurchase programs:

the implementation of any stock option plan giving entitlement to purchase shares in the Sanofi parent company;

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

- the allotment or sale of shares to employees under statutory profit sharing schemes and employee savings plans;
- the consideration-free allotment of shares (i.e. restricted share plans);
- the cancellation of some or all of the repurchased shares;
- market-making in the secondary market by an investment services provider under a liquidity contract in compliance with the ethical code recognized by the *Autorité des Marchés Financiers* (AMF);
- the delivery of shares on the exercise of rights attached to securities giving access to the capital by redemption, conversion, exchange, presentation of a warrant or any other means;
- the delivery of shares (in exchange, as payment, or otherwise) in connection with mergers and acquisitions;
- the execution by an investment services provider of purchases, sales or transfers by any means, in particular via off-market trading; or
- any other purpose that is or may in the future be authorized under the applicable laws and regulations.

Sanofi is not subject to any constraints on equity capital imposed by third parties.

Total equity includes *Equity attributable to equity holders of Sanofi* and *Equity attributable to non-controlling interests*, as shown in the consolidated balance sheet. Sanofi defines Debt, net of cash and cash equivalents as (i) the sum of short-term debt, long-term debt and interest rate derivatives and currency derivatives used to hedge debt, minus (ii) the sum of cash and cash equivalents and interest rate derivatives and currency derivatives used to hedge cash and cash equivalents.

**B.28. NEW PRONOUNCEMENTS ISSUED BY THE IASB AND APPLICABLE FROM 2017 ONWARDS**

The note below describes standards, amendments and interpretations issued by the IASB that will have mandatory application in 2017 or subsequent years, and Sanofi's position regarding future application. Sanofi has not early adopted any of those standards, amendments or interpretations.

**B.28.1. Standards**

At the end of May 2014 the IASB issued IFRS 15 (Revenue from Contracts with Customers). IFRS 15 is a converged standard common to both IFRS and US generally accepted accounting principles (US GAAP), and will replace IAS 18 (Revenue) and IAS 11 (Construction Contracts).

## Edgar Filing: Sanofi - Form 20-F

In April 2016 the IASB issued clarifications (amendments to IFRS 15) on how to (i) identify a performance obligation,

(ii) determine whether a company is a principal or an agent, and (iii) account for the revenue from granting a license. Adoption of those clarifications by the European Union is pending.

IFRS 15 includes new revenue recognition principles, in particular as regards identifying a performance obligation and allocating the transaction price in the case of contracts with multiple components. It also changes how contracts are analyzed in the case of revenue generated by licensing arrangements, and how variable consideration is recognized. The standard also contains new disclosure requirements.

Sanofi began its IFRS 15 implementation project with a diagnostic phase. The different categories of contracts with customers representative of Sanofi operations in the main countries have been analyzed. Sanofi has not identified any major changes compared to the treatment currently applied under IAS 18. However, further analyses are currently being finalized on the following issues:

- contracts with distributors, to determine whether the IFRS 15 concept of transfer of control might lead to a different conclusion when performing agent/principal analysis;
- licensing arrangements;
- other entity specific transactions.

Sanofi intends to apply IFRS 15 with effect from January 1, 2018 using the full retrospective method of adoption.

In July 2014 the IASB issued IFRS 9 (Financial Instruments). With effect from January 1, 2018, IFRS 9 will replace the currently applicable standards on the presentation, recognition and measurement of financial instruments (IAS 32 and IAS 39). IFRS 9 covers three key issues: classification and measurement, impairment, and hedge accounting. The standard has been adopted by the European Union, and is mandatorily applicable to annual reporting periods beginning on or after January 1, 2018. Given the nature of its operations, Sanofi does not anticipate any major change other than the fair value through other comprehensive income option, which could be applied to some shareholdings classified as available-for-sale financial assets under IAS 39. Analyses are also in progress regarding implementation of the new IFRS 9 credit risk recognition model (using the expected losses approach versus the incurred losses approach), in particular as regards accounts receivable. Sanofi intends to apply IFRS 9 with effect from January 1, 2018.

In January 2016 the IASB issued IFRS 16 (Leases), which aligns the accounting treatment of operating leases with that already applied to finance leases (i.e. recognition in the balance sheet of a liability for future lease payments, and of an asset for the associated rights of use). Application of IFRS 16 will also require a change in the presentation of lease expenses both in the income statement (i.e. depreciation and interest expense) and in the statement of

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

cash flows (the amount allocated to repayment of the liability will be reported as a cash outflow from financing activities, while the amount allocated to the asset will be reported as a cash outflow from investing activities). IFRS 16 is applicable to annual reporting periods beginning on or after January 1, 2019; its adoption by the European Union is pending. The impacts of IFRS 16 are currently under review.

**B.28.2. Amendments, Annual Improvements and Interpretations**

In 2016, the IASB issued two pronouncements relating to financial statement disclosures, which are applicable to annual reporting periods beginning on or after January 1, 2017 subject to their adoption by the European Union:

- amendments to IAS 7 (Statement of Cash Flows), on changes in net debt;
- amendment to IFRS 12 (Disclosure of Interests in Other Entities), on interests in other entities classified as held-for-sale assets under IFRS 5 (Non-current Assets Held for Sale and Discontinued Operations).

**C/ Principal Alliances****C.1. ALLIANCE ARRANGEMENTS WITH REGENERON PHARMACEUTICALS, INC. (REGENERON)****Collaboration agreement on the discovery, development and commercialization of human therapeutic antibodies**

In November 2007, Sanofi and Regeneron signed agreements (amended in November 2009) for the discovery, development and commercialization of fully human therapeutic antibodies. Under the 2009 amended agreements Sanofi committed to funding the discovery and pre-clinical development of fully human therapeutic antibodies by a maximum of \$160 million per year through 2017. Sanofi has an option to develop and commercialize antibodies discovered by Regeneron pursuant to the collaboration. Following the signature in July 2015 of the immuno-oncology collaboration agreement described below, \$75 million (spread over three years) was reallocated to that new agreement.

If the option is exercised, Sanofi co-develops the antibody with Regeneron and is responsible for funding. Sanofi and Regeneron share co-promotion rights and profits on sales of the co-developed antibodies. On receipt of the first positive Phase III trial results for any such antibody, the subsequent Phase III costs for that antibody are split 80% Sanofi, 20% Regeneron. Amounts received from Regeneron under those arrangements are recognized by Sanofi as a reduction in the line item **Research and development expenses**. Once a product begins to be commercialized, and provided that the share of quarterly results under the agreement represents a profit, Sanofi is entitled to an additional profit-

share (capped at 10% of Regeneron's share of quarterly profits) until Regeneron has paid 50% of the cumulative development costs incurred by the parties to the collaboration. In addition, Sanofi may be required to make milestone payments based on aggregate sales of all antibodies. As of December 31, 2016 the cumulative development costs incurred by the two parties were 5.1 billion ( 3.0 billion funded 100% by Sanofi, and 2.1 billion funded 80% by Sanofi and 20% by Regeneron). On the later of (i) 24 months before the scheduled launch date or (ii) the first positive Phase III trial results, Sanofi and Regeneron will share the commercial expenses of the antibodies jointly developed under the license agreement. Sanofi recognizes all the sales of those antibodies. Profits and losses arising from commercial operations in the United States are split 50/50. Outside the United States, Sanofi is entitled to between 55% and 65% of profits depending on sales of the antibodies, and bears 55% of any losses. The share of profits and losses attributable to Regeneron under the agreement is recognized in the line items **Other operating income** or **Other operating expenses**, which are components of **Operating income**. In addition, Regeneron is entitled to receive payments of up to \$250 million contingent on the attainment of specified levels of sales outside the United States.

## Edgar Filing: Sanofi - Form 20-F

If Sanofi opts not to exercise its license option for an antibody, it will receive a royalty from Regeneron on sales of that antibody.

### **Collaboration agreement on the discovery, development and commercialization of antibodies in the field of immuno-oncology**

On July 28, 2015, Sanofi and Regeneron entered into a new global collaboration to discover, develop and commercialize new antibody cancer treatments in the emerging field of immuno-oncology. As part of the agreement, the two companies will jointly develop a programmed cell death protein 1 (PD-1) inhibitor antibody currently in Phase II, and initiate clinical trials from 2016 with new therapeutic candidates based on ongoing innovative preclinical programs. Sanofi has made an upfront payment of \$640 million to Regeneron. The two companies will invest approximately \$1 billion from discovery through proof of concept (POC) development (usually a Phase IIa study) of monotherapy and novel combinations of immuno-oncology antibody candidates to be funded 25% by Regeneron (\$250 million) and 75% by Sanofi (\$750 million). Under the terms of the discovery program, Sanofi is entitled to an additional profit-share (capped at 10% of Regeneron's share of quarterly profits) until the payments from Regeneron reach 50% of the clinical development costs initially funded by Sanofi.

Sanofi and Regeneron also committed to provide additional funding of no more than \$650 million on a 50/50 basis (\$325 million per company) for the development of REGN2810, a PD-1 inhibitor. In addition, Sanofi will make a one-time milestone payment of \$375 million to Regeneron in

**F- 31**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

the event that sales of a PD-1 product and any other collaboration antibody sold for use in combination with a PD-1 product were to exceed, in the aggregate, \$2 billion in any consecutive 12-month period. Finally, the two companies agreed to reallocate \$75 million (spread over three years) to immuno-oncology antibody research and development from Sanofi's \$160 million annual contribution to their existing antibody collaboration, which otherwise continues as announced in November 2009. Beyond the committed funding, additional funding will be allocated as programs enter post-POC development.

Under the terms of the development program agreement, Sanofi can exercise its license option for candidates derived from the program.

Once Sanofi has exercised a license option for a candidate, future development of that candidate will be conducted either by Sanofi or Regeneron.

Where development is conducted by Sanofi, the entire cost of developing that candidate will be funded by Sanofi, and Regeneron will reimburse half of those costs, subject to a cap of 10% of Regeneron's quarterly profits.

Where development is conducted by Regeneron, the two parties will share the development costs equally.

**C.2. ALLIANCE ARRANGEMENTS WITH BRISTOL-MYERS SQUIBB (BMS)**

Two of Sanofi's leading products were jointly developed with BMS: the anti-hypertensive agent irbesartan (Aprovel®/Avapro®/Karvea®) and the anti-atherothrombosis treatment clopidogrel bisulfate (Plavix®/Iscover®).

On September 27, 2012, Sanofi and BMS signed an agreement relating to their alliance following the loss of exclusivity of Plavix® and Avapro®/Avalide® in many major markets.

Under the terms of this agreement, which took effect on January 1, 2013, BMS returned to Sanofi its rights to Plavix® and Avapro®/Avalide® in all markets worldwide with the exception of Plavix® in the United States and Puerto Rico, giving Sanofi sole control and freedom to operate commercially in respect of those products. In exchange, BMS will receive royalty payments on Sanofi's sales of branded and unbranded Plavix® and Avapro®/Avalide® worldwide (except for Plavix® in the United States and Puerto Rico) until 2018, and will also receive a payment of \$200 million from Sanofi in December 2018, part of which will be used to buy out the non-controlling interests (see Note D.18.). Rights to Plavix® in the United States and Puerto Rico remain unchanged and continue to be governed by the terms of the original agreement until December 2019.

In all of the territories managed by Sanofi (including the United States and Puerto Rico for Avapro®/Avalide®) as defined in the agreement, Sanofi recognizes in its consolidated financial statements the revenue and expenses generated by its own operations. The share of profits reverting to BMS subsidiaries is presented within *Net income attributable to non-controlling interests* in the income statement.

In the territory managed by BMS (United States and Puerto Rico for Plavix®), Sanofi recognizes its share of profits and losses within the line item *Share of profit/(loss) of associates and joint ventures*.

**D/ Presentation of the financial statements****D.1. IMPACT OF CHANGES IN THE SCOPE OF CONSOLIDATION DUE TO ACQUISITIONS AND DIVESTMENTS****D.1.1. Regeneron Pharmaceuticals, Inc. (Regeneron)**

## Edgar Filing: Sanofi - Form 20-F

During 2016 and 2015, Sanofi acquired further shares in the biopharmaceutical company Regeneron at a cost of 115 million in 2016 and 117 million in 2015. Sanofi's investment in Regeneron had a carrying amount of 2,548 million as of December 31, 2016, compared with 2,245 million as of December 31, 2015 (see Note D.6.). This represents an equity interest of 22.1% as of December 31, 2016, compared with 22.1% as of December 31, 2015.

During 2014, Sanofi acquired 7 million Regeneron shares, raising its equity interest to 22.3% as of December 31, 2014, versus 15.9% as of December 31, 2013. Since the start of April 2014 this interest has been accounted for by the equity method, following the nomination of a Sanofi designee to the Regeneron Board of Directors. Previously, the investment in Regeneron was reported in the balance sheet in the

Available-for-sale financial assets category and measured at market value in accordance with IAS 39 (Financial Instruments: Recognition and Measurement). As of the date on which the equity method was first applied, the investment was measured at acquisition cost in accordance with IAS 28 (Investments in Associates and Joint Ventures). Under IAS 28, the cost of the investment is equivalent to the aggregate amount of the successive acquisition prices paid (including acquisition-related costs) for the interests in Regeneron (see Note B.1.). Consequently, the changes in the market value of the investment in Regeneron that had previously been recognized in *Other comprehensive income* were reversed out on first-time application of the equity method. Goodwill is calculated on each successive acquisition of shares; it represents the excess of the acquisition price over the share of the identifiable net assets acquired, measured in accordance with IFRS 3 (Business Combinations).

### F- 32

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The main effects of the change to the equity method in accounting for the Regeneron investment are set forth below:

	Reclassification				
	from available-				
	December 31,	for-sale	Acquisitions	Other	December 31,
( million)	2013	financial	during	movements <sup>(d)</sup>	2014
		assets <sup>(b)</sup>	2014 <sup>(c)</sup>		
Investments in associates and joint ventures	-	256	1,629	57	1,942
Available-for-sale financial assets	3,157	(3,157)	-	-	-
Shareholders' equity <sup>(a)</sup>	2,607	(2,607)	-	57	57
Deferred tax liabilities	294	(294)	-	-	-
<b>Historical cost of acquisition</b>	<b>256</b>	<b>-</b>	<b>1,629</b>	<b>-</b>	<b>1,885</b>

(a) Amount net of taxes.

(b) Reversal of changes in the value of the investment previously recognized in Other comprehensive income.

(c) Acquisition price (including acquisition-related costs) of the 7 million shares acquired during 2014.

(d) Mainly comprises 126 million for Sanofi's share of net losses (including the effect of amortizing fair value remeasurements of the acquired share of the intangible assets and inventories of Regeneron) and a currency translation difference of 175 million.

**D.1.2. DISSOLUTION OF THE SANOFI PASTEUR MSD JOINT VENTURE**

On March 8, 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) announced their intention to end Sanofi Pasteur MSD (SPMSD), their joint venture in the vaccines business, in order to pursue their development strategies separately in Europe.

SPMSD, owned on a 50/50 basis by Sanofi Pasteur and MSD, was originally created in 1994 to develop and commercialize vaccines originating from the two companies' pipelines in order to improve and promote public health in 19 European countries.

Following the announcement, Sanofi's investment in SPMSD was reclassified to the line item *Assets held for sale or exchange* and ceased to be accounted for by the equity method.

The transaction was completed in two stages on December 30 and December 31, 2016:

**Divestment by Sanofi of its interest in SPMSD:**

On December 30, 2016, Sanofi sold its interest in SPMSD to MSD.

The consideration for the divestment was (i) a fixed sum of 127 million received on January 4, 2017 and (ii) contingent consideration based on a percentage of MSD sales from 2017-2024 of specified products previously distributed by SPMSD and receivable in annual installments over the same period. As of December 31, 2016, the fair value of the contingent consideration was measured at 458 million and recognized in the available-for-sale financial assets category (see Note D.7.).

The pre-tax gain on the divestment, amounting to 211 million, is presented within the line item *Other gains and losses, and litigation* (see Note D.28.).

**Acquisition of the European Vaccines business previously included in SPMSD:**

This transaction was finalized on December 31, 2016. The table below sets forth the provisional purchase price allocation:

( million)	Fair value at acquisition date
Other intangible assets <sup>(a)</sup>	465
Inventories	43
Other current assets	2
Deferred taxes	(4)
Other non-current liabilities	(5)
<b>Net assets at December 31, 2016</b>	<b>501</b>
Goodwill	5
<b>Purchase price</b>	<b>506</b>

(a) See Note D.4.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The purchase price primarily consists of (i) a fixed sum of 154 million paid on January 4, 2017 and (ii) contingent consideration of 354 million based on a percentage of future sales made by Sanofi Pasteur during the 2017-2024 period of specified former SPMSD products, to be paid in annual installments over that period.

In accordance with IFRS 3 (Business Combinations), this contingent consideration has been recognized in *Liabilities related to business combinations and to non-controlling interests* (see Note D.18.).

Had the acquisition occurred on January 1, 2016, it would have generated incremental sales of 262 million.

Acquisition-related costs recognized in profit or loss during the period amounted to 3 million, mainly recorded within the line item *Other operating expenses*.

**D.1.3. Other acquisitions and divestments**

The impacts of the other acquisitions made during 2016 and 2015 are not material for Sanofi.

In 2014 Sanofi took control of Globalpharma Co. LLC, a pharmaceutical company based in Dubai, with the intention of using it as the foundation of a platform for the manufacture and marketing of Sanofi's generics portfolio in the Middle East. The impacts of this acquisition are not material.

No other divestments were made by Sanofi in 2016, 2015 or 2014 that materially affected the scope of consolidation.

**D.2. EXCHANGE OF THE ANIMAL HEALTH BUSINESS**

In addition to the exclusivity agreement of December 2015 on a future exchange of Sanofi's Animal Health business

(Merial) and Boehringer Ingelheim's consumer healthcare business, the two groups announced on June 27, 2016 that they had successfully concluded the negotiations ongoing since the end of 2015 by signing contracts to secure the deal. The transaction was finalized on January 1, 2017 (see Note G.).

Consequently, and in accordance with the classification and presentation requirements of IFRS 5 (see Note B.7.), all assets of the Animal Health business included in the exchange and all liabilities directly related to those assets are classified in the line items *Assets held for sale or exchange* and *Liabilities related to assets held for sale or exchange*, respectively, in the consolidated balance sheets as of December 31, 2016 and 2015. Similarly, because the Animal Health business qualifies as a discontinued operation under IFRS 5 (see Note B.7.), the net income or loss from that business is presented separately in the consolidated income statement within the line item *Net income/(loss) of the held-for-exchange Animal Health business*. This presentation in a separate line item in the income statement applies to operations for the year ended December 31, 2016 and for the comparative periods presented.

For detailed information about the contribution of the Animal Health business to the consolidated financial statements refer to Note D.36., Held-for-exchange Animal Health business .

As of December 31, 2016 the Animal Health business no longer qualified as an operating segment, given the finalization of the exchange deal with Boehringer Ingelheim on January 1, 2017.



**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.3. PROPERTY, PLANT AND EQUIPMENT**

Property, plant and equipment (including assets held under finance leases) comprise:

<i>( million)</i>	Land	Buildings	Plant and equipment	Fixtures, fittings & other	Property, plant & equipment in process	Total
<b>Gross value at January 1, 2014</b>	<b>364</b>	<b>6,497</b>	<b>8,749</b>	<b>2,107</b>	<b>1,844</b>	<b>19,561</b>
Changes in scope of consolidation	-	(3)	2	-	3	2
Acquisitions and other increases	-	6	60	47	980	1,093
Disposals and other decreases	(9)	(16)	(30)	(116)	(17)	(188)
Currency translation differences	16	233	191	41	54	535
Transfers <sup>(a)</sup>	1	198	447	136	(905)	(123)
<b>Gross value at December 31, 2014</b>	<b>372</b>	<b>6,915</b>	<b>9,419</b>	<b>2,215</b>	<b>1,959</b>	<b>20,880</b>
Changes in scope of consolidation	(4)	1	(8)	1	(22)	(32)
Acquisitions and other increases	-	11	76	59	1,172	1,318
Disposals and other decreases	(3)	(4)	(17)	(126)	(23)	(173)
Currency translation differences	5	144	122	24	25	320
Transfers <sup>(a)</sup>	(1)	269	463	228	(1,083)	(124)
Reclassification of the Animal Health business <sup>(b)</sup>	(33)	(604)	(313)	(54)	(76)	(1,080)
<b>Gross value at December 31, 2015</b>	<b>336</b>	<b>6,732</b>	<b>9,742</b>	<b>2,347</b>	<b>1,952</b>	<b>21,109</b>
Acquisitions and other increases	-	9	48	51	1,232	1,340
Disposals and other decreases	(10)	(111)	(350)	(104)	(37)	(612)
Currency translation differences	1	81	36	(1)	15	132
Transfers <sup>(a)</sup>	-	247	558	128	(1,025)	(92)
<b>Gross value at December 31, 2016</b>	<b>327</b>	<b>6,958</b>	<b>10,034</b>	<b>2,421</b>	<b>2,137</b>	<b>21,877</b>
<b>Accumulated depreciation &amp; impairment at January 1, 2014</b>	<b>(20)</b>	<b>(2,589)</b>	<b>(5,166)</b>	<b>(1,456)</b>	<b>(148)</b>	<b>(9,379)</b>
Changes in scope of consolidation	-	4	2	-	-	6
Depreciation expense	-	(356)	(577)	(192)	-	(1,125)
Impairment losses	(2)	(37)	(26)	(4)	(28)	(97)
Disposals	3	9	23	113	15	163
Currency translation differences	(1)	(64)	(78)	(24)	(2)	(169)
Transfers <sup>(a)</sup>	3	54	42	14	4	117
<b>Accumulated depreciation &amp; impairment at December 31, 2014</b>	<b>(17)</b>	<b>(2,979)</b>	<b>(5,780)</b>	<b>(1,549)</b>	<b>(159)</b>	<b>(10,484)</b>
Changes in scope of consolidation	6	5	12	-	22	45
Depreciation expense	-	(376)	(607)	(208)	-	(1,191)
Impairment losses	-	(38)	(42)	(11)	(41)	(132)
Disposals	-	3	15	122	13	153
Currency translation differences	-	(33)	(49)	(17)	-	(99)
Transfers <sup>(a)</sup>	-	34	90	(4)	(1)	119
Reclassification of the Animal Health business <sup>(b)</sup>	-	252	145	26	-	423
<b>Accumulated depreciation &amp; impairment at December 31, 2015</b>	<b>(11)</b>	<b>(3,132)</b>	<b>(6,216)</b>	<b>(1,641)</b>	<b>(166)</b>	<b>(11,166)</b>
Depreciation expense	-	(356)	(595)	(190)	-	(1,141)
Impairment losses	(3)	(31)	(17)	(30)	(78)	(159)
Disposals	3	107	348	100	33	591
Currency translation differences	-	(37)	(16)	(2)	(2)	(57)
Transfers <sup>(a)</sup>	4	22	16	6	26	74
<b>Accumulated depreciation &amp; impairment at December 31, 2016</b>	<b>(7)</b>	<b>(3,427)</b>	<b>(6,480)</b>	<b>(1,757)</b>	<b>(187)</b>	<b>(11,858)</b>
Carrying amount at December 31, 2014	355	3,936	3,639	666	1,800	10,396
Carrying amount at December 31, 2015	325	3,600	3,526	706	1,786	9,943

Carrying amount at December 31, 2016	320	3,531	3,554	664	1,950	10,019
--------------------------------------	-----	-------	-------	-----	-------	--------

(a) This line also includes the effect of the reclassification of assets to **Assets held for sale or exchange**.

(b) This line comprises the property, plant and equipment of the Animal Health business, reclassified to **Assets held for sale or exchange** as of December 31, 2015 in accordance with IFRS 5 (see Notes D.2. and D.36.).

**F- 35**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Acquisitions during 2016 amounted to 1,340 million. The Pharmaceuticals segment made acquisitions totaling 1,069 million, primarily investments in industrial facilities ( 761 million excluding Genzyme in 2016, compared with 594 million in 2015 and 452 million in 2014) and in constructing and equipping research sites ( 164 million in 2016, versus 82 million in 2015 and 55 million in 2014). Genzyme accounted for 8 million of Pharmaceuticals segment acquisitions in 2016 (versus 80 million in 2015 and 113 million in 2014). The Vaccines segment made 271 million of acquisitions in 2016 (versus 260 million in 2015 and 202 million in 2014). Acquisitions of property, plant and equipment during the year included 17 million of capitalized interest costs (versus 15 million in 2015 and 20 million in 2014).

Firm orders of property, plant and equipment were 545 million as of December 31, 2016 ( 436 million as of December 31, 2015 and 448 million as of December 31, 2014). Property, plant and equipment pledged as security for liabilities amounted to 241 million as of December 31, 2016 (versus 249 million as of December 31, 2015 and 242 million as of December 31, 2014).

Impairment tests of property, plant and equipment conducted using the method described in Note B.6. resulted in the recognition during 2016 of net impairment losses of 159 million. In 2015 and 2014, net impairment losses totaled 132 million and 97 million respectively, in both cases relating primarily to the Pharmaceuticals segment.

The table below shows amounts for items of property, plant and equipment held under finance leases:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Land	3	3	3
Buildings	102	101	99
Other property, plant and equipment	8	8	4
<b>Total gross value</b>	<b>113</b>	<b>112</b>	<b>106</b>
Accumulated depreciation and impairment	(79)	(69)	(55)
<b>Carrying amount</b>	<b>34</b>	<b>43</b>	<b>51</b>

Future minimum lease payments due under finance leases as of December 31, 2016 were 66 million (versus 83 million as of December 31, 2015 and 74 million as of December 31, 2014), including 13 million of interest (versus 15 million as of December 31, 2015 and 12 million as of December 31, 2014).

The payment schedule is as follows:

<b>December 31, 2016</b>	<b>Payments due by period</b>			
<i>( million)</i>	<b>Less than 1 year</b>	<b>1 to 3 years</b>	<b>3 to 5 years</b>	<b>More than 5 years</b>
<b>Total</b>				
<b>Finance lease obligations</b>				

Edgar Filing: Sanofi - Form 20-F

· principal	53	19	15	5	14
· interest	13	4	4	3	2
<b>Total</b>	<b>66</b>	<b>23</b>	<b>19</b>	<b>8</b>	<b>16</b>

**D.4. GOODWILL AND OTHER INTANGIBLE ASSETS**

**Goodwill**

Movements in goodwill comprise:

<i>( million)</i>	<b>Goodwill</b>
<b>Balance at January 1, 2014</b>	<b>37,134</b>
Acquisitions during the period	23
Currency translation differences	2,040
<b>Balance at December 31, 2014</b>	<b>39,197</b>
Reclassification of the Animal Health business <sup>(a)</sup>	(1,510)
Currency translation differences	1,870
<b>Balance at December 31, 2015</b>	<b>39,557</b>
Acquisitions during the period	5
Currency translation differences	725
<b>Balance at December 31, 2016</b>	<b>40,287</b>

(a) Comprises the goodwill on the Animal Health business, now reclassified to *Assets held for sale or exchange*.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Acquisition of the European Vaccines business previously included in the Sanofi Pasteur MSD joint venture**

The final purchase price allocation for the European Vaccines business resulted in the recognition of intangible assets (other than goodwill) totaling 465 million at the acquisition date. These assets consist of the vaccines portfolio previously held by the Sanofi Pasteur MSD joint venture comprising pediatric combination, adult booster and endemics vaccines that reverted to Sanofi on December 31, 2016 (see Note D.1.2.).

**Genzyme acquisition (2011)**

The Genzyme final purchase price allocation resulted in the recognition of intangible assets (other than goodwill) totaling 10,059 million at the acquisition date. That figure included 7,727 million for marketed products in the fields of rare diseases (primarily Cerezyme®, Fabrazyme® and Myozyme®), renal endocrinology (primarily Renagel®), biosurgery (primarily Synvisc®), and oncology. Also included were intangible assets valued at 2,148 million at the acquisition date relating to Genzyme in-process research and development projects, primarily Lemtrada® (alemtuzumab) and eliglustat. The Genzyme brand was attributed a fair value of 146 million.

Goodwill arising from the acquisition of Genzyme amounted to 5,031 million as of December 31, 2016 (versus 4,946 million as of December 31, 2015 and 4,727 million as of December 31, 2014).

As of December 31, 2016, the carrying amount of marketed products and the Genzyme brand represented more than 99% of the intangible assets of Genzyme (other than goodwill), and in-process research and development represented less than 1%.

During 2015, some of the Genzyme acquired research and development ( 474 million) came into commercial use, and

started being amortized from the date of marketing approval. The main product involved was Cerdelga® (eliglustat) outside the United States.

During 2014, some of the Genzyme acquired research and development ( 778 million) came into commercial use, and started being amortized from the date of marketing approval. The main products involved were Cerdelga® (eliglustat) and Lemtrada® (alemtuzumab) in the United States.

**Aventis acquisition (2004)**

On August 20, 2004, Sanofi acquired Aventis, a global pharmaceutical group created in 1999 by the merger between Rhône-Poulenc and Hoechst.

As part of the process of creating the new group, the two former parent companies Sanofi-Synthélabo (renamed Sanofi) and Aventis were merged on December 31, 2004.

The total purchase price as measured under IFRS 3 (Business Combinations) was 52,908 million, of which 15,894 million was settled in cash.

Goodwill arising from the acquisition of Aventis amounted to 31,124 million as of December 31, 2016 (versus 30,587 million as of December 31, 2015 and 29,143 million as of December 31, 2014).

Rights to marketed products and goodwill arising on the Aventis acquisition were allocated on the basis of the split of Sanofi's operations into business and geographical segments, and valued in the currency of the relevant geographical segment (mainly euros and US dollars) with assistance from an independent valuer.

## Edgar Filing: Sanofi - Form 20-F

During 2014, some of the Aventis acquired research and development ( 47 million) came into commercial use, and started being amortized from the date of marketing approval. The main product involved was Jevtana® in Japan.

**F- 37**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Movements in other intangible assets comprise:

<i>( million)</i>	Acquired R&D	Products, trademarks and other rights	Software	Total other intangible assets
<b>Gross value at January 1, 2014</b>	<b>4,502</b>	<b>48,103</b>	<b>1,052</b>	<b>53,657</b>
Changes in scope of consolidation	-	61	-	61
Acquisitions and other increases	164	281	138	583
Disposals and other decreases	(175)	(95)	(46)	(316)
Currency translation differences	230	3,541	42	3,813
Transfers <sup>(a)</sup>	(1,239)	1,239	54	54
<b>Gross value at December 31, 2014</b>	<b>3,482</b>	<b>53,130</b>	<b>1,240</b>	<b>57,852</b>
Acquisitions and other increases	1,179	912	154	2,245
Disposals and other decreases	(204)	(1,321)	(27)	(1,552)
Currency translation differences	189	3,610	35	3,834
Transfers <sup>(a)</sup>	(741)	653	11	(77)
Reclassification of the Animal Health business <sup>(c)</sup>	(51)	(4,982)	(182)	(5,215)
<b>Gross value at December 31, 2015</b>	<b>3,854</b>	<b>52,002</b>	<b>1,231</b>	<b>57,087</b>
Changes in scope of consolidation	-	465	-	465
Acquisitions and other increases	142	127	148	417
Disposals and other decreases	(305) <sup>(d)</sup>	(687)	(73)	(1,065)
Currency translation differences	55	1,124	17	1,196
Transfers <sup>(a)</sup>	(97)	76	3	(18)
<b>Gross value at December 31, 2016</b>	<b>3,649</b>	<b>53,107</b>	<b>1,326</b>	<b>58,082</b>
<b>Accumulated amortization &amp; impairment at January 1, 2014</b>	<b>(2,509)</b>	<b>(34,968)</b>	<b>(785)</b>	<b>(38,262)</b>
Amortization expense	-	(2,482)	(92)	(2,574)
Impairment losses, net of reversals <sup>(b)</sup>	153	(127)	-	26
Disposals and other decreases	175	87	45	307
Currency translation differences	(161)	(2,561)	(28)	(2,750)
Transfers <sup>(a)</sup>	301	(301)	(56)	(56)
<b>Accumulated amortization &amp; impairment at December 31, 2014</b>	<b>(2,041)</b>	<b>(40,352)</b>	<b>(916)</b>	<b>(43,309)</b>
Amortization expense	-	(2,651)	(108)	(2,759)
Impairment losses, net of reversals <sup>(b)</sup>	(343)	(427)	(3)	(773)
Disposals and other decreases	204	1,257	27	1,488
Currency translation differences	(124)	(2,662)	(23)	(2,809)
Transfers <sup>(a)</sup>	-	39	(6)	33
Reclassification of the Animal Health business <sup>(c)</sup>	3	2,908	157	3,068
<b>Accumulated amortization &amp; impairment at December 31, 2015</b>	<b>(2,301)</b>	<b>(41,888)</b>	<b>(872)</b>	<b>(45,061)</b>
Amortization expense	-	(1,712)	(104)	(1,816)
Impairment losses, net of reversals <sup>(b)</sup>	(60)	(137)	-	(197)
Disposals and other decreases	108	673	73	854
Currency translation differences	(41)	(931)	(12)	(984)
Transfers <sup>(a)</sup>	4	(2)	(1)	1
<b>Accumulated amortization &amp; impairment at December 31, 2016</b>	<b>(2,290)</b>	<b>(43,997)</b>	<b>(916)</b>	<b>(47,203)</b>
Carrying amount at December 31, 2014	1,441	12,778	324	14,543
Carrying amount at December 31, 2015	1,553	10,114	359	12,026

<b>Carrying amount at December 31, 2016</b>	<b>1,359</b>	<b>9,110</b>	<b>410</b>	<b>10,879</b>
---	--------------	--------------	------------	---------------

(a) *The Transfers line mainly relates to acquired R&D that came into commercial use during the period and is being amortized from the date of marketing approval.*

(b) *See Note D.5.*

(c) *Comprises the other intangible assets of the Animal Health business, now reclassified to Assets held for sale or exchange.*

(d) *Includes the return of product rights to Hanmi in 2016 (see Note D.21.1.)*

**F- 38**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Products, trademarks and other rights (excluding items relating to the Animal Health business, reported within the line item *Assets held for sale or exchange*, see Note D.36.), mainly comprise:

· marketed products, with a carrying amount of 8.4 billion as of December 31, 2016 (versus 9.4 billion as of December 31, 2015 and 12.3 billion as of December 31, 2014) and a weighted average amortization period of approximately ten years;

· trademarks, with a carrying amount of 0.2 billion as of December 31, 2016 (compared with 0.3 billion as of December 31, 2015 and 0.4 billion as of December 31, 2014) and a weighted average amortization period of approximately 13 years.

The table below provides information about the principal marketed products, representing 85% of the carrying amount of that item as of December 31, 2016:

( million)	Gross value	Accumulated amortization & impairment	Carrying amount at December 31, 2016	Amortization period (years) <sup>(a)</sup>	Residual amortization period (years) <sup>(b)</sup>	Carrying amount at December 31, 2015	Carrying amount at December 31, 2014
Genzyme	11,074	(6,065)	5,009	10	7	5,759	5,788
Aventis	35,182	(34,087)	1,095	9	4	1,548	1,993
Chattem	1,414	(484)	930	22	17	956	910
Zentiva	910	(782)	128	9	4	187	249
<b>Total: principal marketed products</b>	<b>48,580</b>	<b>(41,418)</b>	<b>7,162</b>			<b>8,450</b>	<b>8,940</b>

(a) Weighted averages. The amortization periods for these products vary between one and 25 years.

(b) Weighted averages.

Acquisitions of other intangible assets (excluding software) during 2016 amounted to 269 million.

Some of the acquired research and development has come into commercial use, and has started being amortized from the date of marketing approval. The main such items were the diabetes treatments Lyxumia® and Soliqua 100/33 ( 52 million).

## Edgar Filing: Sanofi - Form 20-F

During 2015, some of the acquired research and development came into commercial use, and started being amortized from the date of marketing approval. The main such item was the dengue fever vaccine ( 230 million).

During 2014, some of the acquired research and development derived from collaboration agreements came into commercial use, and started being amortized from the date of marketing approval. The main such item was Apleway® (tofogliflozin) in Japan ( 35 million).

Amortization of other intangible assets is recognized in the income statement within the line item *Amortization of intangible assets*, except for amortization of software and other rights of an industrial or operational nature which is recognized in the relevant classification of expense by function as shown in the table below.

( million)	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
Cost of sales	28	25	18
Research and development expenses	16	13	12
Selling and general expenses	56	52	46
Other operating expenses	5	4	2
<b>Total</b>	<b>105</b>	<b>94</b>	<b>78</b>

(a) Income statement items relating to the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.5. IMPAIRMENT OF INTANGIBLE ASSETS AND PROPERTY, PLANT AND EQUIPMENT****Goodwill**

The recoverable amount of cash generating units (CGUs) is determined by reference to the value in use of each CGU, based on discounted estimates of the future cash flows from the CGU, in accordance with the policies described in Note B.6.1. In light of (i) the new organizational structure adopted by Sanofi from January 1, 2016, as a result of which it is no longer meaningful to break down CGUs by geographical region, and (ii) the completion of the exchange of the Animal Health business on January 1, 2017, goodwill has now been reallocated to two CGUs: Pharmaceuticals and Vaccines.

Goodwill is monitored internally at the level of each of the two CGUs mentioned above. Each CGU combines on an overall, worldwide basis all aspects of key decision-making relating to commercial operations, R&D activities and industrial affairs for that CGU. Sanofi considers such decisions to have a significant influence on the generation of cash inflows for each CGU.

The reallocation of goodwill to the new CGUs triggered the performance of impairment testing, which did not indicate any requirement to recognize impairment losses. Goodwill was also tested for impairment using the previous allocation between CGUs, and no requirement to recognize impairment losses was identified on that basis either.

The allocation of goodwill as of December 31, 2016 is shown below:

<i>( million)</i>	<b>Pharmaceuticals</b>	<b>Vaccines</b>	<b>Total</b>
<b>Goodwill</b>	<b>39,005</b>	<b>1,282</b>	<b>40,287</b>

The value in use of each CGU was determined by applying an after-tax discount rate to estimated future after-tax cash flows.

A separate discount rate is used for each CGU to reflect the specific economic conditions of the CGU.

The rates used for impairment testing in 2016 were 7.6% for the Pharmaceuticals CGU and 7.7% for the Vaccines CGU; an identical value in use for Sanofi as a whole would be obtained by applying a uniform 7.6% rate to both of the CGUs.

The pre-tax discount rates applied to estimated pre-tax cash flows are calculated by iteration from the previously-determined value in use. Those pre-tax discount rates were 10.9% for the Pharmaceuticals CGU and 11.1% for the Vaccines CGU, and equate to a uniform rate of 10.9% for Sanofi as a whole.

The assumptions used in testing goodwill for impairment are reviewed annually. Apart from the discount rate, the principal assumptions used in 2016 were as follows:

- the perpetual growth rates applied to future cash flows were 0.6% for the Pharmaceuticals CGU and 1.5% for the Vaccines CGU;
- Sanofi also applies assumptions on the probability of success of current research and development projects, and more generally on its ability to renew the product portfolio in the longer term.

Value in use (determined as described above) is compared with the carrying amount, and this comparison is then subjected to sensitivity analyses with reference to the principal parameters, including:

- changes in the discount rate;
- changes in the perpetual growth rate;
- fluctuations in operating margin.

No impairment of goodwill would need to be recognized in the event of a reasonable change in the assumptions used in 2016.

A value in use calculation for each of the CGUs would not result in an impairment loss using:

- a discount rate up to 3.5 percentage points above the rates actually used; or
- a perpetual growth rate up to 4.3 percentage points below the rates actually used; or
- an operating margin up to 8.9 percentage points below the rates actually used.

No impairment losses were recognized against goodwill in the years ended December 31, 2016, 2015 or 2014.

#### **Other intangible assets**

When there is evidence that an asset may have become impaired, the asset's value in use is calculated by applying an after-tax discount rate to the estimated future after-tax cash flows from that asset. For the purposes of impairment testing, the tax cash flows relating to the asset are determined using a notional tax rate incorporating the notional tax benefit that would result from amortizing the asset if its value in use were regarded as its depreciable amount for tax purposes. Applying after-tax discount rates to after-tax cash flows gives the same values in use as would be obtained by applying pre-tax discount rates to pre-tax cash flows.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The after-tax discount rates used in 2016 for impairment testing of other intangible assets in the Pharmaceuticals and Vaccines CGUs were obtained by adjusting Sanofi's weighted average cost of capital to reflect specific country and business risks, giving after-tax rates in a range from 6% to 10.5%.

In most instances, there are no market data that would enable fair value less costs to sell to be determined other than by means of a similar estimate based on future cash flows. Consequently, the recoverable amount is in substance equal to the value in use.

In 2016, impairment testing of other intangible assets (excluding software) resulted in the recognition of a 192 million net impairment loss, comprising 58 million on research and development projects in the Pharmaceuticals and Vaccines segments and 134 million on rights for a number of marketed products in the Pharmaceuticals segment.

In 2015, impairment testing of other intangible assets (excluding software) resulted in the recognition of a 767 million net impairment loss, comprising:

- 340 million on research and development projects in the Pharmaceuticals and Vaccines segments, in particular (i) Synvisc-One® in osteoarthritis of the hip and (ii) the rotavirus vaccine project (Shantha); and

- 427 million on rights for a number of marketed products in the Pharmaceuticals segment, in particular (i) Afrezza® in the United States following termination of the license and collaboration agreement with MannKind Corporation and (ii) Auvi-Q®/Allerject® in the United States and Canada following the voluntary recall of the product.

The amount of net impairment losses reclassified to *Net income/(loss) of the held-for-exchange Animal Health business* for the year ended December 31, 2015 was 3 million.

In 2014, impairment testing of other intangible assets (excluding software) resulted in a net reversal of 31 million of impairment losses, mainly comprising:

- the partial reversal (amounting to 356 million) of the impairment loss recognized in 2013 on Lemtrada®, following FDA approval of the product in the United States in November 2014;

- a net impairment loss of 203 million arising from various research projects in the Pharmaceuticals and Vaccines segments, (i) following the discontinuation of development programs, in particular collaborations in anti-infectives with Alopexx (SAR 279 356) and Kalobios (KB001-A) and (ii) on the basis of revised commercial prospects, in particular on the rotavirus vaccine project (Shantha); and

## Edgar Filing: Sanofi - Form 20-F

impairment losses of 123 million taken against rights for a number of marketed products in the Pharmaceuticals and Vaccines segments (mainly Consumer Healthcare assets in the Emerging Markets region).  
The amount of net impairment losses reclassified to *Net income/(loss) of the held-for-exchange Animal Health business* for the year ended December 31, 2014 was 4 million.

### Property, plant and equipment

Impairment losses taken against property, plant and equipment are disclosed in Note D.3.

## D.6. INVESTMENTS IN ASSOCIATES AND JOINT VENTURES

For definitions of the terms associate and joint venture, refer to Note B.1.

Investments in associates and joint ventures comprise:

( million)	%	2016	2015	2014
Regeneron Pharmaceuticals, Inc. <sup>(a)</sup>	interest 22.1	2,548	2,245	1,942
Onduo LLC	50.0	181	-	-
Sanofi Pasteur MSD <sup>(b)/(c)</sup>	-	-	252	261
Infraserv GmbH & Co. Höchst KG <sup>(b)</sup>	31.2	79	85	90
Entities and companies managed by Bristol-Myers Squibb <sup>(d)</sup>	49.9	44	43	42
Other investments	-	38	51	49
<b>Total</b>		<b>2,890</b>	<b>2,676</b>	<b>2,384</b>

(a) See Note D.1.1.

(b) Joint ventures.

(c) See Notes B.1. and D.1.2.

(d) Under the terms of the agreements with BMS (see Note C.2.), Sanofi's share of the net assets of entities majority-owned by BMS is recorded in *Investments in associates and joint ventures*.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

With effect from the start of April 2014, the investment in Regeneron Pharmaceuticals Inc. is accounted for by the equity method (see Note D.1.).

On March 8, 2016, Sanofi Pasteur and MSD (known as Merck in the United States and Canada) announced their intention to end their Sanofi Pasteur MSD (SPMSD) joint

venture in order to pursue their own distinct growth strategies in Europe. The transaction closed on December 31, 2016 (see Notes B.1. and D.1.2.). Following the announcement, Sanofi's interest in SPMSD was reclassified to the line item *Assets held for sale or exchange*.

The table below shows Sanofi's overall share of (i) the profit or loss and (ii) other comprehensive income of associates and joint ventures, showing the split between associates and joint ventures according to IFRS 12 (the amounts for each individual associate or joint venture are not material):

	2016		2015		2014	
	Joint ventures	Associates	Joint ventures	Associates	Joint ventures	Associates
( million)						
Share of profit/(loss) of associates and joint ventures <sup>(a)/(b)</sup>	29	105	27	(49)	48	(100)
Share of other comprehensive income of associates and joint ventures	(3)	58	1	235	(5)	179
<b>Total</b>	<b>26</b>	<b>163</b>	<b>28</b>	<b>186</b>	<b>43</b>	<b>79</b>

(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (see Notes D.2. and D.36.).

(b) The SPMSD joint venture ceased to be accounted for by the equity method on March 8, 2016, the date on which it was announced that the joint venture was to be dissolved (see Notes B.1. and D.1.2.).

The financial statements include commercial transactions contracted on normal market terms, between Sanofi and some associates and joint ventures that are classified as related parties. The principal transactions and balances with related parties (including Regeneron with effect from the start of April 2014) are summarized below:

( million)	2016	2015	2014
Sales <sup>(a)</sup>	39	218	210
Royalties and other income <sup>(a)</sup>	156	91	25
Accounts receivable	101	81	57
Purchases and other expenses (including research expenses) <sup>(a)</sup>	708	762	613
Accounts payable	161	196	216

Other liabilities	65	10	9
-------------------	----	----	---

(a) For the year ended December 31, 2016, these items include transactions between Sanofi and SPMSD during the period from January 1 through March 8, 2016 (the date of the announcement that the joint venture was to be dissolved; see Notes B.1. and D.1.2.).

Funding commitments to associates and joint ventures amounted to 12 million as of December 31, 2016, most of which related to joint ventures.

For off balance sheet commitments of an operational nature involving joint ventures, see Note D.21.1.

## Regeneron

Key items from the consolidated financial statements of Regeneron, after adjustments to comply with IFRS but before fair value remeasurements, are set forth below:

( million)	2016	2015	2014 <sup>(a)</sup>
Net sales and other revenues	4,393	3,698	1,659
Net income/(loss) for the period	714	232	(149)
Other comprehensive income for the period, net of taxes	(19)	(39)	37
Comprehensive income/(loss)	695	193	(112)

(a) From April 1 to December 31, 2014.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

( million)	December 31, 2016	December 31, 2015	December 31, 2014
Current assets	3,001	2,704	1,748
Non-current assets	4,304	4,529	2,727
<b>Total assets</b>	<b>7,305</b>	<b>7,233</b>	<b>4,475</b>
Current liabilities	1,178	745	543
Non-current liabilities	1,218	1,903	1,348
<b>Total liabilities</b>	<b>2,396</b>	<b>2,648</b>	<b>1,891</b>
<b>Consolidated shareholders' equity of Regeneron</b>	<b>4,909</b>	<b>4,585</b>	<b>2,584</b>

The table below shows a reconciliation to the carrying amount of the investment:

( million)	December 31, 2016	December 31, 2015	December 31, 2014
% interest	22%	22%	22%
Share of equity attributable to Sanofi	1,084	1,012	577
Goodwill	835	779	667
Fair value remeasurements of assets and liabilities at the acquisition date	1,065	1,039	975
Other items <sup>(a)</sup>	(436)	(585)	(277)
Carrying amount of the investment in Regeneron	2,548	2,245	1,942

(a) Primarily Sanofi's share of the accumulated profits and losses and other changes in the net assets of Regeneron for the periods prior to first-time application of the equity method, and thereafter (i) Sanofi's share of stock-option expense recognized against equity in the books of Regeneron, (ii) Sanofi's share of deferred taxes on stock options recognized against equity in the books of Regeneron in accordance with IAS 12 paragraph 68C and (iii) the effects of the elimination of internal profits between Sanofi and Regeneron.

As of December 31, 2016, the market value of Sanofi's investment in Regeneron was 8,159 million (based on a quoted stock market price of \$367.09 per share as of that date), versus 11,523 million as of December 31, 2015 (based on a quoted stock market price of \$542.87 per share). As of December 31, 2014, the market value of the investment was 7,724 million (based on a quoted stock market price of \$410.25 per share); that amount was recognized as an available-for-sale financial asset.

Under the terms of the investment agreement signed at the start of 2014, Sanofi is required to compute the level of its ownership interest in Regeneron on a quarterly basis, and to maintain that interest at the highest level in order to retain a designee on the Regeneron Board of Directors. Once Sanofi's ownership interest passes 25%, the minimum interest requirement is fixed at 25%.

**D.7. OTHER NON-CURRENT ASSETS**

**Other non-current assets comprise:**

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Available-for-sale financial assets	1,583	1,609	1,361
Pre-funded pension obligations (Note D.19.1.)	30	49	59
Long-term loans and advances and other non-current receivables	776	671	711
Financial assets recognized under the fair value option	329	276	225
Derivative financial instruments (Note D.20.)	102	120	219
<b>Total</b>	<b>2,820</b>	<b>2,725</b>	<b>2,575</b>

**F- 43**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Available-for-sale financial assets****Quoted equity securities**

Equity interests classified as available-for-sale financial assets include the following publicly traded investments:

- An equity investment in Alnylam Pharmaceuticals, Inc. (Alnylam), acquired at the start of 2014. On October 5, 2016, Alnylam announced that it was terminating its revusiran development program, as a result of which its share price fell by 48% on October 6, 2016. Consequently, Sanofi has recognized an impairment loss reflecting the difference between the historical acquisition cost of its shares in Alnylam and the market value of those shares as of December 31, 2016. That impairment loss amounted to 457 million as of December 31, 2016. Based on the quoted market price, Sanofi's equity interest was valued at 364 million as of December 31, 2016 (versus 869 million as of December 31, 2015 and 728 million as of December 31, 2014).
  - An equity investment in Voyager Therapeutics, Inc. carried out under the February 2015 collaboration agreement with that company, valued at 30 million as of December 31, 2016 and representing an equity interest of approximately 9% as of that date (versus 50 million as of December 31, 2015, also for an equity interest of approximately 9%).
  - An equity injection into JHL Biotech, Inc. carried out under a collaboration agreement with that company dated December 5, 2016, valued at 58 million as of December 31, 2016, and representing an equity interest of approximately 13% as of that date;
  - Financial assets held to meet obligations under post-employment benefit plans, totaling 372 million as of December 31, 2016 (versus 353 million as of December 31, 2015 and 347 million as of December 31, 2014).
- Sanofi's investment in Regeneron Pharmaceuticals Inc. is included in *Investments in associates and joint ventures* with effect from April 2014 (see Notes D.1. and D.6.).

Sanofi's equity interest in Nichi-Iko Pharmaceuticals Co. Ltd. was divested in full during 2016. The carrying amount of that investment in the balance sheet was 63 million as of December 31, 2015 and 37 million as of December 31, 2014.

Sanofi's equity interest in Merrimack Pharmaceuticals, Inc. was divested in full during 2015. The carrying amount of that investment in the balance sheet was 49 million as of December 31, 2014.

**Unquoted equity investments**

Available-for-sale financial assets also include equity investments not quoted in an active market. The carrying amount of those investments was 112 million as of December 31, 2016, 102 million as of December 31, 2015 and 79 million as of December 31, 2014.

**Other available-for-sale financial assets**

## Edgar Filing: Sanofi - Form 20-F

In connection with the dissolution of the Sanofi Pasteur MSD (SPMSD) joint venture, Sanofi Pasteur has recognized an available-for-sale financial asset of \$458 million for contingent consideration receivable by Sanofi Pasteur based on a percentage of MSD's future sales during the 2017-2024 period of specified products previously distributed by SPMSD (see Notes B.1. and D.1.2). The fair value of the contingent consideration was determined by applying the royalty percentage stipulated in the contract to discounted sales projections. A reduction of one percentage point in the discount rate would increase the contingent consideration asset by approximately 4%.

A 10% decline in stock prices of quoted equity investments classified as available-for-sale financial assets would have had the following impact as of December 31, 2016:

<i>( million)</i>	<b>Sensitivity</b>
Other comprehensive income before tax	(17)
Income before tax	(38)
<b>Total</b>	<b>(55)</b>

A 10% decline in the quoted market prices of Sanofi's other available-for-sale financial assets combined with a simultaneous 0.5% rise in the yield curve would have had the following impact as of December 31, 2016:

<i>( million)</i>	<b>Sensitivity</b>
Other comprehensive income before tax	(16)
Income before tax	-
<b>Total<sup>(a)</sup></b>	<b>(16)</b>

(a) Represents approximately 4.8% of the value of the assets involved.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Other disclosures about available-for-sale financial assets**

Other comprehensive income recognized in respect of available-for-sale financial assets represented unrealized gains (net of taxes) amounting to 158 million as of December 31, 2016 (including an immaterial amount relating to the Animal Health business); 213 million as of December 31, 2015; and 234 million as of December 31, 2014.

**Long-term loans, advances and other non-current receivables**

Long-term loans, advances and other non-current receivables include tax receivables due after more than one year.

**Financial assets recognized under the fair value option**

Financial assets recognized under the fair value option represent a portfolio of financial investments held to fund a deferred compensation plan provided to certain employees.

**D.8. ASSETS HELD FOR SALE OR EXCHANGE AND LIABILITIES RELATED TO ASSETS HELD FOR SALE OR EXCHANGE**

Assets held for sale or exchange, and liabilities related to assets held for sale or exchange, comprise:

<i>( million)</i>		December 31, 2016	December 31, 2015	December 31, 2014
Animal Health business	<b>D.36.</b>	6,376	5,626	-
Other		45	126	10
<b>Assets held for sale or exchange</b>		<b>6,421</b>	<b>5,752</b>	<b>10</b>
Animal Health business	<b>D.36.</b>	1,165	983	-
Other		30	-	-
<b>Liabilities related to assets held for sale or exchange</b>		<b>1,195</b>	<b>983</b>	<b>-</b>

**D.9. INVENTORIES**

Inventories comprise the following:

<i>( million)</i>	December 31, 2016			December 31, 2015			December 31, 2014		
	Gross value	Write- down	Carrying amount	Gross value	Write- down	Carrying amount	Gross value	Write- down	Carrying amount
Raw materials	1,053	(104)	949	1,050	(90)	960	1,053	(79)	974
Work in process	4,512	(710)	3,802	4,043	(561)	3,482	4,021	(488)	3,533
Finished goods	2,341	(200)	2,141	2,282	(208)	2,074	2,258	(203)	2,055
<b>Total</b>	<b>7,906</b>	<b>(1,014)</b>	<b>6,892</b>	<b>7,375</b>	<b>(859)</b>	<b>6,516</b>	<b>7,332</b>	<b>(770)</b>	<b>6,562</b>

## Edgar Filing: Sanofi - Form 20-F

Write-downs include inventories of products on hand pending marketing approval.

Inventories pledged as security for liabilities amounted to 24 million as of December 31, 2016 (compared with 25 million as of December 31, 2015 and 46 million as of December 31, 2014).

### D.10. ACCOUNTS RECEIVABLE

An analysis of accounts receivable is set forth below:

( million)	December 31, 2016	December 31, 2015	December 31, 2014
Gross value	7,506	7,553	7,326
Allowances	(195)	(167)	(177)
<b>Carrying amount</b>	<b>7,311</b>	<b>7,386</b>	<b>7,149</b>

**F- 45**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The impact of allowances against accounts receivable in 2016 was a net expense of 32 million (versus 53 million in 2015 and 37 million in 2014).

The gross value of overdue receivables was 597 million as of December 31, 2016, versus 677 million as of December 31, 2015 and 849 million as of December 31, 2014.

<i>( million)</i>	<b>Overdue accounts</b>		<b>Overdue</b>			
	<b>gross value</b>	<b>&lt;1 month</b>	<b>1 to 3 months</b>	<b>3 to 6 months</b>	<b>6 to 12 months</b>	<b>&gt; 12 months</b>
December 31, 2016	597	133	103	121	42	198
December 31, 2015	677	171	147	117	83	159
December 31, 2014	849	277	189	126	87	170

Amounts overdue by more than one month relate mainly to public-sector customers.

Some Sanofi subsidiaries have assigned receivables to factoring companies or banks without recourse. The amount of receivables that met the conditions described in

Note B.8.7. and were therefore derecognized was 428 million as of December 31, 2016 ( 414 million as of December 31, 2015) 428 million as of December 31, 2014). The residual guarantees relating to such transfers were immaterial as of December 31, 2016.

**D.11. OTHER CURRENT ASSETS**

An analysis of other current assets is set forth below:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Taxes recoverable	1,034	1,006	1,391
Other receivables <sup>(a)</sup>	705	461	470
Prepaid expenses	333	300	296
Interest rate derivatives measured at fair value (see Note D.20.)	3	39	98
Currency derivatives measured at fair value (see Note D.20.)	105	59	111
Other current financial assets	31	13	9
<b>Total</b>	<b>2,211</b>	<b>1,878</b>	<b>2,375</b>

## Edgar Filing: Sanofi - Form 20-F

(a) This item mainly comprises advance payments to suppliers. In 2016, it additionally includes the impact of transactions which closed at the end of 2016 and for which payment was received in January 2017.

### **D.12. FINANCIAL ASSETS AND LIABILITIES MEASURED AT FAIR VALUE**

Under IFRS 7 (Financial Instruments: Disclosures), fair value measurements must be classified using a fair value hierarchy with the following levels:

- level  
1: quoted prices in active markets for identical assets and liabilities (without modification or repackaging);
- level  
2: quoted prices in active markets for similar assets and liabilities, and valuation techniques in which all important inputs are derived from observable market data;
- level  
3: valuation techniques in which not all important inputs are derived from observable market data.

The valuation techniques used are described in Note B.8.6.

**F- 46**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows the balance sheet amounts of assets and liabilities measured at fair value.

	Note	2016			2015			2014		
		Level in the fair value hierarchy			Level in the fair value hierarchy			Level in the fair value hierarchy		
( million)		Level 1	Level 2	Level 3	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<b>Financial assets measured at fair value in the balance sheet:</b>										
Quoted equity investments	D.7.	1,000	-	-	1,451	-	-	1,282	-	-
Unquoted equity investments	D.7.	-	-	112	-	-	102	-	-	79
Quoted debt securities	D.7.	13	-	-	56	-	-	-	-	-
Contingent consideration relating to divestments	D.7.	-	-	458	-	-	-	-	-	-
Financial assets recognized under the fair value option	D.7.	329	-	-	276	-	-	225	-	-
Non-current derivatives	D.7.	-	102	-	-	120	-	-	219	-
Current derivatives	D.11.	-	108	-	-	98	-	-	209	-
Mutual fund investments	D.13.	6,210	-	-	5,042	-	-	2,537	-	-
<b>Financial assets measured at fair value</b>		<b>7,552</b>	<b>210</b>	<b>570</b>	<b>6,825</b>	<b>218</b>	<b>102</b>	<b>4,044</b>	<b>428</b>	<b>79</b>
<b>Financial liabilities measured at fair value in the balance sheet:</b>										
CVRs issued in connection with the acquisition of Genzyme	D.18.	85	-	-	24	-	-	154	-	-
Bayer contingent purchase consideration arising from the acquisition of Genzyme	D.18.	-	-	1,013	-	-	1,040	-	-	896
Other contingent consideration arising from business combinations	D.18.	-	-	355	-	-	6	-	-	36
Liabilities related to non-controlling interests	D.18.	-	-	123	-	-	181	-	-	178
Non-current derivatives		-	-	-	-	3	-	-	1	-
Current derivatives	D.19.4.	-	132	-	-	82	-	-	216	-
<b>Financial liabilities measured at fair value</b>		<b>85</b>	<b>132</b>	<b>1,491</b>	<b>24</b>	<b>85</b>	<b>1,227</b>	<b>154</b>	<b>217</b>	<b>1,110</b>

No transfers between the different levels of the fair value hierarchy occurred during 2016.

In connection with the dissolution of the Sanofi Pasteur MSD (SPMSD) joint venture, which was completed on December 31, 2016, Sanofi Pasteur recognized the following items (see Notes B.1. and D.1.2.):

- a financial asset of 458 million for contingent consideration receivable by Sanofi Pasteur based on a percentage of MSD's future sales during the 2017-2024 period of specified products previously distributed by SPMSD;

- a financial liability of 354 million for contingent consideration payable to MSD based on a percentage of future sales made by Sanofi Pasteur during the 2017-2024 period of specified products previously distributed by SPMSD.

**D.13. CASH AND CASH EQUIVALENTS**

( million)	2016	2015	2014
Cash	1,077	1,361	1,843
Cash equivalents <sup>(a)</sup>	9,196	7,787	5,498
<b>Cash and cash equivalents<sup>(b)</sup></b>	<b>10,273</b>	<b>9,148</b>	<b>7,341</b>

(a) As of December 31, 2016, cash equivalents mainly comprised (i) 6,210 million invested in euro and US dollar denominated money-market mutual funds (December 31, 2015: 5,042 million; December 31, 2014: 2,537 million); (ii) 1,469 million of term deposits (December 31, 2015: 1,594 million; December 31, 2014: 1,756 million); (iii) 617 million in commercial paper (December 31, 2015: 461 million; December 31, 2014: 495 million); and (iv) 553 million held by captive insurance and reinsurance companies in accordance with insurance regulations (December 31, 2015: 385 million; December 31, 2014: 587 million).

(b) Includes an immaterial amount held by Sanofi's Venezuelan subsidiaries as of December 31, 2016 (versus 90 million as of December 31, 2015 and 242 million as of December 31, 2014); see Note A.4.

**F- 47**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.14. NET DEFERRED TAX POSITION**

An analysis of the net deferred tax position is set forth below:

( million)	2016	2015	2014
Deferred taxes on:			
Consolidation adjustments (intragroup margin in inventory)	1,095	1,074	1,205
Provision for pensions and other employee benefits	1,538	1,522	1,661
Remeasurement of other acquired intangible assets <sup>(a)</sup>	(2,797)	(3,370)	(4,095)
Recognition of acquired property, plant and equipment at fair value	(44)	(48)	(59)
Equity interests in subsidiaries and investments in other entities <sup>(b)</sup>	(818)	(833)	(906)
Tax losses available for carry-forward	1,070	1,162	738
Stock options and other share-based payments	126	131	119
Accrued expenses and provisions deductible at the time of payment <sup>(c)</sup>	2,202	2,061	1,970
Other	5	120	122
<b>Net deferred tax asset/(liability)</b>	<b>2,377</b>	<b>1,819</b>	<b>755</b>

(a) Includes the following deferred tax liabilities as of December 31, 2016: 377 million relating to the remeasurement of the other intangible assets of Aventis, and 1,870 million relating to Genzyme.

(b) In some countries, Sanofi is liable for withholding taxes and other tax charges when dividends are distributed. Consequently, Sanofi recognizes a deferred tax liability on the reserves of French and foreign subsidiaries (approximately 37.8 billion) which it regards as likely to be distributed in the foreseeable future. In determining the amount of the deferred tax liability as of December 31, 2016, Sanofi took into account changes in the ownership structure of certain subsidiaries, and the effects of changes in the taxation of dividends in France following the ruling of the Court of Justice of the European Union in the Steria case and the resulting amendments to the 2015 Finance Act.

(c) Includes deferred tax assets related to restructuring provisions, amounting to 334 million as of December 31, 2016, 394 million as of December 31, 2015, and 405 million as of December 31, 2014.

The reserves of Sanofi subsidiaries that would be taxable if distributed but for which no distribution is planned, and for which no deferred tax liability has therefore been recognized, totaled 25.2 billion as of December 31, 2016, compared with 23.9 billion as of December 31, 2015 and 20.1 billion as of December 31, 2014.

Most of Sanofi's tax loss carry-forwards are available indefinitely. For a description of policies on the recognition of deferred tax assets, refer to Note B.22. The recognition of

deferred tax assets is determined on the basis of profit forecasts for each tax group, and of the tax consequences of the strategic opportunities available to Sanofi. Those forecasts are consistent with Sanofi's medium-term strategic plan, and are based on time horizons that take account of the period of availability of tax loss carry-forwards and the specific circumstances of each tax group. Deferred tax assets relating to tax loss carry-forwards as of December 31, 2016 totaled 1,501 million, of which 431 million were not recognized.

## Edgar Filing: Sanofi - Form 20-F

The table below shows when tax losses available for carry-forward are due to expire:

( million)	<b>Tax losses available for carry-forward<sup>(a)</sup></b>
2017	36
2018	40
2019	19
2020	25
2021	71
2022 and later	4,985
<b>Total as of December 31, 2016</b>	<b>5,176</b>
<b>Total as of December 31, 2015</b>	<b>5,209<sup>(b)</sup></b>
<b>Total as of December 31, 2014</b>	<b>3,753<sup>(c)</sup></b>

(a) Excluding tax loss carry-forwards on asset disposals. Such carry-forwards amounted to 13 million as of December 31, 2016; and zero as of December 31, 2015 and December 31, 2014.

(b) Deferred tax assets relating to tax loss carry-forwards as of December 31, 2015 amounted to 1,721 million, of which 559 million were not recognized.

(c) Deferred tax assets relating to tax loss carry-forwards as of December 31, 2014 amounted to 1,237 million, of which 499 million were not recognized.

**F- 48**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Use of tax loss carry-forwards is limited to the entity in which they arose. In jurisdictions where tax consolidations are in place, tax losses can be netted against taxable income generated by entities in the same tax group.

Deferred tax assets not recognized because their future recovery was not regarded as probable given the expected results of the entities in question amounted to 561 million in 2016, 666 million in 2015 and 586 million in 2014.

**D.15. CONSOLIDATED SHAREHOLDERS EQUITY****D.15.1. Share capital**

As of December 31, 2016, the share capital was 2,584,044,648, consisting of 1,292,022,324 shares with a par value of 2. Treasury shares held by Sanofi are as follows:

	Number of shares (million)	% of share capital for the period
December 31, 2016	20.0	1.55%
December 31, 2015	4.0	0.30%
December 31, 2014	9.5	0.72%
January 1, 2014	3.6	0.27%

Treasury shares are deducted from shareholders' equity. Gains and losses on disposals of treasury shares are recorded directly in equity and are not recognized in net income for the period.

Movements in the share capital of the Sanofi parent company over the last three years are set forth below:

Date	Transaction	Number of shares	Share capital <sup>(a)</sup>	Additional paid-in capital <sup>(a)</sup>
<b>December 31, 2013</b>		<b>1,324,320,881</b>	<b>2,649</b>	<b>6,274</b>
During 2014	Capital increase by exercise of stock subscription options	10,974,771	22	658
During 2014	Capital increase by issuance of restricted shares	1,856,847	4	(4)

Edgar Filing: Sanofi - Form 20-F

Board meeting of April 28, 2014	Reduction in share capital by cancellation of treasury shares	(8,136,828)	(16)	(588)
Board meeting of October 27, 2014	Reduction in share capital by cancellation of treasury shares	(9,648,226)	(20)	(726)
<b>December 31, 2014</b>		<b>1,319,367,445</b>	<b>2,639</b>	<b>5,614</b>
During 2015	Capital increase by exercise of stock subscription options	9,000,127	18	555
During 2015	Capital increase by issuance of restricted shares	3,071,173	6	(6)
Board meeting of April 29, 2015	Reduction in share capital by cancellation of treasury shares	(18,482,786)	(37)	(1,454)
Board meeting of October 28, 2015	Reduction in share capital by cancellation of treasury shares	(7,259,200)	(15)	(670)
<b>December 31, 2015</b>		<b>1,305,696,759</b>	<b>2,611</b>	<b>4,039</b>
During 2016	Capital increase by exercise of stock subscription options	3,418,421	7	212
During 2016	Capital increase by issuance of restricted shares	3,664,248	7	(7)
Board meeting of April 28, 2016	Reduction in share capital by cancellation of treasury shares	(22,561,090)	(45)	(1,655)
Board meeting of July 22, 2016	Capital increase by exercise of stock subscription options	1,803,986	4	96
<b>December 31, 2016</b>		<b>1,292,022,324</b>	<b>2,584</b>	<b>2,685</b>

(a) Amounts expressed in millions of euros.

F- 49

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

For the disclosures about the management of capital required under IFRS 7, refer to Note B.27.

A total of 3,418,421 shares were issued in 2016 as a result of the exercise of Sanofi stock subscription options.

In addition, a total of 3,664,248 shares vested and were issued in 2016 under restricted share plans.

**15.2. Restricted share plans**

Restricted share plans are accounted for in accordance with the policies described in Note B.24.3. The principal characteristics of those plans are as follows:

Type of plan	2016	2015	2014
	Performance share plan	Performance share plan	Performance share plan
Date of Board meeting approving the plan	May 4, 2016	June 24, 2015	March 5, 2014
Total number of shares awarded	4,097,925	3,832,840	3,908,135
Of which plans subject to a 4-year service period	-	2,546,420	2,605,515
Fair value per share awarded <sup>(a)</sup>	-	79.52	59.68
Of which plans subject to a 3-year service period	4,097,925	1,286,420	1,302,620
Fair value per share awarded <sup>(a)</sup>	61.06	82.96	63.26
<b>Fair value of plan at the date of grant ( million)</b>	<b>250</b>	<b>309</b>	<b>238</b>

(a) Quoted market price per share at the date of grant, adjusted for dividends expected during the vesting period.

The total expense recognized for all restricted share plans (excluding Animal Health) in the year ended December 31, 2016 was 219 million (including 26 million for the Vaccines segment), compared with 187 million in the year ended December 31, 2015 and 177 million in the year ended December 31, 2014.

The number of restricted shares not yet fully vested as of December 31, 2016 was 13,543,254, comprising 4,051,325 under the 2016 plans; 3,667,620 under the 2015 plans; 3,595,420 under the 2014 plans; and 2,228,889 under the 2013 plans.

The number of restricted shares not yet fully vested was 14,076,259 as of December 31, 2015 and 14,025,905 as of December 31, 2014.

On March 5, 2014, the Board of Directors approved a performance share unit (PSU) plan, vesting at the end of a three-year service period and subject to performance conditions.

## Edgar Filing: Sanofi - Form 20-F

Because PSUs are cash-settled instruments, they are measured at the grant date, at the end of each reporting period, and at the settlement date. The fair value is determined on the basis of the quoted market price per share as of the measurement date, adjusted for expected dividends during the vesting period.

The fair value of the PSU plan (based on vested rights and inclusive of social security charges) as of December 31, 2016, and recognized as a liability as of that date, was 27 million.

### **D.15.3. Capital increases**

On March 3, 2016, the Sanofi Board of Directors approved an employee share ownership plan in the form of a capital increase reserved for employees. Employees were offered the opportunity to subscribe to the capital increase at a price of 57.25 per share, representing 80% of the average of the quoted market prices of Sanofi shares during the 20 trading days preceding June 8, 2016.

The subscription period was open from June 13 through June 24, 2016. The plan resulted in a total of 1,756,972 shares being subscribed for, and the issuance of a further 47,014 shares as an employer's contribution under the terms of the plan.

An expense of 16 million (excluding Animal Health) was recognized for this plan in the year ended December 31, 2016, of which 3 million was for the employer's contribution.

There were no capital increases reserved for employees in either 2015 or 2014.

### **D.15.4. Repurchase of Sanofi shares**

On May 4, 2016, the Annual General Meeting of Sanofi shareholders approved a share repurchase program for a period of 18 months. Under that program (and that program alone), Sanofi repurchased 19,947,202 of its own shares during 2016 for a total amount of 1,503 million.

On May 4, 2015, the Annual General Meeting of Sanofi shareholders approved a share repurchase program for a period of 18 months. Under that program (and that program

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

alone), Sanofi repurchased 18,764,233 of its own shares during 2016 for a total amount of 1,402 million, and 6,527,368 shares during 2015 for a total amount of 551 million.

On May 5, 2014, the Annual General Meeting of Sanofi shareholders approved a share repurchase program for a period of 18 months. Under that program (and that program alone), Sanofi repurchased 13,748,572 of its own shares during 2015 for a total amount of 1,230 million, and

15,662,113 shares during 2014 for a total amount of 1,201 million.

**D.15.5. Reductions in share capital**

Reductions in share capital for the accounting periods presented are described in the table included at Note D.15.1. above. Those reductions have no impact on shareholders' equity.

**D.15.6. Currency translation differences**

Currency translation differences comprise the following:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Attributable to equity holders of Sanofi	1,787	701	(1,211)
Attributable to non-controlling interests	(18)	(22)	(28)
<b>Total</b>	<b>1,769</b>	<b>679</b>	<b>(1,239)</b>

The balance as of December 31, 2016 includes an after-tax amount of 66 million relating to hedges of net investments in foreign operations (refer to Note B.8.4. for a description of the relevant accounting policy), compared with 66 million as of December 31, 2015 and 72 million as of December 31, 2014.

That balance also includes 144 million of currency translation differences relating to the Animal Health

business, presented in *Assets held for sale or exchange* and *Liabilities related to assets held for sale or exchange* as of December 31, 2016 (versus 195 million as of December 31, 2015).

The movement in *Currency translation differences* is mainly attributable to the US dollar.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.15.7. Other comprehensive income**

Movements within other comprehensive income are shown below:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Balance, beginning of period</b>	<b>45</b>	<b>(2,315)</b>	<b>(1,745)</b>
<i>Attributable to equity holders of Sanofi</i>	67	(2,287)	(1,707)
<i>Attributable to non-controlling interests</i>	(22)	(28)	(38)
Actuarial gains/(losses):			
· Actuarial gains/(losses) excluding associates and joint ventures (see Note D.19.1.)	(104)	650	(863)
· Actuarial gains/(losses) of associates and joint ventures, net of taxes	(2)	2	(6)
· Tax effects <sup>(a)</sup>	(22)	(187)	303
<b>Items not subsequently reclassifiable to profit or loss<sup>(b)</sup></b>	<b>(128)</b>	<b>465</b>	<b>(566)</b>
Available-for-sale financial assets:			
· Change in fair value (excluding associates and joint ventures) <sup>(c)(d)</sup>	(104)	(29)	(2,768)
· Change in fair value (associates and joint ventures, net of taxes)	(1)	(8)	8
· Tax effects	50	16	250
Cash flow hedges:			
· Change in fair value (excluding associates and joint ventures) <sup>(e)</sup>	30	(3)	-
· Change in fair value (associates and joint ventures, net of taxes)	1	-	-
· Tax effects	(10)	1	-
Change in currency translation differences:			
· Currency translation differences on foreign subsidiaries (excluding associates and joint ventures) <sup>(e)</sup>	1,033	1,681	2,334
· Currency translation differences (associates and joint ventures)	57	243	172
· Hedges of net investments in foreign operations	-	(9)	-
· Tax effects	-	3	-
<b>Items subsequently reclassifiable to profit or loss<sup>(f)</sup></b>	<b>1,056</b>	<b>1,895</b>	<b>(4)</b>
<b>Balance, end of period</b>	<b>973</b>	<b>45</b>	<b>(2,315)</b>
<i>Attributable to equity holders of Sanofi</i>	992	67	(2,287)
<i>Attributable to non-controlling interests</i>	(19)	(22)	(28)

(a) Includes in 2016 (37) million related to changes in tax rates.

(b) Items not subsequently reclassifiable to profit or loss and attributable to the Animal Health business: (3) million in 2016, (6) million in 2015 and 4 million in 2014.

(c) Includes reclassifications to profit or loss: 447 million in 2016, (35) million in 2015 and (79) million in 2014.

(d) The movements in 2014 relate mainly to Regeneron.

## Edgar Filing: Sanofi - Form 20-F

(e) Includes 2 million reclassified to profit or loss in 2016 and (3) million in 2015; the amounts reclassified in 2014 were immaterial.

(f) Items subsequently reclassifiable to profit or loss and attributable to the Animal Health business: (51) million in 2016 (currency translation differences); 92 million in 2015 (currency translation differences); and 169 million in 2014 ( 168 million of currency translation differences, 1 million of changes in fair value).

**F- 52**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.15.8. Stock options****Stock option plans awarded**

On May 4, 2016, the Board of Directors granted 402,750 stock subscription options at an exercise price of \$75.90 per share. The vesting period is four years, and the plan expires on May 4, 2026.

On June 24, 2015, the Board of Directors granted 435,000 stock subscription options at an exercise price of \$89.38 per share. The vesting period is four years, and the plan expires on June 24, 2025.

On March 5, 2014, the Board of Directors granted 1,009,250 stock subscription options at an exercise price of \$73.48 per share. The vesting period is four years, and the plan expires on March 5, 2024.

**Measurement of stock option plans**

The fair value of the stock subscription option plan awarded in 2016 is \$3 million. That amount is recognized as an expense over the vesting period, with the opposite entry recognized directly in equity. On that basis, an expense of \$0.4 million was recognized in the year ended December 31, 2016.

The fair value of the stock subscription option plan awarded in 2015 is \$7 million.

Sanofi used the following assumptions in determining the fair value of the plans:

- dividend yield: 4.51% (2016 plan), 3.64% (2015 plan);
- volatility of Sanofi shares, computed on a historical basis: 24.54% (2016 plan), 27.52% (2015 plan);
- risk-free interest rate: 0.056% (2016 plan), 0.65% (2015 plan); and
- plan maturity: 7 years (2016 and 2015 plans). The plan maturity is the average expected remaining life of the options, based on observations of historical employee behavior.

Fair values per option awarded are \$6.60, 16.12 and 12.61 for the 2016, 2015 and 2014 plans, respectively.

The expense recognized for stock option plans, and the amounts recognized in equity, are \$6 million for 2016; 6 million for 2015; and 15 million for 2014 (including \$0.3 million for the Vaccines segment).

As of December 31, 2016, the total unrecognized cost of unvested stock options was \$9 million (compared with 12 million as of December 31, 2015 and 12 million as of December 31, 2014), to be recognized over a weighted average period of two years. The current tax benefit related to the exercise of stock options in 2016 was \$2 million (versus 12 million in 2015 and 15 million in 2014).

**Stock purchase option plans**

The table shows all Sanofi stock purchase option plans still outstanding or under which options were exercised in the year ended December 31, 2016.

Source	Date of grant	Number of options granted	Start date of exercise period	Expiry date	Exercise price ( )	Number of options outstanding as of December 31, 2016
Synthélabo	01/12/1996	208,000	01/12/2001	01/12/2016	8.56	-
Synthélabo	04/05/1996	228,800	04/05/2001	04/05/2016	10.85	-
Synthélabo	03/30/1999	716,040	03/31/2004	03/30/2019	38.08	136,843
<b>Total</b>						<b>136,843</b>

Sanofi shares acquired to cover stock purchase option plans are deducted from shareholders' equity. The exercise of all outstanding stock purchase options would increase shareholders' equity by 5 million.

**Stock subscription option plans**

Details of the terms of exercise of stock subscription options granted under the various plans are presented below in Sanofi share equivalents. These plans were awarded to certain corporate officers and employees of Sanofi companies.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table shows all Sanofi stock subscription option plans still outstanding or under which options were exercised in the year ended December 31, 2016.

Source	Date of grant	Number of options granted	Start date of exercise period	Expiry date	Exercise price ( )	Number of options outstanding as of December 31, 2016
Sanofi-aventis	12/14/2006	11,772,050	12/15/2010	12/14/2016	66.91	-
Sanofi-aventis	12/13/2007	11,988,975	12/14/2011	12/13/2017	62.33	3,186,133
Sanofi-aventis	03/02/2009	7,736,480	03/04/2013	03/01/2019	45.09	2,019,542
Sanofi-aventis	03/01/2010	8,121,355	03/03/2014	02/28/2020	54.12	3,159,714
Sanofi-aventis	03/09/2011	874,500	03/10/2015	03/09/2021	50.48	516,012
Sanofi	03/05/2012	814,050	03/06/2016	03/05/2022	56.44	628,659
Sanofi	03/05/2013	788,725	03/06/2017	03/05/2023	72.19	635,274
Sanofi	03/05/2014	1,009,250	03/06/2018	03/05/2024	73.48	947,875
Sanofi	06/24/2015	435,000	06/25/2019	06/24/2025	89.38	433,500
Sanofi	05/04/2016	402,750	05/05/2020	05/04/2026	75.90	402,250
<b>Total</b>						<b>11,928,959</b>

The exercise of all outstanding stock subscription options would increase shareholders equity by approximately 707 million. The exercise of each option results in the issuance of one share.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Summary of stock option plans**

A summary of stock options outstanding at each balance sheet date, and of changes during the relevant periods, is presented below:

	Number of options	Weighted average exercise price per share ( )	Total ( million)
<b>Options outstanding at January 1, 2014</b>	<b>35,708,847</b>	<b>61.01</b>	<b>2,179</b>
<i>Options exercisable</i>	25,813,742	63.15	1,630
Options granted	1,009,250	73.48	74
Options exercised	(11,001,611)	61.84	(681)
Options cancelled <sup>(a)</sup>	(114,230)	60.66	(7)
Options forfeited	-	-	-
<b>Options outstanding at December 31, 2014</b>	<b>25,602,256</b>	<b>61.14</b>	<b>1,565</b>
<i>Options exercisable</i>	22,225,731	60.79	1,351
Options granted	435,000	89.38	39
Options exercised	(9,033,607)	63.50	(573)
Options cancelled <sup>(a)</sup>	(179,634)	60.04	(11)
Options forfeited	(956,400)	70.38	(67)
<b>Options outstanding at December 31, 2015</b>	<b>15,867,615</b>	<b>60.03</b>	<b>953</b>
<i>Options exercisable</i>	13,028,045	57.56	750
Options granted	402,750	75.90	31
Options exercised	(3,441,429)	63.83	(220)
Options cancelled <sup>(a)</sup>	(161,863)	68.09	(11)
Options forfeited	(601,271)	67.00	(40)
<b>Options outstanding at December 31, 2016</b>	<b>12,065,802</b>	<b>59.03</b>	<b>713</b>
<i>Options exercisable</i>	9,646,903	54.67	527

(a) Mainly due to the grantees leaving Sanofi.

The table below provides summary information about options outstanding and exercisable as of December 31, 2016:

	Outstanding		Exercisable		
	Number of options	Average residual life (years)	Weighted average exercise price per share ( )	Number of options	Weighted average exercise price per share ( )
<i>Range of exercise prices per share</i>					
From 30.00 to 40.00 per share	136,843	2.24	38.08	136,843	38.08
From 40.00 to 50.00 per share	2,019,542	2.16	45.09	2,019,542	45.09
From 50.00 to 60.00 per share	4,304,385	3.58	54.02	4,304,385	54.02

Edgar Filing: Sanofi - Form 20-F

From 60.00 to 70.00 per share	3,186,133	0.95	62.33	3,186,133	62.33
From 70.00 to 80.00 per share	1,985,399	7.30	73.56	-	-
From 80.00 to 90.00 per share	433,500	8.48	89.38	-	-
<b>Total</b>	<b>12,065,802</b>			<b>9,646,903</b>	

F- 55

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.15.9. Number of shares used to compute diluted earnings per share**

Diluted earnings per share is computed using the number of shares outstanding plus stock options with dilutive effect and restricted shares.

<i>(million)</i>	2016	2015	2014
Average number of shares outstanding	1,286.6	1,306.2	1,315.8
Adjustment for stock options with dilutive effect	2.6	6.0	6.3
Adjustment for restricted shares	6.8	8.5	9.0
<b>Average number of shares outstanding used to compute diluted earnings per share</b>	<b>1,296.0</b>	<b>1,320.7</b>	<b>1,331.1</b>

In 2016, 2.4 million stock options were not taken into account in calculating diluted earnings per share because they had no dilutive effect, compared with 0.4 million in 2015 and 1.7 million in 2014.

**D.16. NON-CONTROLLING INTERESTS**

Non-controlling interests did not represent a material component of Sanofi's consolidated financial statements in the years ended December 31, 2016, 2015 and 2014.

**D.17. DEBT, CASH AND CASH EQUIVALENTS**

Changes in financial position during the period were as follows:

<i>( million)</i>	2016	2015	2014
Long-term debt	16,815	13,118	13,276
Short-term debt and current portion of long-term debt	1,764	3,436	1,538
Interest rate and currency derivatives used to hedge debt	(100)	(156)	(295)
<b>Total debt</b>	<b>18,479</b>	<b>16,398</b>	<b>14,519</b>
Cash and cash equivalents	(10,273)	(9,148)	(7,341)
Interest rate and currency derivatives used to hedge cash and cash equivalents	-	4	(7)
<b>Debt, net of cash and cash equivalents</b>	<b>8,206</b>	<b>7,254</b>	<b>7,171</b>

Debt, net of cash and cash equivalents is a financial indicator used by management and investors to measure Sanofi's overall net indebtedness.

**Reconciliation of carrying amount to value on redemption**

<i>( million)</i>	Carrying amount at December 31, 2016	Amortized cost	Adjustment to debt measured at fair value	Value on redemption		
				December 31, 2016	December 31, 2015	December 31, 2014
Long-term debt	16,815	79	(129)	16,765	13,023	13,125
Short-term debt and current portion of long-term debt	1,764	-	-	1,764	3,422	1,536

Edgar Filing: Sanofi - Form 20-F

Interest rate and currency derivatives used to hedge debt	(100)	-	90	(10)	(35)	(121)
<b>Total debt</b>	<b>18,479</b>	<b>79</b>	<b>(39)</b>	<b>18,519</b>	<b>16,410</b>	<b>14,540</b>
Cash and cash equivalents	(10,273)	-	-	(10,273)	(9,148)	(7,341)
Interest rate and currency derivatives used to hedge cash and cash equivalents	-	-	-	-	4	(7)
<b>Debt, net of cash and cash equivalents</b>	<b>8,206</b>	<b>79</b>	<b>(39)</b>	<b>8,246</b>	<b>7,266</b>	<b>7,192</b>

F- 56

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**a) Principal financing transactions during the year**

Sanofi carried out two bond issues in 2016. In April 2016, a 1.8 billion issue was carried out in three tranches:

- 500 million of bonds maturing April 2019, bearing interest at an annual rate of 0%;
  - 600 million of bonds maturing April 2024, bearing interest at an annual rate of 0.625%;
  - 700 million of bonds maturing April 2028, bearing interest at an annual rate of 1.125%.
- In September 2016, a 3 billion bond issue was carried out in three tranches:

- 1 billion of bonds maturing January 2020, bearing interest at an annual rate of 0%;
- 850 million of bonds maturing September 2022, bearing interest at an annual rate of 0%;
- 1.15 billion of bonds maturing January 2027, bearing interest at an annual rate of 0.5%.

The above bond issues were carried out under an EMTN public bond issue program.

Two bond issues were redeemed on maturity:

- the March 2011 fixed-rate bond issue of \$1.5 billion that matured on March 29, 2016;
- the May 2009 fixed-rate bond issue of 1.5 billion that matured on May 18, 2016.

Sanofi also had two syndicated credit facilities of 4 billion each in place as of December 31, 2016 in order to manage its liquidity in connection with current operations. One of those facilities has been extended to December 3, 2021 following the exercise of a second extension option in November 2016. The other facility expires on December 17, 2020. Sanofi has no further extension options for its credit facilities.

**b) Debt, net of cash and cash equivalents by type, at value on redemption**

Edgar Filing: Sanofi - Form 20-F

( million)	2016			2015			2014		
	non-current	current	Total	non-current	current	Total	non-current	current	Total
Bond issues	16,657	823	17,480	12,484	2,991	15,475	12,579	843	13,422
Other bank borrowings	61	715	776	477	176	653	486	355	841
Finance lease obligations	34	19	53	49	18	67	47	15	62
Other borrowings	13	4	17	13	9	22	13	4	17
Bank credit balances	-	203	203	-	228	228	-	319	319
Interest rate and currency derivatives used to hedge debt	(9)	(1)	(10)	(11)	(24)	(35)	(32)	(89)	(121)
<b>Total debt</b>	<b>16,756</b>	<b>1,763</b>	<b>18,519</b>	<b>13,012</b>	<b>3,398</b>	<b>16,410</b>	<b>13,093</b>	<b>1,447</b>	<b>14,540</b>
Cash and cash equivalents	-	(10,273)	(10,273)	-	(9,148)	(9,148)	-	(7,341)	(7,341)
Interest rate and currency derivatives used to hedge cash and cash equivalents	-	-	-	-	4	4	-	(7)	(7)
<b>Debt, net of cash and cash equivalents</b>	<b>16,756</b>	<b>(8,510)</b>	<b>8,246</b>	<b>13,012</b>	<b>(5,746)</b>	<b>7,266</b>	<b>13,093</b>	<b>(5,901)</b>	<b>7,192</b>

Bond issues carried out by Sanofi under the Euro Medium Term Note (EMTN) program comprise:

- October 2009 issue [ISIN: XS0456451771] of 800 million, maturing October 2019, bearing annual interest at 4.125%;
- November 2012 issue [ISIN: FR0011355791] of 750 million, maturing November 2017, bearing annual interest at 1%;
- September 2013 issue [ISIN: FR0011560333] of 1 billion, maturing September 2020, bearing annual interest at 1.875%;
- November 2013 issue [ISIN: FR0011625433] of 1 billion, maturing November 2023, bearing annual interest at 2.5%.
- September 2014 issue [ISIN: FR0012146751] of 750 million, maturing September 2018, bearing annual interest at 3-month Euribor +0.23%;
- September 2014 issue [ISIN: FR0012146777] of 1 billion, maturing March 2022, bearing annual interest at 1.125%;

**F- 57**

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

- September 2014 issue [ISIN: FR0012146801] of 1.51 billion (including 260 million issued in November 2015), maturing September 2026, bearing annual interest at 1.75%;
- September 2015 issue [ISIN: FR0012969012] of 750 million, maturing March 2019, bearing annual interest at 3-month Euribor +0.30%;
- September 2015 issue [ISIN: FR0012969020] of 500 million, maturing September 2021, bearing annual interest at 0.875%;
- September 2015 issue [ISIN: FR0012969038] of 750 million, maturing September 2025, bearing annual interest at 1.5%;
- April 2016 issue [ISIN: FR0013143989] of 500 million, maturing April 2019, bearing annual interest at 0%;
- April 2016 issue [ISIN: FR0013143997] of 600 million, maturing April 2024, bearing annual interest at 0.625%;
- April 2016 issue [ISIN: FR0013144003] of 700 million, maturing April 2028, bearing annual interest at 1.125%;
- September 2016 issue [ISIN: FR0013201613] of 1 billion, maturing January 2020, bearing annual interest at 0%;
- September 2016 issue [ISIN: FR0013201621] of 850 million, maturing November 2022, bearing annual interest at 0%;
- September 2016 issue [ISIN: FR0013201639] of 1.15 billion, maturing January 2027, bearing annual interest at 0.5%.

Bond issues carried out by Sanofi under the public bond issue program (shelf registration statement) registered with the US Securities and Exchange Commission (SEC) comprise:

- March 2011 issue [ISIN: US80105NAG07] of \$2 billion, maturing March 2021, bearing annual interest at 4%;
- April 2013 issue [ISIN: US801060AB05] of \$1.5 billion, maturing April 2018, bearing annual interest at 1.25%.

The US dollar issues have been retained in that currency and have not been swapped into euros.

The only outstanding bond issue carried out by Genzyme Corp. is the June 2010 issue [ISIN: US372917AS37] of \$500 million, maturing June 2020, bearing annual interest at 5%.

The line Other borrowings mainly comprises:

## Edgar Filing: Sanofi - Form 20-F

- participating shares issued between 1983 and 1987, of which 82,698 remain outstanding, with a carrying amount of 13 million;
- Series A participating shares issued in 1989, of which 3,271 remain outstanding, with a carrying amount of 0.2 million.

In order to manage its liquidity needs for current operations, Sanofi has:

- a syndicated credit facility of 4 billion, drawable in euros and in US dollars, now due to expire on December 17, 2020 following the exercise of a second one-year extension option in November 2015;
- a syndicated credit facility of 4 billion, drawable in euros and in US dollars, now due to expire on December 3, 2021 following the exercise of a second one-year extension option in November 2016.

Sanofi also has two commercial paper programs, of 6 billion in France and \$10 billion in the United States. In 2016, only the US program was used, with an average drawdown of 2.6 billion and a maximum drawdown of 5.4 billion. As of December 31, 2016, neither of those programs was being utilized.

The financing in place as of December 31, 2016 at the level of the holding company (which manages most of Sanofi's financing needs centrally) is not subject to any financial covenants, and contains no clauses linking credit spreads or fees to the credit rating.

### F- 58

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****c) Debt by maturity, at value on redemption**

December 31, 2016 ( million)	Total	Current			Non-current			2022 and later
		2017	2018	2019	2020	2021		
Bond issues	17,480	823	2,174	2,050	2,475	2,398	7,560	
Other bank borrowings	776	715	16	8	14	-	23	
Finance lease obligations	53	19	13	2	2	3	14	
Other borrowings	17	4	-	-	-	-	13	
Bank credit balances	203	203	-	-	-	-	-	
Interest rate and currency derivatives used to hedge debt	(10)	(1)	(6)	(3)	-	-	-	
<b>Total debt</b>	<b>18,519</b>	<b>1,763</b>	<b>2,197</b>	<b>2,057</b>	<b>2,491</b>	<b>2,401</b>	<b>7,610</b>	
Cash and cash equivalents	(10,273)	(10,273)	-	-	-	-	-	
Interest rate and currency derivatives used to hedge cash and cash equivalents	-	-	-	-	-	-	-	
<b>Debt, net of cash and cash equivalents</b>	<b>8,246</b>	<b>(8,510)</b>	<b>2,197</b>	<b>2,057</b>	<b>2,491</b>	<b>2,401</b>	<b>7,610</b>	

December 31, 2015 ( million)	Total	Current			Non-current			2021 and later
		2016	2017	2018	2019	2020		
Bond issues	15,475	2,991	750	2,128	1,550	1,459	6,597	
Other bank borrowings	653	176	438	8	12	14	5	
Finance lease obligations	67	18	17	14	7	2	9	
Other borrowings	22	9	-	-	-	-	13	
Bank credit balances	228	228	-	-	-	-	-	
Interest rate and currency derivatives used to hedge debt	(35)	(24)	(1)	(1)	(6)	(3)	-	
<b>Total debt</b>	<b>16,410</b>	<b>3,398</b>	<b>1,204</b>	<b>2,149</b>	<b>1,563</b>	<b>1,472</b>	<b>6,624</b>	
Cash and cash equivalents	(9,148)	(9,148)	-	-	-	-	-	
Interest rate and currency derivatives used to hedge cash and cash equivalents	4	4	-	-	-	-	-	
<b>Debt, net of cash and cash equivalents</b>	<b>7,266</b>	<b>(5,746)</b>	<b>1,204</b>	<b>2,149</b>	<b>1,563</b>	<b>1,472</b>	<b>6,624</b>	

December 31, 2014 ( million)	Total	Current			Non-current			2020 and later
		2015	2016	2017	2018	2019		
Bond issues	13,422	843	2,735	750	1,985	800	6,309	
Other bank borrowings	841	355	16	437	17	7	9	
Finance lease obligations	62	15	15	16	10	-	6	
Other borrowings	17	4	-	-	-	-	13	
Bank credit balances	319	319	-	-	-	-	-	
Interest rate and currency derivatives used to hedge debt	(121)	(89)	(23)	(1)	-	(6)	(2)	
<b>Total debt</b>	<b>14,540</b>	<b>1,447</b>	<b>2,743</b>	<b>1,202</b>	<b>2,012</b>	<b>801</b>	<b>6,335</b>	

Edgar Filing: Sanofi - Form 20-F

Cash and cash equivalents	(7,341)	(7,341)	-	-	-	-	-
Interest rate and currency derivatives used to hedge cash and cash equivalents	(7)	(7)	-	-	-	-	-
<b>Debt, net of cash and cash equivalents</b>	<b>7,192</b>	<b>(5,901)</b>	<b>2,743</b>	<b>1,202</b>	<b>2,012</b>	<b>801</b>	<b>6,335</b>

**F- 59**

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2016, the main undrawn confirmed general-purpose credit facilities at holding company level amounted to 8 billion, of which half expires in 2020 and half in 2021.

As of December 31, 2016, no single counterparty represented more than 7% of Sanofi's undrawn confirmed credit facilities.

**d) Debt by interest rate, at value on redemption**

The tables below split debt, net of cash and cash equivalents between fixed and floating rate, and by maturity or contractual repricing date, as of December 31, 2016. The figures shown are values on redemption, before the effects of derivative instruments:

( million)	<b>Total</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022 and later</b>
Fixed-rate debt	16,404	1,256	1,418	1,297	2,475	2,398	7,560
of which EUR	12,591						
of which US dollar	3,813						
<b>% fixed-rate</b>	<b>89%</b>						
Floating-rate debt (maturity based on contractual repricing date)	2,115	2,115	-	-	-	-	-
of which EUR	1,877						
of which US dollar	43						
<b>% floating-rate</b>	<b>11%</b>						
<b>Debt</b>	<b>18,519</b>	<b>3,371</b>	<b>1,418</b>	<b>1,297</b>	<b>2,475</b>	<b>2,398</b>	<b>7,560</b>
Cash and cash equivalents	(10,273)	(10,273)	-	-	-	-	-
of which EUR	(8,007)						
of which US dollar	(1,291)						
<b>% floating-rate</b>	<b>100%</b>						
<b>Debt, net of cash and cash equivalents</b>	<b>8,246</b>	<b>(6,902)</b>	<b>1,418</b>	<b>1,297</b>	<b>2,475</b>	<b>2,398</b>	<b>7,560</b>

Since the financing of the Genzyme acquisition, Sanofi has managed its net debt in two currencies: the euro and the US dollar. The floating-rate portion of this debt exposes Sanofi to rises in interest rates, primarily in the Eonia and Euribor benchmark rates (for the euro) and in the US Libor and *Federal Fund Effective rates* (for the US dollar).

To optimize the cost of debt and/or reduce the volatility of debt, Sanofi uses derivative instruments (interest rate swaps, cross currency swaps and interest rate options) that alter the fixed/floating rate split of debt or the maturity based on contractual repricing dates, as shown below:

( million)	<b>Total</b>	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022 and later</b>
Fixed-rate debt	13,651	828	1,418	(253)	2,475	1,923	7,260
of which EUR	10,313						
of which US dollar	3,338						
<b>% fixed-rate</b>	<b>74%</b>						
Floating-rate debt (maturity based on contractual repricing date)	4,868	4,868	-	-	-	-	-

Edgar Filing: Sanofi - Form 20-F

of which EUR	4,155						
of which US dollar	518						
<b>% floating-rate</b>	<b>26%</b>						
<b>Debt</b>	<b>18,519</b>	<b>5,696</b>	<b>1,418</b>	<b>(253)</b>	<b>2,475</b>	<b>1,923</b>	<b>7,260</b>
Cash and cash equivalents	(10,273)	(10,273)	-	-	-	-	-
of which EUR	(8,007)						
of which US dollar	(1,291)						
<b>% floating-rate</b>	<b>100%</b>						
<b>Debt, net of cash and cash equivalents</b>	<b>8,246</b>	<b>(4,577)</b>	<b>1,418</b>	<b>(253)</b>	<b>2,475</b>	<b>1,923</b>	<b>7,260</b>

F- 60

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows the fixed/floating rate split of debt, net of cash and cash equivalents at value on redemption after taking account of derivative instruments as of December 31, 2015 and 2014:

<i>( million)</i>	<b>2015</b>	<b>%</b>	<b>2014</b>	<b>%</b>
Fixed-rate debt	10,435	64%	9,103	63%
Floating-rate debt	5,975	36%	5,437	37%
<b>Debt</b>	<b>16,410</b>	<b>100%</b>	<b>14,540</b>	<b>100%</b>
Cash and cash equivalents	(9,144)		(7,348)	
<b>Debt, net of cash and cash equivalents</b>	<b>7,266</b>		<b>7,192</b>	

The weighted average interest rate on debt as of December 31, 2016 was 1.6% before derivative instruments and 1.4% after derivative instruments. All cash and cash equivalents were invested at an average rate of 0.6% as of December 31, 2016.

The projected full-year sensitivity to interest rate fluctuations of debt, net of cash and cash equivalents for 2017 is as follows:

<i>Change in EUR and USD short-term interest rates</i>	<b>Impact on pre-tax net income ( million)</b>	<b>Impact on pre-tax income/(expense) recognized directly in equity ( million)</b>
+100 bp	54	-
+25 bp	14	-
-25 bp	(14)	-
-100 bp	(54)	-

**e) Debt by currency, at value on redemption**

The table below shows debt, net of cash and cash equivalents by currency at December 31, 2016, before and after derivative instruments contracted to convert third party debt into the functional currency of the borrower entity:

<i>( million)</i>	<b>Before derivative instruments</b>	<b>After derivative instruments</b>
EUR	6,460	6,460
USD	2,565	2,565
CNY	(287)	(287)
BRL	(144)	(144)
INR	(120)	(120)
Other currencies	(228)	(228)
<b>Debt, net of cash and cash equivalents</b>	<b>8,246</b>	<b>8,246</b>

The table below shows debt, net of cash and cash equivalents by currency at December 31, 2015 and 2014, after derivative instruments contracted to convert third party debt into the functional currency of the borrower entity:

<i>( million)</i>	<b>2015</b>	<b>2014</b>
EUR	3,356	3,446
USD	4,221	3,863
Other currencies	(311)	(117)
<b>Debt, net of cash and cash equivalents</b>	<b>7,266</b>	<b>7,192</b>

**F- 61**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****f) Market value of debt**

The market value of debt, net of cash and cash equivalents and of derivatives and excluding accrued interest, was 8,663 million as of December 31, 2016 (versus 7,633 million as of December 31, 2015 and 7,730 million as of December 31, 2014). This compares with a value on redemption of 8,246 million as of December 31, 2016 (versus 7,266 million as of December 31, 2015 and 7,192 million as of December 31, 2014).

The fair value of debt is determined by reference to quoted market prices at the balance sheet date in the case of quoted instruments (level 1 in the IFRS 7 hierarchy, see Note D.12.), and by reference to the fair value of interest rate and currency derivatives used to hedge debt (level 2 in the IFRS 7 hierarchy, see Note D.12.).

**g) Future contractual cash flows relating to debt and debt hedging instruments**

The table below shows the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt:

December 31, 2016 ( million)	Payments due by period						2022 and later
	Total	2017	2018	2019	2020	2021	
<b>Debt</b>	<b>19,937</b>	<b>1,951</b>	<b>2,477</b>	<b>2,304</b>	<b>2,708</b>	<b>2,537</b>	<b>7,960</b>
principal	18,451	1,678	2,217	2,054	2,491	2,401	7,610
interest <sup>(a)</sup>	1,486	273	260	250	217	136	350
<b>Net cash flows related to derivative instruments</b>	<b>(104)</b>	<b>(42)</b>	<b>(33)</b>	<b>(29)</b>	<b>(2)</b>	<b>1</b>	<b>1</b>
<b>Total</b>	<b>19,833</b>	<b>1,909</b>	<b>2,444</b>	<b>2,275</b>	<b>2,706</b>	<b>2,538</b>	<b>7,961</b>

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2016.

Future contractual cash flows are shown on the basis of the carrying amount in the balance sheet at the reporting date, without reference to any subsequent management decision that might materially alter the structure of Sanofi's debt or its hedging policy.

The tables below show the amount of future undiscounted contractual cash flows (principal and interest) relating to debt and to derivative instruments designated as hedges of debt as of December 31, 2015 and 2014:

December 31, 2015 ( million)	Payments due by period						2021 and later
	Total	2016	2017	2018	2019	2020	
<b>Debt</b>	<b>17,960</b>	<b>3,653</b>	<b>1,471</b>	<b>2,389</b>	<b>1,794</b>	<b>1,668</b>	<b>6,985</b>
principal	16,325	3,308	1,215	2,146	1,564	1,472	6,620
interest <sup>(a)</sup>	1,635	345	256	243	230	196	365
<b>Net cash flows related to derivative instruments</b>	<b>(165)</b>	<b>(78)</b>	<b>(38)</b>	<b>(26)</b>	<b>(21)</b>	<b>(2)</b>	<b>-</b>
<b>Total</b>	<b>17,795</b>	<b>3,575</b>	<b>1,433</b>	<b>2,363</b>	<b>1,773</b>	<b>1,666</b>	<b>6,985</b>

## Edgar Filing: Sanofi - Form 20-F

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2015.

December 31, 2014	Payments due by period						2020 and
( million)	Total	2015	2016	2017	2018	2019	later
<b>Debt</b>	<b>16,199</b>	<b>1,702</b>	<b>3,080</b>	<b>1,422</b>	<b>2,216</b>	<b>1,003</b>	<b>6,776</b>
principal	14,464	1,348	2,771	1,196	2,007	804	6,338
interest <sup>(a)</sup>	1,735	354	309	226	209	199	438
<b>Net cash flows related to derivative instruments</b>	<b>(217)</b>	<b>(71)</b>	<b>(72)</b>	<b>(33)</b>	<b>(21)</b>	<b>(19)</b>	<b>(1)</b>
<b>Total</b>	<b>15,982</b>	<b>1,631</b>	<b>3,008</b>	<b>1,389</b>	<b>2,195</b>	<b>984</b>	<b>6,775</b>

(a) Interest flows are estimated on the basis of forward interest rates applicable as of December 31, 2014.

**F- 62**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.18. LIABILITIES RELATED TO BUSINESS COMBINATIONS AND TO NON-CONTROLLING INTERESTS**

For a description of the nature of the liabilities reported in the line item *Liabilities related to business combinations and to non-controlling interests*, refer to Note B.8.5. The principal acquisitions are described in Note D.1.

The liabilities related to business combinations and to non-controlling interests shown in the table below are level 3 instruments under the IFRS 7 fair value hierarchy (see Note D.12.) except for the CVRs issued in connection with the acquisition of Genzyme, which are level 1 instruments.

Movements in liabilities related to business combinations and to non-controlling interests are shown below:

( million)	Liabilities related to non-controlling interests <sup>(a)</sup>	CVRs issued in connection with acquisition of Genzyme <sup>(b)</sup>	Bayer contingent consideration arising from the acquisition of Genzyme	Other	Total <sup>(d)</sup>
<b>Balance at January 1, 2014</b>	<b>148</b>	<b>59</b>	<b>650</b>	<b>51</b>	<b>908</b>
New business combinations	43	-	-	-	43
Payments made	(1)	(1)	(7)	(3)	(12)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount) <sup>(c)</sup>	-	82	238	(17)	303
Other movements	(19)	-	-	-	(19)
Currency translation differences	7	14	15	5	41
<b>Balance at December 31, 2014</b>	<b>178</b>	<b>154</b>	<b>896</b>	<b>36</b>	<b>1,264</b>
New business combinations	-	-	-	-	-
Payments made	-	-	(63)	(7)	(70)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount) <sup>(c)</sup>	-	(143)	104	(14)	(53)
Other movements	(5)	-	-	(11)	(16)
Currency translation differences	8	13	103	2	126
<b>Balance at December 31, 2015</b>	<b>181</b>	<b>24</b>	<b>1,040</b>	<b>6</b>	<b>1,251</b>
New business combinations	-	-	-	354	354
Payments made	-	-	(137)	(3)	(140)
Fair value remeasurements through profit or loss: (gain)/loss (including unwinding of discount) <sup>(c)</sup>	-	58	78	(1)	135
Other movements	(58)	-	-	-	(58)
Currency translation differences	-	3	32	(1)	34
<b>Balance at December 31, 2016</b>	<b>123</b>	<b>85</b>	<b>1,013</b>	<b>355</b>	<b>1,576</b>

(a) Includes put options granted to non-controlling interests and commitment to future buyout of non-controlling interests held by BMS.

(b) Based on the quoted market price per CVR of \$0.38 as of December 31, 2016; \$0.11 as of December 31, 2015; and \$0.79 as of December 31, 2014.

## Edgar Filing: Sanofi - Form 20-F

(c) Amounts reported within the income statement line item *Fair value remeasurement of contingent consideration liabilities*, and mainly comprising unrealized gains and losses.

(d) Portion due after more than one year: 1,378 million as of December 31, 2016 ( 1,121 million as of December 31, 2015 and 1,133 million as of December 31, 2014); portion due within less than one year: 198 million as of December 31, 2016 ( 130 million as of December 31, 2015 and 131 million as of December 31, 2014).

**F- 63**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As part of a business combination involving the acquisition of Sanofi Pasteur operations previously included in the former Sanofi Pasteur MSD (SPMSD) joint venture, Sanofi recognized contingent consideration of 354 million payable to Merck based on a percentage of future sales made by Sanofi Pasteur during the 2017-2024 period of specified products previously distributed by SPMSD (see Notes B.1. and D.1.2.). The fair value of the contingent consideration was determined by applying the royalty percentage stipulated in the contract to discounted sales projections. A reduction of one percentage point in the discount rate would increase the contingent consideration liability by approximately 4%.

The Bayer contingent consideration liability was assumed on the acquisition of Genzyme in 2011.

In a business combination completed in May 2009, prior to Sanofi's acquisition of control over Genzyme, Genzyme acquired from Bayer Schering Pharma A.G. (Bayer) the worldwide development and marketing rights to alemtuzumab (under the brand name Lemtrada®), a molecule under development for multiple sclerosis, as well as the rights to the products Campath®, Fludara® and Leukine®. In exchange, Bayer is entitled to receive the following payments:

- a percentage of sales of alemtuzumab up to a maximum of \$1,250 million or over a maximum period of ten years, whichever is achieved first;

- milestone payments based on specified levels of worldwide sales of alemtuzumab beginning in 2021, unless Genzyme exercises its right to buy out those milestone payments by making a one-time payment not exceeding \$900 million.

The fair value of the Bayer contingent consideration liability was measured at 1,013 million as of December 31, 2016, versus 1,040 million as of December 31, 2015 and 896 million as of December 31, 2014.

The fair value of the Bayer liability is determined by applying the above contractual terms to sales projections that have been weighted to reflect the probability of success, and discounted. A reduction of one percentage point in the discount rate would increase the fair value of the liability by approximately 4%.

The table below sets forth the maximum amount of contingent consideration payable and firm commitments to buy out non-controlling interests:

December 31, 2016 ( million)	Total	Less than 1 year	Payments due by period		More than 5 years
			From 1 to 3 years	From 3 to 5 years	
Commitments relating to contingent consideration in connection with business combinations <sup>(a)</sup> and buyouts of non-controlling interests <sup>(b)</sup>	4,832	186	602	3,732	312

(a) Includes 1.8 billion for the Bayer contingent consideration (versus 1.9 billion as of December 31, 2015 and 1.8 billion as of December 31, 2014) and 2.5 billion for the CVRs issued in connection with the acquisition of Genzyme (versus 2.6 billion as of December 31, 2015 and 2.3 billion as of December 31, 2014).

(b) This line does not include put options granted to non-controlling interests.

## Edgar Filing: Sanofi - Form 20-F

Total commitments relating to contingent consideration in connection with business combinations and buyouts of non-controlling interests were 5,073 million as of December 31, 2015 and 4,745 million as of December 31, 2014. The reduction in these commitments during 2016 was mainly attributable to commitments connected with the Genzyme acquisition (i.e. annual payments on the Bayer contingent consideration, and a reduction in the CVR-related commitment). These reductions were partly offset by the contingent consideration recognized in connection with the ending of the Sanofi Pasteur MSD joint venture (see Note D.1.2.).

**F- 64**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.19. PROVISIONS AND OTHER LIABILITIES**

Provisions and other non-current liabilities break down as follows:

	Provisions for pensions & other post- employment benefits (D.19.1.)	Provisions for other long-term benefits	Restructuring provisions (D.19.2.)	Other provisions (D.19.3.)	Other non- current liabilities	Total
( million)						
<b>Balance at January 1, 2014</b>	<b>4,025</b>	<b>543</b>	<b>1,061</b>	<b>3,008</b>	<b>98</b>	<b>8,735</b>
Changes in scope of consolidation	-	-	-	1	-	1
Increases in provisions and other liabilities	225 <sup>(a)</sup>	145	140	352 <sup>(b)</sup>	35	897
Provisions utilized	(486) <sup>(a)</sup>	(69)	(13)	(203)	-	(771)
Reversals of unutilized provisions	(52) <sup>(a)</sup>	-	(8)	(207) <sup>(c)</sup>	-	(267)
Transfers	31	(6)	(372)	(28)	-	(375)
Net interest related to employee benefits, and unwinding of discount	133	9	22	50	-	214
Unrealized gains and losses	-	-	-	1	-	1
Currency translation differences	134	28	5	102	11	280
Actuarial gains and losses on defined-benefit plans <sup>(d)</sup>	863	-	-	-	-	863
<b>Balance at December 31, 2014</b>	<b>4,873</b>	<b>650</b>	<b>835</b>	<b>3,076</b>	<b>144</b>	<b>9,578</b>
Changes in scope of consolidation	-	-	-	13	-	13
Increases in provisions and other liabilities	290 <sup>(a)</sup>	108	265	475 <sup>(b)</sup>	114	1,252
Provisions utilized	(366) <sup>(a)</sup>	(73)	(16)	(130)	-	(585)
Reversals of unutilized provisions	(39) <sup>(a)</sup>	(7)	(12)	(256) <sup>(c)</sup>	(1)	(315)
Transfers	43	3	(317)	(57)	-	(328)
Reclassification of the Animal Health business <sup>(e)</sup>	(76)	(34)	(3)	(34)	(2)	(149)
Net interest related to employee benefits, and unwinding of discount	109	5	5	37	2	158
Unrealized gains and losses	-	-	-	-	5	5
Currency translation differences	124	26	5	22	13	190
Actuarial gains and losses on defined-benefit plans <sup>(d)</sup>	(650)	-	-	-	-	(650)
<b>Balance at December 31, 2015</b>	<b>4,308</b>	<b>678</b>	<b>762</b>	<b>3,146</b>	<b>275</b>	<b>9,169</b>
Increases in provisions and other liabilities	220 <sup>(a)</sup>	130	475	402 <sup>(b)</sup>	-	1,227
Provisions utilized	(294) <sup>(a)</sup>	(86)	(7)	(195)	(2)	(584)
Reversals of unutilized provisions	1 <sup>(a)</sup>	(11)	(39)	(458) <sup>(c)</sup>	-	(507)
Transfers	(85)	(6)	(450)	(182)	(67)	(790)
Net interest related to employee benefits, and unwinding of discount	108	6	4	29	2	149
Currency translation differences	10	9	(1)	35	8	61
Actuarial gains and losses on defined-benefit plans <sup>(d)</sup>	109	-	-	-	-	109
<b>Balance at December 31, 2016</b>	<b>4,377</b>	<b>720</b>	<b>744</b>	<b>2,777</b>	<b>216</b>	<b>8,834</b>

(a) In the case of Provisions for pensions and other post-employment benefits, the Increases in provisions line corresponds to rights vesting in employees during the period, and past service cost; the Provisions utilized line corresponds to contributions paid into pension funds, and plan settlements; and the Reversals of unutilized provisions line corresponds to plan curtailments.

(b)

## Edgar Filing: Sanofi - Form 20-F

*Amounts charged during the period mainly comprise provisions to cover tax exposures in various countries, and changes to estimates of future expenditures on environmental risks.*

*(c) Reversals relate mainly to provisions for tax exposures, reversed either because (i) the statute of limitations deadline was reached during the reporting period or (ii) proceedings with tax authorities in various countries were resolved during the period with a more favorable outcome than initially anticipated.*

*(d) Amounts recognized in **Other comprehensive income** (see Note D.15.7.).*

*(e) The liabilities of the Animal Health business, which in 2014 were presented in the relevant balance sheet line item for each class of liability, were reclassified in 2015 to **Liabilities related to assets held for sale or exchange** in accordance with IFRS 5 (see Notes D.2. and D.36.).*

**F- 65**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Other current liabilities are described in Note D.19.4.

**D.19.1. Provisions for pensions and other post-employment benefits**

Sanofi offers its employees pension plans and other post-employment benefit plans. The specific features of the plans (benefit formulas, fund investment policy and fund assets held) vary depending on the applicable laws and regulations in each country where the employees work. These employee benefits are accounted for in accordance with the revised IAS 19 (see Note B.23.).

Sanofi's pension obligations in four major countries represented over 90% of the total value of the defined-benefit liability and over 89% of the total value of plan assets as of December 31, 2016. The features of the principal defined-benefit plans in each of those four countries are described below.

**France*****Lump-sum retirement benefit plans***

All employees working for Sanofi in France are entitled on retirement to a lump-sum payment, the amount of which depends both on their length of service and on the rights guaranteed by collective and internal agreements. The employee's final salary is used in calculating the amount of these lump-sum retirement benefits. These plans represent approximately 30% of Sanofi's total obligation in France.

***Defined-benefit pension plans***

These plans provide benefits from the date of retirement. Employees must fulfil a number of criteria to be eligible for these benefits. All but one of these plans are closed to new entrants. These plans represent approximately 68% of Sanofi's total obligation in France.

**Germany*****Top-up defined-benefit pension plan***

The benefits offered under this pension plan are wholly funded by the employer (there are no employee contributions) via a Contractual Trust Agreement (CTA), under which benefits are estimated on the basis of an average career salary. Employees are entitled to receive an annuity under this plan if their salary exceeds the social security ceiling. The amount of the pension is calculated by reference to a range of vesting rates corresponding to salary bands. The plan also includes disability and death benefits. This plan represents approximately 72% of Sanofi's total obligation in Germany.

***Sanofi-Aventis plus (SAV plus)***

Starting April 2015, a new top-up pension plan (SAV plus) replaced the previous top-up defined-benefit plan. New entrants joining the plan after April 1, 2015 contribute to a defined-contribution plan that is partially funded via the company's CTA.

All employees whose salary exceeds the social security ceiling are automatically covered by the plan. The employer's contribution is 15% of the amount by which the employee's salary exceeds the social security ceiling.

***Multi-employer plan (Pensionskasse)***

## Edgar Filing: Sanofi - Form 20-F

This is a defined-benefit plan that is treated as a defined-contribution plan, in accordance with the accounting policies described in Note B.23. Currently, contributions cover the level of annuities. Only the portion relating to the future revaluation of the annuities is included in the defined-benefit pension obligation. The obligation relating to this revaluation amounted to 663 million as of December 31, 2016, versus 670 million as of December 31, 2015 and 745 million as of December 31, 2014. This plan represents approximately 19% of Sanofi's total defined-benefit obligation in Germany.

### United States

#### *Defined-benefit pension plans*

In the United States, there are two types of defined-benefit plan:

- Qualified plans within the meaning of the Employee Retirement Income Security Act of 1974 (ERISA), which provide guaranteed benefits to eligible employees during retirement, and in the event of death or disability. Employees can elect to receive a reduced annuity, in exchange for an annuity to be paid in the event of their death to a person designated by them. An annuity is granted under the plan if the employee dies before retirement age. Eligible employees do not pay any contributions. These plans are closed to new entrants, and the vesting of rights for future service periods is partially frozen. They represent around 68% of Sanofi's total obligations in the United States.

- Non-qualified plans within the meaning of ERISA provide top-up retirement benefits to some eligible employees depending on the employee's level of responsibility and subject to a salary cap. These plans represent approximately 9% of Sanofi's total obligation in the United States.

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***Healthcare cover and life insurance***

Sanofi companies provide some eligible employees with healthcare cover and life insurance during the retirement period (the company's contributions are capped at a specified level). This plan represents approximately 23% of Sanofi's total obligation in the United States.

In 2016, the obligations under these plans were partially outsourced, and one-off lump-sum payments were offered to some eligible plan members. The effect was to reduce the obligation by 246 million and plan assets by 243 million.

**United Kingdom**

***Defined-benefit pension plans***

Sanofi operates a number of pension plans in the United Kingdom that reflect past acquisitions. The two most significant arrangements are the Sanofi plan and the Genzyme Limited plan; both are defined-benefit plans, and both have been closed since October 1, 2015. With effect from that date, employees can no longer pay into these plans. The Genzyme Limited plan was merged with the Sanofi plan effective January 1, 2017.

Under these defined-benefit plans, an annuity is paid from the retirement date. This annuity is calculated on the basis of the employee's length of service as of September 30, 2015,

and of the employee's final salary (or salary on the date he or she leaves Sanofi).

The rates used for the vesting of rights vary from member to member. For most members, rights vest at the rate of 1.25% or 1.50% of final salary for each qualifying year of service giving entitlement. The notional retirement age varies according to the category to which the member belongs, but in most cases retirement is at age 65. Members may choose to retire before or after the notional retirement age (60 years), in which case the amount of the annual pension is adjusted to reflect the revised estimate of the length of the retirement phase. Pensions are usually indexed to the Retail Price Index (RPI). Members paid a fixed-percentage contribution into their pension plan (the percentage varies according to the employee category), and the employer topped up the contribution to the required amount. These plans represent approximately 99% of Sanofi's total obligation in the United Kingdom.

For future service periods subsequent to October 1, 2015, employees will belong to a new defined-contribution plan.

**Actuarial assumptions used to measure Sanofi's obligations**

Actuarial valuations of Sanofi's benefit obligations were computed by management with assistance from external actuaries as of December 31, 2016, 2015 and 2014.

Those calculations were based on the following financial and demographic assumptions:

2016				2015				2014			
France	Germany	US	UK	France	Germany	US	UK	France	Germany	US	UK

Edgar Filing: Sanofi - Form 20-F

Discount rate <sup>(a)/(b)</sup>	1.00%	1.00%			1.50%	1.50%			1.25%	1.25%		
	or	or			or	or			or	or		
General inflation rate <sup>(c)</sup>	1.50%	1.50%	4.00%	2.75%	2.25%	2.25%	4.00%	4.00%	1.75%	1.75%	3.75%	3.75%
Pension benefit indexation	1.25%				1.25%				1.25%			
	to				to				to			
Healthcare cost inflation rate	2.25%	1.75%	-	2.70%	2.25%	1.75%	-	3.15%	2.25%	1.75%	-	3.20%
Retirement age	2.00%	-(d)	5.96%	1.50%	2.00%	-(d)	6.10%	1.50%	2.00%	-(d)	6.80%	1.25%
	62		55		62		55		61		55	
Mortality table	to 67	62	to 70	60	to 67	62	to 70	60	to 67	62	to 70	60
		Heubeck								Heubeck		
	TGH/	RT	RP2014		TGH/	Heubeck	RP2014		TGH/	RT	RP2014	
			G. Scale	SAPS			G. Scale	SAPS			G. Scale	SAPS
	TGF 05	2005 G	MP2016	S2	TGF 05	2005 G	MP2015	S2	TGF 05	2005 G	MP2014	SAPS

(a) The discount rates used are based on market rates for high quality corporate bonds with a duration close to that of the expected benefit payments under the plans. The benchmarks used to determine discount rates were the same in 2016, 2015 and 2014.

(b) The rate depends on the duration of the plan (seven to ten years and more than ten years, respectively).

(c) Inflation for the euro zone will from now on be determined using the average break-even inflation rate of French and German government bonds, with reference to the duration of the principal plans. This new methodology is regarded as a closer approximation of actual financial market behavior than the macro-economic approach used previously.

(d) No post-employment healthcare benefits are provided in Germany.

**F- 67**

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**Weighted average duration of obligation for pensions and other long-term benefits in principal countries**

The table below shows the duration of Sanofi's obligations in the principal countries:

(years)	2016				France	2015				2014			
	France	Germany	US	UK		Germany	US	UK	France	Germany	US	UK	
Weighted average duration	13	14	13	17	13	14	14	17	14	14	14	17	

**Sensitivity analysis**

The table below shows the sensitivity of Sanofi's obligations for pensions and other post-employment benefits to changes in key actuarial assumptions:

( million)	Change in assumption	Pensions and other post-employment benefits, by principal country			
		France	Germany	US	UK
<b>Measurement of defined- benefit obligation</b>					
Discount rate	-0.50%	+163	+240	+187	+287
General inflation rate	+0.50%	+85	+245	+2	+189
Pension benefits indexation	+0.50%	+105	+233	-	+145
Healthcare cost inflation rate	+0.50%	+3	-	+28	-
Mortality table	+1 year	+70	+91	+69	+105

**F- 68**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below reconciles the net obligation in respect of Sanofi's pension and other post-employment benefit plans with the amounts recognized in the consolidated financial statements:

( million)	Pensions and other post-employment benefits		
	2016	2015	2014
<b>Measurement of the obligation:</b>			
Beginning of period	12,825	13,302	11,251
Reclassification of the Animal Health business <sup>(a)</sup>	-	(266)	-
Current service cost	216	262	214
Interest cost	359	362	418
Actuarial losses/(gains) due to changes in demographic assumptions	(71)	(37)	(25)
Actuarial losses/(gains) due to changes in financial assumptions	928	(679)	1,618
Actuarial losses/(gains) due to experience adjustments	(18)	(13)	(30)
Plan amendments	(2)	18	5
Plan curtailments	(52)	(39)	(16)
Plan settlements specified in the terms of the plan	(49)	(61)	(54)
Plan settlements not specified in the terms of the plan	(254)	(6)	(110)
Benefits paid	(531)	(556)	(507)
Changes in scope of consolidation and transfers	71	36	(2)
Currency translation differences	(334)	502	540
<b>Obligation at end of period</b>	<b>13,088</b>	<b>12,825</b>	<b>13,302</b>
<b>Fair value of plan assets:</b>			
Beginning of period	8,566	8,488	7,241
Reclassification of the Animal Health business <sup>(a)</sup>	-	(208)	-
Interest income on plan assets	251	254	285
Difference between actual return and interest income on plan assets	730	(79)	700
Administration costs	(9)	(13)	(11)
Plan settlements specified in the terms of the plan	(49)	(61)	(54)
Plan settlements not specified in the terms of the plan	(256)	(6)	(63)
Contributions from plan members	3	4	5
Employer's contributions	168	225	354
Benefits paid	(405)	(415)	(375)
Changes in scope of consolidation and transfers	86	-	-
Currency translation differences	(344)	377	406
<b>Fair value of plan assets at end of period</b>	<b>8,741</b>	<b>8,566</b>	<b>8,488</b>
<b>Net amount shown in the balance sheet:</b>			
Net obligation	4,347	4,259	4,814
<b>Net amount shown in the balance sheet at end of period</b>	<b>4,347</b>	<b>4,259</b>	<b>4,814</b>

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

( million)	Pensions and other post-employment benefits		
	2016	2015	2014
<b>Amounts recognized in the balance sheet:</b>			
Pre-funded obligations (see Note D.7.)	(30)	(49)	(59)
Obligations provided for	4,377	4,308	4,873
<b>Net amount recognized at end of period</b>	<b>4,347</b>	<b>4,259</b>	<b>4,814</b>
<b>Benefit cost for the period:</b>			
Current service cost	216	262	214
Past service cost	(2)	18	5
Net interest (income)/cost	108	108	133
(Gains)/losses on plan settlements not specified in the terms of the plan	2	-	(47)
Actuarial (gains)/losses on plan curtailments	(52)	(39)	(16)
Contributions from plan members	(3)	(4)	(5)
Administration costs and taxes paid during the period	9	13	11
<b>Expense recognized directly in profit or loss</b>	<b>278</b>	<b>358</b>	<b>295</b>
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	109	(650)	863
<b>Expense/(gain) for the period</b>	<b>387</b>	<b>(292)</b>	<b>1,158</b>

(a) This line comprises the relevant assets and liabilities of the Animal Health business, reclassified as of December 31, 2015 to **Assets held for sale or exchange** and **Liabilities related to assets held for sale or exchange**, respectively, in accordance with IFRS 5 (see Notes D.2. and D.36.).

The tables below show Sanofi's net liability in respect of pension plans and other post-employment benefits by geographical region:

December 31, 2016 ( million)	Pensions and other post-employment benefits					
	by geographical region					
	France	Germany	US	UK	Other	Total
Measurement of obligation	2,361	3,535	2,874	3,065	1,253	13,088
Fair value of plan assets	857	2,304	1,760	2,866	954	8,741
<b>Net amount shown in the balance sheet at end of period</b>	<b>1,504</b>	<b>1,231</b>	<b>1,114</b>	<b>199</b>	<b>299</b>	<b>4,347</b>

December 31, 2015 ( million)	Pensions and other post-employment benefits					
	by geographical region					
	France	Germany	US	UK	Other	Total
Measurement of obligation	2,270	3,502	2,986	2,948	1,119	12,825
Fair value of plan assets	841	2,216	1,806	2,852	851	8,566
<b>Net amount shown in the balance sheet at end of period</b>	<b>1,429</b>	<b>1,286</b>	<b>1,180</b>	<b>96</b>	<b>268</b>	<b>4,259</b>

December 31, 2014 ( million)	Pensions and other post-employment benefits					
	by geographical region					
	France	Germany	US	UK	Other	Total
Measurement of obligation	2,522	3,809	2,819	2,996	1,156	13,302
Fair value of plan assets	865	2,207	1,837	2,745	834	8,488

Net amount shown in the balance sheet at end of period	1,657	1,602	982	251	322	4,814
--	-------	-------	-----	-----	-----	-------

F- 70

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows the fair value of plan assets relating to Sanofi's pension and other post-employment plans, split by asset category:

	2016	2015	2014
<b>Securities quoted in an active market</b>	<b>98.2%</b>	<b>97.0%</b>	<b>96.8%</b>
Cash and cash equivalents	2.4%	2.7%	1.0%
Equity instruments	35.2%	35.6%	40.7%
Bonds and similar instruments	54.3%	52.8%	50.1%
Real estate	3.8%	3.5%	3.7%
Derivatives	(0.1)%	0.3%	0.1%
Commodities	1.3%	1.0%	1.1%
Other	1.3%	1.1%	0.3%
<b>Other securities</b>	<b>1.8%</b>	<b>3.0%</b>	<b>3.2%</b>
Hedge funds	0.0%	1.5%	1.5%
Insurance policies	1.8%	1.5%	1.7%
<b>Total</b>	<b>100%</b>	<b>100%</b>	<b>100%</b>

Sanofi has a long-term objective of maintaining or increasing the extent to which its obligations are covered by assets. To this end, Sanofi uses an asset-liability management strategy, matching plan assets to its pension obligations. This policy aims to ensure the best fit between the assets held on the one hand, and the associated liabilities and expected future payments to plan members on the other. To meet this aim, Sanofi operates a risk monitoring and management strategy (mainly focused on interest rate risk and inflation risk), while investing a growing proportion of assets in high-quality bonds with comparable maturities to those of the underlying obligations.

Sanofi did not alter its asset-liability management strategy or its key risk monitoring policy during 2016.

The tables below show the service cost for Sanofi's pension and other post-employment benefit plans, by geographical region:

	Pensions and other post-employment benefits by geographical region					
	France	Germany	US	UK	Other	Total
( million)						
<b>Service cost for 2016</b>						
Current service cost	70	42	62	-	42	216
Past service cost	-	-	-	-	(2)	(2)
Net interest cost/(income) including administration costs and taxes paid during the period	30	23	48	6	10	117
(Gains)/losses on plan settlements not specified in the terms of the plan	-	-	(2)	-	4	2
Actuarial (gains)/losses on plan curtailments	(51)	2	-	-	(3)	(52)
Contributions from plan members	-	-	-	-	(3)	(3)
<b>Expense recognized directly in profit or loss</b>	<b>49</b>	<b>67</b>	<b>108</b>	<b>6</b>	<b>48</b>	<b>278</b>
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	70	1	(161)	165	34	109
<b>Expense/(gain) for the period</b>	<b>119</b>	<b>68</b>	<b>(53)</b>	<b>171</b>	<b>82</b>	<b>387</b>

F- 71

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	Pensions and other post-employment benefits by geographical region					Total
	France	Germany	US	UK	Other	
<i>( million)</i>						
<b>Service cost for 2015</b>						
Current service cost	78	47	74	14	49	262
Past service cost	16	1	-	-	1	18
Net interest cost/(income) including administration costs and taxes paid during the period	28	23	44	13	13	121
(Gains)/losses on plan settlements not specified in the terms of the plan	-	-	-	-	-	-
Actuarial (gains)/losses on plan curtailments	(38)	-	-	-	(1)	(39)
Contributions from plan members	-	-	-	(1)	(3)	(4)
<b>Expense recognized directly in profit or loss</b>	<b>84</b>	<b>71</b>	<b>118</b>	<b>26</b>	<b>59</b>	<b>358</b>
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	(235)	(211)	(30)	(144)	(30)	(650)
<b>Expense/(gain) for the period</b>	<b>(151)</b>	<b>(140)</b>	<b>88</b>	<b>(118)</b>	<b>29</b>	<b>(292)</b>

	Pensions and other post-employment benefits by geographical region					Total
	France	Germany	US	UK	Other	
<i>( million)</i>						
<b>Service cost for 2014</b>						
Current service cost	72	35	50	17	40	214
Past service cost	1	4	-	-	-	5
Net interest cost/(income) including administration costs and taxes paid during the period	49	36	34	12	13	144
(Gains)/losses on plan settlements not specified in the terms of the plan	(19)	-	(28)	-	-	(47)
Actuarial (gains)/losses on plan curtailments	(11)	3	-	-	(8)	(16)
Contributions from plan members	-	-	-	(1)	(4)	(5)
<b>Expense recognized directly in profit or loss</b>	<b>92</b>	<b>78</b>	<b>56</b>	<b>28</b>	<b>41</b>	<b>295</b>
Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses)	175	338	225	60	65	863
<b>Expense/(gain) for the period</b>	<b>267</b>	<b>416</b>	<b>281</b>	<b>88</b>	<b>106</b>	<b>1,158</b>

There were no significant events affecting Sanofi's pension and other post-employment benefit plans during 2016.

An analysis of the Remeasurement of net defined-benefit (asset)/liability (actuarial gains and losses) line in the preceding tables is set forth below:

	2016				2015				2014			
	France	Germany	US	UK	France	Germany	US	UK	France	Germany	US	UK
<i>( million)</i>												
Actuarial gains/(losses) arising during the period <sup>(a)</sup>	(70)	(1)	161	(165)	235	210	30	144	(175)	(338)	(225)	(60)
Comprising:												
Gains/(losses) on experience adjustments <sup>(b)</sup>	58	149	77	442	26	16	(116)	9	132	130	147	238
Gains/(losses) on demographic assumptions	(6)	-	79	-	10	-	46	(21)	88	-	(62)	-
Gains/(losses) on financial assumptions	(122)	(150)	5	(607)	199	194	100	156	(395)	(468)	(310)	(298)

*(a) Gains and losses arising from changes in assumptions are due primarily to changes in the discount rate.*

*(b) Experience adjustments are mainly due to the effect of trends in the financial markets on plan assets.*

**F- 72**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The net pre-tax actuarial loss (excluding associates and joint ventures) recognized directly in equity in the year ended December 31, 2016 was 3,006 million, compared with 2,898 million for the year ended December 31, 2015 and 3,548 million for the year ended December 31, 2014.

The present value of Sanofi's wholly or partially funded obligations in respect of pension and other post-employment benefit plans as of December 31, 2016 was 11,713 million, compared with 11,473 million as of December 31, 2015 and 11,933 million as of December 31, 2014. The present value of Sanofi's unfunded obligations was 1,375 million as of December 31, 2016, versus 1,352 million as of December 31, 2015 and 1,369 million as of December 31, 2014.

The total expense for pensions and other post-employment benefits is allocated between income statement line items as follows:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Cost of sales	60	73	73
Research and development expenses	48	58	45
Selling and general expenses	113	132	108
Other operating (income)/expenses, net	-	-	(56)
Restructuring costs	(51)	(13)	(8)
Other gains and losses, and litigation	-	-	-
Financial expenses	108	108	133
<b>Total</b>	<b>278</b>	<b>358</b>	<b>295</b>

The estimated amounts of employer's contributions to plan assets in 2017 are as follows:

<i>( million)</i>	<b>France</b>	<b>Germany</b>	<b>US</b>	<b>UK</b>	<b>Other</b>	<b>Total</b>
Employer's contributions in 2017 (estimate):						
2017	5	47	-	46	46	144

The table below shows the expected timing of benefit payments under pension and other post-employment benefit plans for the next ten years:

<i>( million)</i>	<b>France</b>	<b>Germany</b>	<b>US</b>	<b>UK</b>	<b>Other</b>	<b>Total</b>
Estimated future benefit payments:						
2017	139	206	191	105	59	700
2018	105	210	157	108	53	633
2019	92	216	153	112	58	631
2020	115	221	159	115	61	671
2021	113	226	158	119	60	676
2022 to 2026	524	1,148	823	652	339	3,486

The table below shows estimates as of December 31, 2016 for the timing of future payments in respect of unfunded pension and other post-employment benefit plans:

**Payments due by period**

Edgar Filing: Sanofi - Form 20-F

<i>( million)</i>	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
<b>Estimated payments</b>	<b>1,374</b>	<b>73</b>	<b>144</b>	<b>153</b>	<b>1,004</b>

**F- 73**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.19.2. Restructuring provisions**

The table below shows movements in restructuring provisions classified in non-current and current liabilities:

( million)	2016	2015	2014
<b>Balance, beginning of period</b>	<b>1,343</b>	<b>1,399</b>	<b>1,801</b>
of which:			
· Classified in non-current liabilities	762	835	1,061
· Classified in current liabilities	581	564	740
Change in provisions recognized in profit or loss for the period	667	508	287
Provisions utilized	(641)	(570)	(740)
Transfers	38	-	14
Reclassification of the Animal Health business <sup>(a)</sup>	-	(12)	-
Unwinding of discount	4	6	25
Currency translation differences	9	12	12
<b>Balance, end of period</b>	<b>1,420</b>	<b>1,343</b>	<b>1,399</b>
of which:			
· Classified in non-current liabilities	744	762	835
· Classified in current liabilities	676	581	564

(a) This line comprises the restructuring provisions of the Animal Health business, reclassified to **Liabilities related to assets held for sale or exchange** as of December 31 2015 (see Notes D.2. and D.36.).

Provisions for employee termination benefits as of December 31, 2016 amounted to 1,159 million (compared with 1,030 million as of December 31, 2015 and 1,235 million as of December 31, 2014), and mainly covered redundancy programs announced as part of the reallocation of sales forces, R&D and industrial operations in France, the United States, and some other European countries. The provision relating to France was 933 million as of December 31, 2016, versus 772 million as of December 31, 2015 and 1,087 million as of December 31, 2014.

The provision for France includes the present value of gross self-funded annuities under various early retirement plans (including ongoing plans, and a new plan implemented at the end of 2016), plus social security charges and levies associated with those annuities and with annuities funded by external bodies. The average residual holding periods under these plans were 2.51 years, 2.64 years and 3.08 years as of December 31, 2016, 2015 and 2014, respectively. In 2016, no premiums were paid in respect of externally-funded annuities: the impact of reforms on existing externally-funded plans ended in 2015, and all plans implemented since 2011 have been self-funded. This compares with premium payments of 4.4 million in the year ended December 31, 2015 and 18 million in the year ended December 31, 2014.

The timing of future termination benefit payments is as follows:

December 31, 2016 ( million)	Benefit payments by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
<b>Employee termination benefits</b>					
· France	933	374	413	142	4
· Other countries	226	182	35	4	5

Edgar Filing: Sanofi - Form 20-F

<b>Total</b>	<b>1,159</b>	<b>556</b>	<b>448</b>	<b>146</b>	<b>9</b>
<b>December 31, 2015</b> ( million)					
	<b>Total</b>	<b>Less than 1 year</b>	<b>Benefit payments by period</b>		
<b>Employee termination benefits</b>			<b>1 to 3 years</b>	<b>3 to 5 years</b>	<b>More than 5 years</b>
· France	772	286	351	120	15
· Other countries	258	197	56	2	3
<b>Total</b>	<b>1,030</b>	<b>483</b>	<b>407</b>	<b>122</b>	<b>18</b>

F- 74

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

December 31, 2014 ( million)	Total	Benefit payments by period			
		Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
<b>Employee termination benefits</b>					
France	1,087	378	447	212	50
Other countries	148	94	48	5	1
<b>Total</b>	<b>1,235</b>	<b>472</b>	<b>495</b>	<b>217</b>	<b>51</b>

Restructuring provisions as of December 31, 2016 also include 163 million ( 199 million as of December 31, 2015) relating to a five-year commitment to Evotec regarding the Toulouse R&D site in France.

**D.19.3. Other provisions**

Other provisions include provisions for risks and litigation relating to environmental, tax, commercial and product liability matters.

( million)	2016	2015	2014
Tax exposures	1,077	1,530	1,469
Environmental risks and remediation	732	708	696
Product liability risks, litigation and other	968	908	911
<b>Total</b>	<b>2,777</b>	<b>3,146</b>	<b>3,076</b>

Provisions for tax exposures are recorded when Sanofi is exposed to a probable risk resulting from a tax position adopted by the company or a subsidiary, and the risk has been quantified at the end of the reporting period, in accordance with the principles described in Note B.22.

Provisions for environmental risks and remediation mainly relate to contingencies arising from business divestitures.

Identified environmental risks are covered by provisions estimated on the basis of the costs Sanofi believes it will be obliged to meet over a period not exceeding (other than in exceptional cases) 30 years. Sanofi expects that 153 million of those provisions will be utilized in 2017, and 350 million over the period from 2018 through 2021.

Product liability risks, litigation and other mainly comprises provisions for risks relating to product liability (including IBNR provisions as described in Note B.12.), government investigations, regulatory or antitrust law claims, or contingencies arising from business divestitures (other than environmental risks).

The main pending legal and arbitral proceedings and government investigations are described in Note D.22.

A full risk and litigation assessment is performed with the assistance of Sanofi's legal advisers, and provisions are recorded as required by circumstances in accordance with the principles described in Note B.12.

**D.19.4. Other current liabilities**

Other current liabilities comprise the following:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Taxes payable	1,134	1,044	948
Employee-related liabilities	1,967	1,920	1,912
Restructuring provisions (see Note D.19.2.)	676	581	564
Interest rate derivatives (see Note D.20.)	2	4	2
Currency derivatives (see Note D.20.)	130	78	214
Amounts payable for acquisitions of non-current assets	451	684	306
Other liabilities	5,815	5,131	3,766
<b>Total</b>	<b>10,175</b>	<b>9,442</b>	<b>7,712</b>

**F- 75**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

This item includes in particular the current portion of provisions for litigation, sales returns and other risks; amounts due to associates and joint ventures (see Note D.6.); and amounts due to governmental agencies and healthcare authorities (see Note D.23.).

**D.20. DERIVATIVE FINANCIAL INSTRUMENTS AND MARKET RISKS**

The table below shows the fair value of derivative instruments as of December 31, 2016, 2015 and 2014:

<i>( million)</i>	Non- current assets	Current assets	Total assets	Non- current liabilities	Current liabilities	Total liabilities	Fair value at December 31, 2016 (net)	Fair value at December 31, 2015 (net)	Fair value at December 31, 2014 (net)
Currency derivatives	3	105	108	-	(130)	(130)	(22)	(19)	(91)
<i>operating</i>	-	26	26	-	(51)	(51)	(25)	16	4
<i>financial</i>	3	79	82	-	(79)	(79)	3	(35)	(95)
Interest rate derivatives	99	3	102	-	(2)	(2)	100	152	302
<b>Total</b>	<b>102</b>	<b>108</b>	<b>210</b>	<b>-</b>	<b>(132)</b>	<b>(132)</b>	<b>78</b>	<b>133</b>	<b>211</b>

**Objectives of the use of derivative financial instruments**

Sanofi uses derivative instruments to manage operating exposure to movements in exchange rates, and financial exposure to movements in interest rates and exchange rates (where the debt or receivable is not contracted in the functional currency of the borrower or lender entity). On occasion, Sanofi uses equity derivatives in connection with the management of its portfolio of equity investments.

Sanofi performs periodic reviews of its transactions and contractual agreements in order to identify any embedded derivatives, which are accounted for separately from the host contract in accordance with IAS 39. Sanofi had no material embedded derivatives as of December 31, 2016, 2015 or 2014.

**Counterparty risk**

As of December 31, 2016, all currency and interest rate hedges were contracted with leading banks, and no single

counterparty accounted for more than 12% of the notional amount of Sanofi's overall currency and interest rate positions.

**a) Currency derivatives used to manage operating risk exposures**

Sanofi operates a foreign exchange risk hedging policy to reduce the exposure of operating income to exchange rate movements. This policy involves regular assessments of Sanofi's worldwide foreign currency exposure, based on foreign currency transactions carried out by the parent company and its subsidiaries. Those transactions mainly comprise sales, purchases, research costs, co-marketing and co-promotion expenses, and royalties. To reduce the exposure of those transactions to exchange rate movements, Sanofi contracts hedges using liquid derivative instruments, mainly forward currency purchases and sales, and also currency swaps.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows operating currency hedging instruments in place as of December 31, 2016, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2016 ( million)	Notional amount	Fair value	Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
			Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
<b>Forward currency sales</b>	<b>3,963</b>	<b>(25)</b>	-	-	-	<b>3,963</b>	<b>(25)</b>
<i>of which US dollar</i>	1,850	(17)	-	-	-	1,850	(17)
<i>of which Chinese yuan renminbi</i>	453	(2)	-	-	-	453	(2)
<i>of which Swiss franc</i>	253	(1)	-	-	-	253	(1)
<i>of which Japanese yen</i>	206	5	-	-	-	206	5
<i>of which Singapore dollar</i>	156	1	-	-	-	156	1
<b>Forward currency purchases</b>	<b>1,517</b>	-	-	-	-	<b>1,517</b>	-
<i>of which US dollar</i>	400	1	-	-	-	400	1
<i>of which Japanese yen</i>	283	(2)	-	-	-	283	(2)
<i>of which Singapore dollar</i>	233	1	-	-	-	233	1
<i>of which Swiss franc</i>	84	-	-	-	-	84	-
<i>of which Hungarian forint</i>	82	-	-	-	-	82	-
<b>Total</b>	<b>5,480</b>	<b>(25)</b>	-	-	-	<b>5,480</b>	<b>(25)</b>

The above positions mainly hedge future material foreign-currency cash flows arising after the end of the reporting period in relation to transactions carried out during the year ended December 31, 2016 and recognized in the balance sheet at that date. Gains and losses on hedging instruments (forward contracts) are calculated and recognized in parallel with the recognition of gains and losses on the hedged items. Due to this hedging relationship, the commercial foreign exchange profit or loss on these items (hedging instruments and hedged transactions) will be immaterial in 2017.

The table below shows operational currency hedging instruments in place as of December 31, 2015, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2015 ( million)	Notional amount	Fair value	Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting	
			Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
<b>Forward currency sales</b>	<b>2,142</b>	<b>27</b>	-	-	-	<b>2,142</b>	<b>27</b>
<i>of which US dollar</i>	672	(2)	-	-	-	672	(2)
<i>of which Chinese yuan renminbi</i>	339	1	-	-	-	339	1
<i>of which Japanese yen</i>	159	(1)	-	-	-	159	(1)
<i>of which Russian rouble</i>	130	22	-	-	-	130	22
<i>of which Singapore dollar</i>	114	-	-	-	-	114	-
<b>Forward currency purchases</b>	<b>905</b>	<b>(11)</b>	-	-	-	<b>905</b>	<b>(11)</b>

Edgar Filing: Sanofi - Form 20-F

<i>of which US dollar</i>	204	-	-	-	-	204	-
<i>of which Russian rouble</i>	109	(9)	-	-	-	109	(9)
<i>of which Singapore dollar</i>	104	(1)	-	-	-	104	(1)
<i>of which Hungarian forint</i>	90	(1)	-	-	-	90	(1)
<i>of which Chinese yuan renminbi</i>	86	2	-	-	-	86	2
<b>Total</b>	<b>3,047</b>	<b>16</b>	-	-	-	<b>3,047</b>	<b>16</b>

F- 77

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows operating currency hedging instruments in place as of December 31, 2014, with the notional amount translated into euros at the relevant closing exchange rate:

December 31, 2014	Notional amount	Of which derivatives designated as cash flow hedges			Of which derivatives not eligible for hedge accounting		
		Fair value	Notional amount	Fair value	Of which recognized in equity	Notional amount	Fair value
( million)							
<b>Forward currency sales</b>	<b>2,981</b>	<b>4</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>2,981</b>	<b>4</b>
<i>of which US dollar</i>	1,409	(34)	-	-	-	1,409	(34)
<i>of which Japanese yen</i>	273	5	-	-	-	273	5
<i>of which Chinese yuan renminbi</i>	237	(6)	-	-	-	237	(6)
<i>of which Russian rouble</i>	211	51	-	-	-	211	51
<i>of which Singapore dollar</i>	126	(1)	-	-	-	126	(1)
<b>Forward currency purchases</b>	<b>1,137</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>1,137</b>	<b>-</b>
<i>of which US dollar</i>	377	6	-	-	-	377	6
<i>of which Singapore dollar</i>	139	2	-	-	-	139	2
<i>of which Japanese yen</i>	109	-	-	-	-	109	-
<i>of which Hungarian forint</i>	99	(2)	-	-	-	99	(2)
<i>of which Mexican peso</i>	69	2	-	-	-	69	2
<b>Total</b>	<b>4,118</b>	<b>4</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>4,118</b>	<b>4</b>

**b) Currency and interest rate derivatives used to manage financial exposure**

The cash pooling arrangements for foreign subsidiaries outside the euro zone, and some of Sanofi's financing activities, expose certain Sanofi entities to financial foreign exchange risk (i.e. the risk of changes in the value of borrowings and loans denominated in a currency other than the functional currency of the borrower or lender). That foreign exchange exposure is hedged by Sanofi using firm financial instruments (usually currency swaps or forward contracts) contracted with banking counterparties.

The table below shows financial currency hedging instruments in place, with the notional amount translated into euros at the relevant closing exchange rate:

( million)	2016			2015			2014		
	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry	Notional amount	Fair value	Expiry
<b>Forward currency sales</b>	<b>5,298</b>	<b>(28)</b>		<b>3,472</b>	<b>(44)</b>		<b>5,869</b>	<b>(111)</b>	
<i>of which US dollar</i>	3,356	(37)	2017	2,171	(30)	2016	4,840	(111)	2015
<i>of which Japanese yen<sup>(a)</sup></i>	1,036	-	2017	612	(9)	2016	571	11	2015
<i>of which Pound sterling</i>	317	7	2017	117	1	2016	104	(2)	2015
<b>Forward currency purchases</b>	<b>5,980</b>	<b>31</b>		<b>2,623</b>	<b>9</b>		<b>2,686</b>	<b>16</b>	
<i>of which US dollar<sup>(b)</sup></i>	3,967	30	2017	610	5	2016	498	2	2015
<i>of which Singapore dollar</i>	878	5	2017	310	-	2016	563	5	2015
<i>of which Czech koruna</i>	332	(1)	2017	245	(1)	2016	137	(1)	2015
<b>Total</b>	<b>11,278</b>	<b>3</b>		<b>6,095</b>	<b>(35)</b>		<b>8,555</b>	<b>(95)</b>	

## Edgar Filing: Sanofi - Form 20-F

(a) *Includes JPY 41,712 million as of December 31, 2016 designated as a cash flow hedge in respect of cash flows forecast for 2017.*

(b) *Includes \$3,116 million as of December 31, 2016 designated as a cash flow hedge in respect of cash flows forecast for 2017 and the first quarter of 2018.*

**F- 78**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

These forward currency contracts generate a net financial foreign exchange gain or loss arising from the interest rate differential between the hedged currency and the euro, given that the foreign exchange gain or loss on the foreign-currency borrowings and loans is offset by the change in the intrinsic value of the hedging instruments. Sanofi may also hedge some future foreign-currency investment or divestment cash flows.

Since the financing of the Genzyme acquisition, Sanofi has managed its net debt in two currencies: the euro and the US dollar (see Note D.17.). The floating-rate portion of this debt exposes Sanofi to rises in interest rates, primarily in the Eonia and Euribor benchmark rates (for the euro) and in the US Libor and Federal Fund Effective rates (for the US dollar). To optimize the cost of debt or reduce the volatility of debt, Sanofi uses interest rate swaps, cross currency swaps and interest rate options to alter the fixed/floating rate split of debt. Such derivative instruments are predominantly denominated in euros and in US dollars.

The table below shows instruments of this type in place as of December 31, 2016:

(\$ million)	Notional amounts by expiry date as of December 31, 2016							Of which designated as fair value hedges		Of which designated as cash flow hedges		
	2017	2019	2020	2021	2022	2023	Total	Fair value	Notional amount	Fair value	Notional amount	Of which recognized in equity
<b>Interest rate swaps</b>												
pay capitalized Eonia / receive 1.58%	-	1,550	-	-	-	-	1,550	88	1,550	88	-	-
pay 3-month Euribor / receive 1.15%	428	-	-	-	-	-	428	3	428	3	-	-
pay 3-month US dollar Libor / receive 2.22%	-	-	475	-	-	-	475	10	475	10	-	-
pay 1.22% / receive 3-month & 6-month US dollar Libor	475	-	-	-	-	-	475	(2)	-	-	475	(2)
pay capitalized Eonia / receive -0.01%	-	-	-	-	300	-	300	1	300	1	-	-
<b>Total</b>	<b>903</b>	<b>1,550</b>	<b>475</b>	<b>-</b>	<b>300</b>	<b>-</b>	<b>3,228</b>	<b>100</b>	<b>2,753</b>	<b>102</b>	<b>475</b>	<b>(2)</b>

F- 79

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows instruments of this type in place as of December 31, 2015:

	Notional amounts by expiry date as of December 31, 2015							Fair value	Of which designated as fair value hedges		Of which designated as cash flow hedges		Of which Fairecognized value in equity
	2016	2017	2019	2020	2021	2022	Total		Notional amount	Fair value	Notional amount	Fairecognized value	
( million)													
<b>Interest rate swaps</b>													
pay 1-month Euribor +0.26% / receive 2.73%	500	-	-	-	-	-	500	14	500	14	-	-	-
pay capitalized Eonia / receive 1.90%	1,000	-	1,550	-	-	-	2,550	128	2,550	128	-	-	-
pay 3-month Euribor / receive 1.15%	-	428	-	-	-	-	428	3	-	-	-	-	-
pay 3-month US dollar Libor / receive 2.22%	-	-	-	459	-	-	459	14	459	14	-	-	-
pay 1.22% / receive 3-month & 6-month US dollar Libor	-	459	-	-	-	-	459	(2)	-	-	459	(2)	(1)
<b>Currency swaps hedging investments</b>													
pay JPY / receive	175	-	-	-	-	-	175	(4)	-	-	-	-	-
pay USD / receive	92	-	-	-	-	-	92	(1)	-	-	-	-	-
<b>Total</b>	<b>1,767</b>	<b>887</b>	<b>1,550</b>	<b>459</b>	<b>-</b>	<b>-</b>	<b>4,663</b>	<b>152</b>	<b>3,509</b>	<b>156</b>	<b>459</b>	<b>(2)</b>	<b>(1)</b>

**F- 80**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows instruments of this type in place as of December 31, 2014:

	Notional amounts by expiry date as of December 31, 2014								Of which designated as fair value hedges		Of which designated as cash flow hedges			
	2015	2016	2017	2019	2020	2021	Total	Fair value	Notional amount	Fair value	Notional amount	Fair value	Of which recognized in equity	
<i>( million)</i>														
<b>Interest rate swaps</b>														
pay 1-month Euribor +0.26% / receive 2.73%	-	500	-	-	-	-	500	26	500	26	-	-	-	-
pay capitalized Eonia / receive 1.90%	-	1,000	-	1,550	-	-	2,550	169	2,550	169	-	-	-	-
pay 3-month Euribor / receive 1.15%	-	-	428	-	-	-	428	3	-	-	-	-	-	-
pay 3-month US dollar Libor / receive 2.22%	-	-	-	-	412	-	412	10	412	10	-	-	-	-
pay 1.22% / receive 3-month & 6-month US dollar Libor	-	-	412	-	-	-	412	(2)	-	-	412	(2)	-	-
<b>Cross-currency swaps</b>														
Pay 4.87% / receive CHF 3.38%	244	-	-	-	-	-	244	89	-	-	244	89	1	-
<b>Currency swaps hedging investments</b>														
pay JPY / receive	530	-	-	-	-	-	530	7	-	-	-	-	-	-
<b>Total</b>	<b>774</b>	<b>1,500</b>	<b>840</b>	<b>1,550</b>	<b>412</b>	<b>-</b>	<b>5,076</b>	<b>302</b>	<b>3,462</b>	<b>205</b>	<b>656</b>	<b>87</b>	<b>1</b>	<b>-</b>

F- 81

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****c) Actual or potential effects of netting arrangements**

The table below is prepared in accordance with the accounting policies described in Note B.8.3.:

( million)	2016		2015		2014	
	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities	Derivative financial assets	Derivative financial liabilities
Gross carrying amounts before offset (a)	210	(132)	218	(85)	428	(217)
Gross amounts offset (in accordance with IAS 32) (b)	-	-	-	-	-	-
<b>Net amounts as reported in the balance sheet (a) (b) = (c)</b>	<b>210</b>	<b>(132)</b>	<b>218</b>	<b>(85)</b>	<b>428</b>	<b>(217)</b>
<b>Effects of other netting arrangements (not fulfilling the IAS 32 criteria for offsetting) (d)</b>						
Financial instruments	(97)	97	(66)	66	(192)	192
Fair value of financial collateral	N/A	N/A	N/A	N/A	N/A	N/A
<b>Net exposure (c) + (d)</b>	<b>113</b>	<b>(35)</b>	<b>152</b>	<b>(19)</b>	<b>236</b>	<b>(25)</b>

**D.21. OFF-BALANCE SHEET COMMITMENTS**

The off balance sheet commitments presented below are shown at their nominal value and do not include the commitments of the held-for-exchange Animal Health business.

**D.21.1. Off balance sheet commitments relating to operating activities**

Off balance sheet commitments relating to Sanofi's operating activities comprise the following:

December 31, 2016	Total	Payments due by period			
		Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
( million)					
Operating leases <sup>(a)</sup>	1,507	261	407	283	556
Irrevocable purchase commitments <sup>(b)</sup>					
· given <sup>(c)</sup>	4,192	2,710	992	187	303
· received	(229)	(123)	(68)	(14)	(24)
Research and development license agreements					
· commitments related to R&D and other commitments <sup>(d)</sup>	1,572	696	535	289	52
· potential milestone payments <sup>(e)</sup>	2,072	80	783	211	998
Firm commitments under the agreement with BMS <sup>(f)</sup>	120	120	-	-	-
<b>Total</b>	<b>9,234</b>	<b>3,744</b>	<b>2,649</b>	<b>956</b>	<b>1,885</b>

## Edgar Filing: Sanofi - Form 20-F

- (a) *Operating leases as of December 31, 2016 include 85 million of commitments to joint ventures.*
  
- (b) *These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments (see Note D.3.) and (ii) goods and services. As of December 31, 2015, irrevocable purchase commitments amounted to 4,007 million given and 268 million received.*
  
- (c) *Irrevocable purchase commitments given as of December 31, 2016 include 419 million of commitments to joint ventures.*
  
- (d) *Commitments related to R&D and other commitments amounted to 1,932 million as of December 31, 2015.*
  
- (e) *This line includes only potential milestone payments on projects regarded as reasonably possible, i.e. on projects in the development phase. Potential milestone payments as of December 31, 2015 amounted to 3,536 million.*
  
- (f) *See Note C.2.*

**F- 82**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Operating leases**

Sanofi leases some of the property and equipment used in the ordinary course of business under operating leases. The majority of future operating lease rental commitments relate to real estate assets; the remainder relate to vehicles and other leased assets. Future minimum lease payments due under non-cancelable operating leases as of December 31, 2016 were 1,507 million (versus 1,567 million as of December 31, 2015 and 1,235 million as of December 31, 2014).

Total rental expense recognized in the year ended December 31, 2016 was 309 million (versus 340 million in the year ended December 31, 2015 and 317 million in the year ended December 31, 2014).

**Research and development license agreements**

In pursuance of its strategy, Sanofi may acquire technologies and rights to products. Such acquisitions may be made in various contractual forms: acquisitions of shares, loans, license agreements, joint development, and co-marketing. These arrangements generally involve upfront payments on signature of the agreement, development milestone payments, and royalties. Some of these complex agreements include undertakings to fund research programs in future years and payments contingent upon achieving specified development milestones, the granting of approvals or licenses, or the attainment of sales targets once a product is commercialized.

The Research and development license agreements line comprises future service commitments to fund research and development or technology, and potential milestone payments regarded as reasonably possible (i.e. all potential milestone payments relating to projects in the development phase, for which the future financial consequences are known and considered as probable and for which there is a sufficiently reliable estimate). It excludes commitments relating to projects in the research phase ( 6.2 billion in 2016, 4.7 billion in 2015, 4.2 billion in 2014), and payments contingent upon the attainment of sales targets once a product is commercialized ( 8.2 billion in 2016, 8.0 billion in 2015, 4.7 billion in 2014).

The major agreements entered into during 2016 were as follows:

- On December 28, 2016, Sanofi and Hanmi Pharmaceutical Co., Ltd. entered into an amendment to the initial license agreement signed on November 5, 2015. Under the terms of the amendment, Sanofi had to return to Hanmi the rights for a weekly-administered insulin, and Hanmi must at its expense assume responsibility for developing the weekly-administered efpeglenatide/insulin combination for a certain period of time, with other contractual terms relating to the combination remaining unchanged. The financial terms of the efpeglenatide collaboration as regards development and registration milestone payments, Hanmi's entitlement to other revenues and Hanmi's contribution to the development costs of efpeglenatide were also amended. In return, Hanmi has agreed to pay 196 million to Sanofi.
- On December 5, 2016, Sanofi and JHL Biotech, Inc. announced a strategic alliance to collaborate on developing and commercializing biological therapeutic treatments in China, with the potential for international expansion. JHL will retain responsibility for development, registration and production, while Sanofi will be responsible for commercialization.
- On March 16, 2016, Sanofi and DiCE Molecules announced a five-year global collaboration to discover potential new therapeutics for up to 12 targets that encompass all disease areas of strategic interest to Sanofi. The collaboration builds upon DiCE's unique technology platform, which leverages directed evolution to select and optimize low molecular weight compounds.

## Edgar Filing: Sanofi - Form 20-F

On January 11, 2016, Sanofi and Innate Pharma announced that they had entered into a collaboration and licensing agreement to apply Innate Pharma's new proprietary technology to the development of innovative bispecific antibody formats engaging natural killer (NK) cells to kill tumor cells through the activating receptor NKp46.

Also on January 11, 2016, Sanofi and Warp Drive Bio (Warp Drive) announced that they had extended and reshaped their existing collaboration utilizing Warp Drive's proprietary SMART (Small Molecule Assisted Receptor Targeting) and Genome Mining platforms to discover novel oncology therapeutics and antibiotics.

Other major agreements entered into by Sanofi in prior years are described below:

Lexicon Pharmaceuticals, Inc. (2015): collaboration and license agreement to develop and commercialize sotagliflozine, an investigational dual inhibitor of sodium-glucose cotransporters 1 and 2 (SGLT-1 and SGLT-2);

BioNTech A.G. (2015): exclusive collaboration and license agreement to discover and develop up to five cancer immunotherapies;

Evotec AG and Apeiron Biologics AG (2015): collaboration and license agreement to discover and develop first-in-class small molecule-based immuno-oncology therapies to treat solid and hematological cancers;

Evotec International GmbH (2015): strategic research collaboration to develop beta cell-modulating diabetes treatments, which may reduce or eliminate the need for insulin injections;

**F- 83**

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

- Regeneron (2015): collaboration agreement on the discovery, development and commercialization of antibodies in the field of immuno-oncology (see Note C.1.);
  - Regeneron (2015): amendment to the September 2003 collaboration agreement on the development and commercialization of Zaltrap® (afibercept) (see Note C.1.);
  - Lead Pharma (2015): research collaboration and license agreement for the discovery, development and commercialization of small-molecule therapies directed against ROR gamma t nuclear hormone receptors to treat auto-immune disorders;
  - Voyager Therapeutics (2015): collaboration agreement for the discovery, development and commercialization of new gene therapies to treat serious disorders of the central nervous system;
  - Immune Design (2014): license agreement for the use of Immune Design's GLAAS® research platform to develop therapeutic agents capable of treating an identified food allergy;
  - Eli Lilly and Company (2014): agreement to pursue regulatory approval for non-prescription Cialis® (tadalafil);
  - Alnylam Pharmaceuticals, Inc. (2014): extension of the strategic agreement to develop and commercialize treatments for rare genetic diseases;
  - UCB (2014): scientific and strategic collaboration for the discovery and development of innovative anti-inflammatory small molecules, which have the potential to treat a wide range of immune-mediated diseases in areas such as gastroenterology and arthritis;
  - Ascendis (2010): licensing and patent transfer agreement on Transcon Linker and Hydrogel Carrier technology. The agreement will enable Sanofi to develop, manufacture and commercialize products combining this technology with active molecules for the treatment of diabetes and related disorders;
  - Avila Therapeutics, Inc. (acquired by Celgene Corporation in 2012): 2010 alliance to discover target covalent drugs for the treatment of cancers, directed towards six signaling proteins that are critical in tumor cells;
  - Regulus Therapeutics, Inc. (2010): discovery, development and commercialization of novel micro-RNA therapeutics in fibrosis; and
  - Exelixis, Inc. (2009): global license agreement for XL765.
- Sanofi and Selecta Biosciences have decided to end their collaboration (dating from 2012) to identify and develop food allergy treatments. Consequently, the commitments arising under this agreement are no longer included as of December 31, 2016.

**Other agreements**

Sanofi has entered into two agreements, with Royalty Pharma (December 2014) and Novaquest (December 2015), which have similar characteristics in that the partners jointly bear a portion of the remaining development cost of the project on a quarterly basis in return for a share of future sales. These transactions are co-investments, whereby the partner acquires an interest in the jointly-developed product by providing funding towards the development program. Consequently, the amounts received by Sanofi will be recorded as a reduction in development costs, to the extent that the development costs incurred by Sanofi are recognized in profit or loss in accordance with the policies described in Note B.4.1.

In February 2014, pursuant to the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits, Sanofi Pasteur and the World Health Organization (WHO) signed a Standard Material Transfer Agreement (SMTA 2). This agreement stipulates that Sanofi Pasteur will, during declared pandemic periods, (i) donate 7.5% of its real-time production of pandemic vaccines against any strain with potential to cause a pandemic, and (ii) reserve a further 7.5% of such production on affordable terms. The agreement cancels and replaces all preceding commitments to donate pandemic vaccines to the WHO.

**D.21.2. Off balance sheet commitments relating to financing activities**

**Credit facilities**

Undrawn credit facilities are as follows:

December 31, 2016		Expiry			
( million)	Total	Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
General-purpose credit facilities	8,000	-	-	8,000	-

**F- 84**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

As of December 31, 2016, total credit facilities amounted to 8,000 million (compared with 8,000 million as of December 31, 2015 and 8,013 million as of December 31, 2014).

**Guarantees**

The table below shows the amount of guarantees given and received:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Guarantees given:</b>	<b>3,946</b>	<b>3,972</b>	<b>3,727</b>
· Guarantees provided to banks in connection with credit facilities	2,189	2,260	2,694
· Other guarantees given	1,757	1,712	1,033
<b>Guarantees received</b>	<b>(211)</b>	<b>(187)</b>	<b>(181)</b>

**D.21.3. Off balance sheet commitments relating to Sanofi entities and business combinations**

Funding commitments to associates and joint ventures are disclosed in Note D.6.

The maximum amount of contingent consideration relating to business combinations is disclosed in Note D.18.

**D.22. LEGAL AND ARBITRAL PROCEEDINGS**

Sanofi and its affiliates are involved in litigation, arbitration and other legal proceedings. These proceedings typically are related to product liability claims, intellectual property rights (particularly claims against generic companies seeking to limit the patent protection of Sanofi products), competition law and trade practices, commercial claims, employment and wrongful discharge claims, tax assessment claims, waste disposal and pollution claims, and claims under warranties or indemnification arrangements relating to business divestitures. Provisions related to legal and arbitral proceedings are recorded in accordance with the principles described in Note B.12.

Most of the issues raised by these claims are highly complex and subject to substantial uncertainties; therefore, the probability of loss and an estimation of damages are difficult to ascertain. Contingent liabilities are cases for which either we are unable to make a reasonable estimate of the expected financial effect that will result from ultimate resolution of the proceeding, or a cash outflow is not probable. In either case, a brief description of the nature of the contingent liability is disclosed and, where practicable, an estimate of its financial effect, an indication of the uncertainties relating to the amount and timing of any outflow, and the possibility of any reimbursement are provided in application of paragraph 86 of IAS 37.

In the cases that have been settled or adjudicated, or where quantifiable fines and penalties have been assessed, we have indicated our losses or the amount of provision accrued that is the estimate of the probable loss.

In a limited number of ongoing cases, while we are able to make a reasonable estimate of the expected loss or range of the possible loss and have accrued a provision for such loss, we believe that publication of this information on a case-by-case basis or by class would seriously prejudice the Company's position in the ongoing legal proceedings or in any related settlement discussions. Accordingly, in those cases, we have disclosed information with respect to the nature of the contingency but have not disclosed our estimate of the range of potential loss, in accordance with paragraph 92 of IAS 37.

## Edgar Filing: Sanofi - Form 20-F

These assessments can involve a series of complex judgments about future events and can rely heavily on estimates and assumptions. Our assessments are based on estimates and assumptions that have been deemed reasonable by management. We believe that the aggregate provisions recorded for the above matters are adequate based upon currently available information. However, given the inherent uncertainties related to these cases and involved in estimating contingent liabilities, we could in the future incur judgments that could have a material adverse effect on our net income in any particular period.

Long term provisions are disclosed in Note D.19. They include:

- Provisions for product liability risks, litigation and other amount to 968 million in 2016. These provisions are mainly related to product liabilities, government investigations, competition law, regulatory claims, warranties in connection with certain contingent liabilities arising from business divestitures other than environmental matters and other claims.
- Provisions for environmental risks and remediation amount to 732 million in 2016, the majority of which are related to contingencies that have arisen from business divestitures.

**F- 85**

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*a) Products*

**Sanofi Pasteur Hepatitis B Vaccine Product Litigation**

Since 1996, more than 180 lawsuits have been filed in various French civil courts against Sanofi Pasteur and/or Sanofi Pasteur MSD S.N.C., the former a French subsidiary of Sanofi, and the latter a joint venture company with Merck & Co., Inc. now terminated, for which past ongoing litigation is now managed by the originating party. In such lawsuits, the plaintiffs allege that they suffer from a variety of neurological disorders and autoimmune diseases, including multiple sclerosis and Guillain-Barré syndrome as a result of receiving the hepatitis B vaccine. To date, only one claim decided against the company has been upheld by the French Supreme Court (*Cour de Cassation*).

In January 2008, both the legal entity Sanofi Pasteur MSD S.N.C., and a corporate officer of this company, as well as, a former corporate officer of Sanofi Pasteur, were placed under investigation in an ongoing criminal inquiry in France relating to alleged side effects caused by the hepatitis B vaccine. In March 2012, Sanofi Pasteur and the former pharmacist in charge, deputy chief executive officer of Sanofi Pasteur were placed under an advised witness status.

**Plavix® Product Litigation in the U.S.**

As of December 31, 2016, around 1,019 lawsuits, involving approximately 5,366 claimants (but 4,393 ingesting plaintiffs) have been filed against affiliates of Sanofi and Bristol-Myers Squibb seeking recovery under U.S. state law for personal injuries allegedly sustained in connection with the use of Plavix®. The actions are held in several jurisdictions, including the federal and/or state courts of New Jersey, New York, California, and Delaware. It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on the Company.

**Taxotere® Product Litigation in the U.S.**

As of December 31, 2016, around 791 lawsuits, involving approximately 944 claimants (but 868 ingesting plaintiffs) have been filed against affiliates of Sanofi under U.S. state law for personal injuries allegedly sustained in connection with the use of Taxotere®. The actions are held in several jurisdictions, including the federal and/or state courts of Louisiana, Missouri, New Jersey, California, and Delaware. It is not possible, at this stage, to assess reliably the outcome of these lawsuits or the potential financial impact on the Company.

**Depakine® Product Litigation in France**

As of January 25, 2017, 29 individual claims and a potential class action have been filed against a French affiliate of Sanofi seeking indemnification under French law for personal injuries allegedly sustained by children in connection with the use of Depakine®, a sodium valproate

antiepileptic treatment, by the mothers during pregnancy. These actions are held in several jurisdictions in France. An investigation is ongoing in relation to a criminal complaint against person unknown filed in May 2015.

The French government has, through the 2017 Finance law adopted on December 29, 2016, set up a public fund which is meant to compensate loss or injury actually suffered in relation to the prescription of sodium valproate and its derivatives.

It is not possible, at this stage, to assess reliably the outcome of these cases or the potential financial impact on the Company.

*b) Patents*

### **Ramipril Canada Patent Litigation**

Sanofi has been involved in a number of legal proceedings involving companies which market generic Altace® (ramipril) in Canada. Notwithstanding proceedings initiated by Sanofi, eight manufacturers obtained marketing authorizations from the Canadian Minister of Health for generic versions of ramipril in Canada. Following the marketing of these products, Sanofi filed patent infringement actions against all those companies. In a patent infringement action, the Federal Court of Canada ruled on June 29, 2009 that the patent asserted by Sanofi was invalid. Sanofi's leave to appeal the judgment was denied in 2012. Each of Teva, Apotex and Riva initiated Section 8 damages claims against Sanofi, seeking compensation for their alleged inability to market a generic ramipril during the time taken to resolve the proceedings against the Canadian Ministry of Health. Sanofi and Teva reached an agreement in June 2012 on a confidential amount to satisfy Teva's claim and in November 2012, Apotex was awarded CAD221 million.

Sanofi appealed both rulings. In March 2014, the Federal Court of Appeal dismissed Sanofi's appeal with respect to Teva and issued a decision in the appeal with respect to Apotex increasing Apotex's damages award, and costs of all appeals (not including costs associated with underlying trial). In May 2014, Sanofi and Apotex executed a settlement agreement in satisfaction of the Federal Court of Appeal's increased damages judgment. On April 20, 2015, the Supreme Court of Canada dismissed Sanofi's appeal of the Court of Appeal decision with respect to Apotex, thereby affirming the decision of the Court of Appeal. The Riva Section 8 case, which had been stayed pending resolution of the Supreme Court Appeal, was settled following court-sponsored mediation in September 2015.

In June 2011, while the Section 8 damages action was proceeding in Federal Court, Apotex commenced an action in the Ontario Superior Court of Justice asserting damages pursuant to, inter alia, the Ontario Statute of Monopolies, the U.K. Statute of Monopolies, and the Trade-marks Act (the Ontario Action). The Ontario Action was stayed pending

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

exhaustion of appeals in the Section 8 damages action and, despite having received full compensation in the Section 8 action, was reinitiated by Apotex after the conclusion of the appeals.

**Praluent® (alirocumab)-related Amgen Patent Litigation in the U.S.**

Amgen filed four separate complaints against Sanofi in the U.S. asserting patent infringement on October 17, October 28, November 11, and November 18, 2014 based on Sanofi and Regeneron plans to submit a U.S. Biologic License Application for alirocumab. Together these complaints allege that Sanofi's alirocumab product infringes seven patents and seek injunctive relief and unspecified damages. These cases were consolidated into one case in December 2014. In March 2016, a jury verdict upheld the validity of Amgen's asserted claims of two patents for antibodies targeting PCSK9. Further, in March 2016, Sanofi, Regeneron and Amgen resolved part of the proceedings related to certain past damages that is contingent on the outcome of our future appeal. In January 2017, the District Court denied Sanofi and Regeneron's motion for a new trial and their motion for Judgment as a Matter of Law (JMOL) and granted an injunction preventing the marketing, selling or manufacturing of Praluent® in the U.S. during the term of the two Amgen patents starting from February 21, 2017. Sanofi and Regeneron have filed a motion to the Court of Appeals to stay the injunction pending the appeal. Sanofi and Regeneron have also appealed the adverse rulings in this case.

**Praluent® (alirocumab)-related Amgen Patent Litigation in Europe**

Amgen has filed three separate patent infringement lawsuits against Sanofi and Regeneron in Europe. On July 25, 2016, Amgen filed a lawsuit in the UK High Court of Justice, Chancery Division Patents Court against five Sanofi entities and Regeneron alleging that alirocumab infringes its 124 (UK) patent, seeking injunctive relief and unspecified damages. Also on July 25, 2016, Amgen filed a lawsuit in Germany in the Regional Court, Dusseldorf against three Sanofi entities and Regeneron alleging that alirocumab infringes its 124 (DE) patent, seeking injunctive relief and unspecified damages. On September 26, 2016, Amgen filed a lawsuit in France in the *Tribunal de Grande Instance* of Paris against two Sanofi entities and Regeneron alleging that alirocumab infringes its 124 (FR) patent, seeking injunctive relief and unspecified damages.

**Praluent® (alirocumab)-related EPO Patent Oppositions**

The European Patent Office (EPO) granted Amgen's European Patent EP2215124 on February 24, 2016. Also on February 24, 2016, Sanofi filed an opposition with the EPO requesting the revocation of Amgen's 124 patent in its entirety for all contracting states on the grounds that the

subject-matter of the opposed patent is not patentable. On November 24, 2016, Sanofi filed a second opposition (in the name of three Sanofi affiliates named as defendants in the German infringement action – see above), and Regeneron filed a separate opposition, requesting revocation of Amgen's 124 patent.

**Praluent® (alirocumab)-related Genentech Patent Litigation in the U.S.**

In July 2015, Sanofi and Regeneron filed administrative and judicial actions against Genentech, Inc. and City of Hope (COH) concerning certain patents on making recombinant antibodies. The administrative action (an Inter Partes Review (IPR)) was filed in the United States Patent & Trademark Office (USPTO) against U.S. Patent No. 6,331,415 ( Cabilly II ) and asserts that prior art anticipates or renders obvious the claims of the noted patent. The judicial action was filed in the United States District Court for the Central District of California and contends that U.S. Patent No. 7,923,221 ( Cabilly III ) is invalid.

In September 2015, Genentech/COH filed a response to Sanofi's judicial action and asserted counterclaims of infringement of Cabilly III and seeks injunctive relief and unspecified damages. In August 2016, the parties agreed to settle all claims and counterclaims between them in various proceedings relating to the Cabilly patents and at parties' request, the District Court and USPTO subsequently dismissed the instant cases. Thus, these matters are closed.

**Lyxumia® (lixisenatide)-related Patent Litigation in the U.S.**

In July 2015, Sanofi filed a judicial action against AstraZeneca Pharmaceuticals LP (AZ) and Amylin Pharmaceuticals, LLC (Amylin) in relation to certain patents concerning GLP-1 agonists and formulations thereof. The action was filed in the United States District Court for the District of Delaware and contends that U.S. Patent Nos. 6,902,744; 7,399,489; and 7,521,423 assigned to AZ/Amylin are invalid and/or not infringed. In addition, in December 2015, Sanofi filed four Inter Partes Reviews (IPRs) in the U.S. Patent & Trademark Office against four separate patents (U.S. Patent Nos. 7,297,761; 7,691,963; 8,445,647; 8,951,962) assigned to AZ/Amylin, asserting that prior art anticipates or renders obvious the claims of the noted patents.

In December 2015, AZ/Amylin filed a response to Sanofi's judicial action and asserted counterclaims of infringement of four U.S. patents (U.S. Patent Nos. 7,399,489; 7,691,963; 8,445,647; 8,951,962) and seek injunctive relief and unspecified damages.

In September 2016, Sanofi and AZ agreed to settle all claims and counterclaims between them in various proceedings relating to exendins or exendin variants. At parties' request, the District Court and USPTO subsequently dismissed the instant cases. Thus, these matters are closed.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Plavix® Litigation (Commonwealth) in Australia**

In August 2007, GenRX (a subsidiary of Apotex) obtained registration of a generic clopidogrel bisulfate product on the Australian Register of Therapeutic Goods. At the same time, GenRX filed a patent invalidation action with the Federal Court of Australia, seeking revocation of Sanofi's Australian enantiomer patent claiming clopidogrel salts (a nullity action). In September 2007, Sanofi obtained a preliminary injunction from the Federal Court preventing commercial launch of this generic clopidogrel bisulfate product until judgment on the substantive issues of patent validity and infringement. In February 2008, Spirit Pharmaceuticals Pty. Ltd. also filed a nullity action against Sanofi's Australian enantiomer patent. The Spirit proceeding was consolidated with the Apotex proceeding.

In August 2008, the Australian Federal Court confirmed that the claim in Sanofi's Australian enantiomer patent directed to clopidogrel bisulfate (the salt form in Plavix®) was valid and the patent infringed. On appeal, the Full Federal Court of Australia held in September 2009 that all claims in the patent are invalid. Sanofi's appeal to the Australia High Court was denied in March 2010. The security bond posted by Sanofi in connection with the preliminary injunction obtained in 2007 was subsequently increased from AUD40 million to AUD204 million (27 million to 140 million as of December 31, 2016). Apotex sought damages in the range of AUD20 million to AUD236 million (14 million to 62 million as of December 31, 2016), plus interest for having been subject to an injunction.

On April 8, 2013, the Australian Department of Health and Ageing filed an application before the Federal Court of Australia seeking payment of damages from Sanofi related to the Apotex preliminary injunction amounting to a range of AUD375 million to AUD529 million (257 million to 363 million as of December 31, 2016), plus interest.

Sanofi and BMS settled the patent litigation with Apotex in November 2014. In light of the Apotex settlement, the Commonwealth has requested that the Court consider a set of legal issues separate from trial that could simplify the trial. In December 2015, the Court held that the relevant statute does not preclude the Commonwealth from seeking damages in cases such as this. Sanofi and BMS have applied for special leave to appeal against this decision.

Sanofi's special appeal to the High Court on the issue of the invalidity of the patent was denied in November 2015. In May 2016, Sanofi's and BMS's application for special leave to appeal to the High Court of Australia was denied. Consequently, the substantive claim on damages sought by the Commonwealth will continue to trial.

***c) Government Investigations, Competition Law and Regulatory Claims*****Lovenox® Antitrust Litigation**

In August 2008, Eisai Inc. (Eisai) brought suit against Sanofi U.S. LLC and Sanofi U.S. Inc. (collectively, Sanofi U.S.) in the U.S. District Court for the District of New Jersey alleging that certain contracting practices for Lovenox® violate federal and state antitrust laws. In March 2014, the Court issued an order granting Sanofi U.S.'s motion for summary judgment on liability and dismissing the case. This decision was upheld in appeal in May 2016.

In July 2016, the parties reached an agreement in principle to resolve all remaining issues at stake in the Federal antitrust litigation, as well as, a separate litigation that had been pending in New Jersey State court. This case is closed.

**U.S. Antitrust/Menactra® Vaccine Pasteur**

In December 2011, a class action was filed in the New Jersey Federal District Court alleging that Sanofi Pasteur Inc. violated Sections 1 and 2 of the Sherman Act by unlawfully monopolizing and restraining trade in the meningococcal market and seeking treble damages and other remedies for alleged anticompetitive overcharges. On August 6, 2012, the Court denied Sanofi Pasteur's motion to dismiss. In September 2015, the Court certified a class, which (subject to certain exclusions), consists of all persons or entities in the United States that purchased Menactra® directly

## Edgar Filing: Sanofi - Form 20-F

from Sanofi Pasteur or its affiliates after March 1, 2010. In December 2016, the case was settled for an amount of US\$61.5 million.

### **Cipro® Antitrust Litigation**

In January 1997, patent litigation regarding the prescription drug Cipro® and involving Barr Laboratories ( Barr ) and Bayer was settled. Hoechst Marion Roussel, Inc. (one of Sanofi's predecessors) ( HMR ), had assisted Barr in funding Barr's challenge of Bayer's patent and was a party to the settlement.

Starting in 2000, both direct purchasers and indirect purchasers filed antitrust lawsuits challenging the Cipro settlement in state and federal courts across the country.

All of the federal cases were coordinated in a federal multidistrict litigation proceeding ( MDL ) in the Eastern District of New York. In 2005, summary judgment was granted in the MDL, with the Court finding that because the settlement was within the scope of the patent, there was no antitrust violation.

The grant of summary judgment in the federal cases was affirmed in the Second and Federal Circuits, and the Supreme Court denied certiorari in the Cipro® cases in 2009 (Federal Circuit) and 2011 (Second Circuit).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

However, in 2013, in a case not involving Sanofi, the U.S. Supreme Court rejected the scope of the patent test in the *FTC v. Actavis* case, while a parallel State Court litigation over the Cipro<sup>®</sup> settlement was still pending in California. A settlement of US\$100 million was reached with California plaintiffs, which was paid in September 2016.

***d) Other litigation and arbitration*****U.S. Shareholder Securities Class Action**

In December 2014, a putative class action lawsuit was filed in the U.S. District Court for the Southern District of New York on behalf of purchasers of Sanofi American Depositary Shares. The complaint, which named Sanofi and certain of its current and former officers as defendants and asserted claims under the Securities Exchange Act of 1934, alleged that Sanofi's public disclosures failed to disclose that Sanofi (i) was making improper payments to healthcare professionals in violation of federal law and (ii) lacked internal controls over financial reporting, which allegedly inflated the price of its securities. In February 2015, a related putative class action lawsuit was filed in the Southern District of New York, alleging the same misconduct, but asserting claims under the Securities Act of 1933. In March 2015, the cases were consolidated, and in May 2015, the plaintiffs filed a consolidated amended complaint, naming Sanofi and its former CEO as defendants and asserting claims under the Exchange Act. In August 2015, the defendants moved to dismiss the consolidated amended complaint, and in January 2016, the Court granted that motion. On February 4, 2016, the plaintiffs filed a motion for reconsideration of the Court's January 2016 dismissal order and for leave to amend the consolidated amended complaint. On June 24, 2016, the Court denied plaintiffs' motion for reconsideration and for leave to amend the consolidated amended complaint. On July 25, 2016, plaintiffs filed a notice of appeal to the U.S. Court of Appeals for the Second Circuit of (i) the District Court's January 2016 decision granting defendants' motion to dismiss and (ii) the District Court's June 2016 decision denying plaintiffs' motion for reconsideration and leave to amend. On November 4, 2016, plaintiffs moved for a voluntary dismissal of the appeal with prejudice. On November 7, 2016, the U.S. Court of Appeals for the Second Circuit granted plaintiffs' motion. The case is over.

**U.S. CVR Securities Class Action**

In December 2013, two putative class action lawsuits were filed in the U.S. District Court for the Southern District of New York on behalf of holders of contingent value rights (CVRs) issued in connection with Sanofi's acquisition of Genzyme in 2011. The complaints, which named Sanofi and certain of its officers as defendants and asserted claims under the Exchange Act, alleged that Sanofi's public disclosures materially misrepresented (i) the efficacy and safety of Lemtrada<sup>®</sup> (alemtuzumab) and (ii) the design of two Lemtrada<sup>®</sup> clinical trials, CARE-MS I and CARE-MS II. Such

alleged misrepresentations, according to the complaints, caused an artificial inflation in the price of the CVRs. In March 2014, the cases were consolidated. Also in March 2014, an additional group of 32 purported CVR holders filed a lawsuit in the Southern District of New York against Sanofi, Genzyme and certain of their officers (the AG Funds Action), asserting claims under the Exchange Act, the Securities Act and California, Massachusetts and Minnesota state law, based on alleged material misrepresentations and omissions regarding Lemtrada<sup>®</sup>, its development and likelihood of success before the U.S. Food and Drug Administration. In April 2014, the plaintiff in the consolidated putative class action (the Consolidated Action) filed an amended shareholder class action complaint, which named Sanofi and certain of its officers as defendants and asserted claims under the Exchange Act. In June 2014, the defendants in the Consolidated and AG Funds Actions filed a motion to dismiss the complaints, and on January 28, 2015, the Court granted that motion. The plaintiffs appealed the dismissals to the U.S. Court of Appeals for the Second Circuit. On March 4, 2016, the U.S. Court of Appeals for the Second Circuit affirmed the decision of the District Court in both actions. The case is over.

**CVR Trustee Claim**

In November 2015, American Stock Transfer & Trust Company LLC (AST), the Trustee of the CVR Agreement between AST and Sanofi-Aventis, dated March 30, 2011, filed a complaint against Sanofi in the U.S. District Court for the Southern District of New York, alleging that Sanofi breached the CVR Agreement and the implied covenant of good faith and fair dealing, including by allegedly failing to use Diligent

## Edgar Filing: Sanofi - Form 20-F

Efforts, as defined in the CVR Agreement, with respect to the regulatory approval and sale of Lemtrada.

On January 29, 2016, Sanofi moved to dismiss Counts II (breach of contract relating to the Product Sales Milestones) and III (breach of the implied covenant of good faith and fair dealing) of the complaint. In May 2016, AST submitted a notice of resignation as Trustee. Before the resignation became effective, AST filed a Supplemental Complaint seeking the entry of a declaratory judgment that it is entitled to, among other things, reimbursement for legal fees and expenses incurred by its outside counsel for the investigation and prosecution of the claims in the case under the CVR Agreement. In June 2016, a new Trustee, UMB Bank, N.A. ( UMB ) was appointed. In July 2016, UMB moved for partial summary judgment on its declaratory judgment claim seeking, among other things, the reimbursement of legal fees and expenses incurred by its outside counsel for the investigation and prosecution of the claims in the case. In September 2016, the Court issued an order denying (in part) Sanofi's motion to dismiss Count II of the complaint, granting Sanofi's motion to dismiss Count III of the complaint in its entirety, and denying UMB's motion for partial summary judgment relating to its request for the payment of the fees.

**F- 89**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

and expenses incurred by its outside counsel. In October 2016, UMB appealed the portion of the order denying its motion for partial summary judgment to the U.S. Court of Appeals for the Second Circuit. In December 2016, the U.S. Court of Appeals for the Second Circuit granted Sanofi's motion to dismiss the appeal for lack of appellate jurisdiction. Discovery is ongoing.

***e) Contingencies arising from certain Business Divestitures***

Sanofi and its subsidiaries, Hoechst and Aventis Agriculture, divested a variety of mostly chemical, including agro-chemical, businesses as well as certain health product businesses in previous years. As a result of these divestitures, the Group is subject to a number of ongoing contractual and legal obligations regarding the state of the sold businesses, their assets, and their liabilities.

**Aventis Behring Retained Liabilities**

The divestment of Aventis Behring and related protein therapies assets became effective on March 31, 2004. The purchase agreement contained customary representations and warranties running from Sanofi as seller to CSL Limited as purchaser. Sanofi has indemnification obligations that generally expired on March 31, 2006 (the second anniversary of the closing date). However, some indemnification obligations, having a longer duration, remain in effect. For example, indemnification obligations relating to the due organization, capital stock and ownership of Aventis Behring Companies ran through March 31, 2014, and product liability indemnification runs through March 31, 2019, subject to an extension for claims related to certain types of product liability notified before such date. Furthermore, for tax-related issues, the indemnification obligation of Sanofi covers all taxable periods that end on or before the closing date and expires thirty days after the expiration of the applicable statute of limitations. In addition, the indemnification obligations relating to certain specified liabilities, including HIV liability, survive indefinitely.

Under the indemnification agreement, Sanofi is generally obligated to indemnify CSL Limited, only to the extent indemnifiable, losses exceeding \$10 million and up to a maximum aggregate amount of \$300 million. For environmental claims, the indemnification due by Sanofi equals 90% of the indemnifiable losses. Product liability claims are generally treated separately, and the aggregate indemnification is capped at \$500 million. Certain indemnification obligations, including those related to HIV liability, as well as tax claims, are not capped in amount.

**Aventis CropScience Retained Liabilities**

The sale by Aventis Agriculture S.A. and Hoechst GmbH (both legacy companies of Sanofi) of their aggregate 76% participation in Aventis CropScience Holding (ACS) to Bayer

and Bayer CropScience AG (BCS), the wholly owned subsidiary of Bayer which holds the ACS shares, was effective on June 3, 2002. The Stock Purchase Agreement (SPA) dated October 2, 2001, contained customary representations and warranties with respect to the sold business, as well as a number of indemnifications, in particular with respect to: environmental liabilities (the representations and warranties and the environmental indemnification are subject to a cap of \$836 million, except for certain legal representations and warranties and specific environmental liabilities); taxes; certain legal proceedings; claims related to StarLink® corn; and certain pre-closing liabilities, in particular, product liability cases (which are subject to a cap of \$418 million within the above global cap of \$836 million). There are various periods of limitation depending upon the nature or subject of the indemnification claim. Further, Bayer and BCS are subject to a number of obligations regarding mitigation and cooperation.

Since December 2005, Aventis Agriculture and Hoechst GmbH have concluded several settlement agreements to resolve a substantial number of disputes with Bayer and BCS, including the termination of arbitration proceedings initiated in August 2003 for an alleged breach of a financial statement-related representation contained in the SPA, and numerous other warranty and indemnification claims, including certain environmental and product liabilities claims. A number of other outstanding claims remain unresolved.

**LLRICE601 and LLRICE604 Arbitration**

## Edgar Filing: Sanofi - Form 20-F

On December 19, 2014, BCS initiated a claim for arbitration against Aventis Agriculture S.A. and Hoechst GmbH seeking indemnification under various provisions of the SPA, with a demand for 787.5 million. Bayer is seeking indemnification for damages allegedly suffered in several hundred individual complaints and lawsuits by rice growers, millers and distributors arising in U.S. state and federal courts against a number of CropScience companies, formerly part of ACS before its divestiture, following the detection in 2006 of trace amounts of genetically-modified rice (the Liberty Link<sup>®</sup> Rice 601 and 604) in samples of commercial long grain rice. Bayer alleges that it has incurred losses in excess of \$1.2 billion in judgments, settlements and litigation costs. The claimed amount corresponds to the residual portion of the indemnification available under the SPA.

Sanofi does not consider that these claims constitute indemnifiable losses under the SPA and is currently opposing Bayer's request to indemnification in the ongoing arbitration proceeding before DIS (German Arbitral Tribunal).

### **Aventis Animal Nutrition Retained Liabilities**

Aventis Animal Nutrition S.A. and Aventis (both legacy companies of Sanofi) signed an agreement for the sale to Drakkar Holdings S.A. of the Aventis Animal Nutrition business effective in April 2002. The sale agreement

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

contained customary representations and warranties. Sanofi's indemnification obligations ran through April 2004, except for environmental indemnification obligations (which ran through April 2012), tax indemnification obligations (which run through the expiration of the applicable statutory limitation period), and antitrust indemnification obligations (which extend indefinitely). The indemnification undertakings are subject to an overall cap of 223 million, with a lower cap for certain environmental claims. Indemnification obligations for antitrust and tax claims are not capped.

**Celanese AG Retained Liabilities**

The demerger of the specialty chemicals business from Hoechst to Celanese AG (now trading as Celanese GmbH) became effective on October 22, 1999. Under the demerger agreement between Hoechst and Celanese, Hoechst expressly excluded any representations and warranties regarding the shares and assets demerged to Celanese. Celanese subsequently contributed rights and obligations relating to environmental liabilities resulting from the demerger agreement to a subsidiary CCC Environmental Management and Solutions GmbH & Co. KG (CCC). The following obligations of Hoechst are ongoing:

- While all obligations of Hoechst (i) resulting from public law or (ii) pursuant to current or future environmental laws or (iii) vis-à-vis third parties pursuant to private or public law related to contamination (as defined) were transferred to Celanese under the demerger agreement in full, after the subsequent contribution CCC can request indemnification from Hoechst for two thirds of any such cost incurred under these obligations.
- To the extent Hoechst is liable to purchasers of certain of its divested businesses (as listed in the demerger agreement), CCC is liable to indemnify Hoechst, as far as environmental damages are concerned, for aggregate liabilities up to 250 million, liabilities exceeding such amount will be borne by Hoechst alone up to 750 million, and amounts exceeding 750 million will be borne  $\frac{2}{3}$  by Hoechst and  $\frac{1}{3}$  by CCC without any further caps. Subsequent to the contribution of rights and obligations relating to environmental liabilities by Celanese, Celanese was jointly liable with CCC until November 2016. Thereafter, Celanese remains liable for known environmental claims specified in 2013. Compensation paid to third parties by Celanese and CCC through December 31, 2016 was significantly below the first threshold of 250 million.

**Rhodia Shareholder Litigation**

In January 2004, two minority shareholders of Rhodia and their respective investment vehicles filed two claims before the Commercial Court of Paris (*Tribunal de Commerce de Paris*) against Aventis, to which Sanofi is successor in

interest, together with other defendants including former directors and statutory auditors of Rhodia from the time of the alleged events. The claimants seek a judgment holding the defendants collectively liable for alleged management errors and for alleged publication of misstatements between 1999 and 2002, and inter alia regarding Rhodia's acquisition of the companies Albright & Wilson and ChiRex. These shareholders seek a finding of joint and several liability for damages to be awarded to Rhodia in an amount of 925 million for alleged harm to it (a derivative action), as well as personal claims of 4.3 million and 125.4 million for their own alleged individual losses. Sanofi contests both the substance and the admissibility of these claims.

Sanofi is also aware of three criminal complaints filed in France by the same plaintiffs and of a criminal investigation order issued by the Paris public prosecutor following the submission of the report issued by the AMF regarding Rhodia's financial communications. In 2006, the Commercial Court of Paris accepted Sanofi's and the other defendants' motion to stay the civil litigation pending the conclusion of the criminal proceedings.

In December 2016, the Court of Appeals of Paris dismissed the appeal lodged by the same plaintiffs against the order of the investigating judge dated October 2015, dismissing all criminal charges in this case. The plaintiffs appealed the December 2016 decision before the French Supreme Court. Following this decision, the plaintiffs may also petition the Commercial Court of Paris and seek the reopening of the commercial cases mentioned above on the basis that the criminal proceedings have now concluded.

**Clariant Retained Liabilities Specialty Chemicals Business**

Hoechst conveyed its specialty chemicals business to Clariant AG (Clariant) pursuant to a 1997 agreement. Clariant has undertaken to indemnify Hoechst for all costs incurred for environmental matters relating to purchased sites. However, certain indemnification obligations of Hoechst for environmental matters in favor of Clariant remain with Hoechst.

Hoechst must indemnify Clariant indefinitely (i) with respect to sites taken over by Clariant, for costs which relate to environmental pollutions attributable to certain activities of Hoechst or of third parties, (ii) for costs attributable to four defined waste deposit sites in Germany which are located outside the sites taken over by Clariant (to the extent exceeding an indexed amount of approximately 20.5 million), (iii) for costs from certain locally concentrated pollutions in the sites taken over by Clariant but not caused by specialty chemicals activities in the past, and (iv) for 75% of the costs relating to a specific waste deposit site in Frankfurt, Germany.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****Infraserv Höchst Retained Liabilities**

By the Asset Contribution Agreement dated December 19/20, 1996, as amended in 1997, Hoechst contributed all lands, buildings, and related assets of the Hoechst site at Frankfurt Höchst to Infraserv GmbH & Co. Höchst KG. Infraserv Höchst undertook to indemnify Hoechst against environmental liabilities at the Höchst site and with respect to certain landfills. As consideration for the indemnification undertaking, Hoechst transferred to Infraserv Höchst approximately 57 million to fund reserves. In 1997, Hoechst also agreed it would reimburse current and future

Infraserv Höchst environmental expenses up to 143 million. As a former owner of the land and as a former user of the landfills, Hoechst may ultimately be liable for costs of remedial action in excess of this amount.

**D.23. PROVISIONS FOR DISCOUNTS, REBATES AND SALES RETURNS**

Adjustments between gross sales and net sales, as described in Note B.14., are recognized either as provisions or as reductions in accounts receivable, depending on their nature.

The table below shows movements in these items:

	Government and State programs <sup>(a)</sup>	Managed care and GPO programs <sup>(b)</sup>	Chargeback incentives	Rebates and discounts	Sales returns	Other deductions	Total
( million)							
<b>Balance at January 1, 2014</b>	<b>843</b>	<b>173</b>	<b>191</b>	<b>851</b>	<b>328</b>	<b>42</b>	<b>2,428</b>
Provision related to current period sales	2,792	665	3,078	5,026	429	7	11,997
Net change in provision related to prior period sales	(60)	26	(1)	(36)	(2)	-	(73)
Payments made	(2,273)	(586)	(3,070)	(4,977)	(400)	(45)	(11,351)
Currency translation differences	137	34	23	12	38	2	246
<b>Balance at December 31, 2014</b>	<b>1,439</b>	<b>312</b>	<b>221</b>	<b>876</b>	<b>393</b>	<b>6</b>	<b>3,247</b>
Provision related to current period sales	4,912	1,954	4,131	5,913	585	31	17,526
Net change in provision related to prior period sales	(35)	-	(20)	(45)	35	-	(65)
Payments made	(4,295)	(1,636)	(4,001)	(5,672)	(541)	(31)	(16,176)
Currency translation differences	152	42	18	11	29	-	252
Reclassification of the Animal Health business <sup>(c)</sup>	-	-	-	(139)	(21)	(1)	(161)
<b>Balance at December 31, 2015</b>	<b>2,173</b>	<b>672</b>	<b>349</b>	<b>944</b>	<b>480</b>	<b>5</b>	<b>4,623</b>
Provision related to current period sales	5,240	1,869	4,132	5,394	547	14	17,196
Net change in provision related to prior period sales	(6)	-	(8)	(20)	18	(1)	(17)
Payments made	(5,078)	(1,796)	(4,204)	(5,230)	(509)	(15)	(16,832)

Edgar Filing: Sanofi - Form 20-F

Currency translation differences	69	26	11	23	14	-	143
<b>Balance at December 31, 2016</b>	<b>2,398</b>	<b>771</b>	<b>280</b>	<b>1,111</b>	<b>550</b>	<b>3</b>	<b>5,113</b>

(a) *Primarily the US government's Medicare and Medicaid programs.*

(b) *Primarily rebates and other price reductions granted to healthcare authorities in the United States.*

(c) *This line comprises the provisions for discounts, rebates and sales returns of the Animal Health business, reclassified to **Liabilities related to assets held for sale or exchange** as of December 31, 2015 (see Notes D.2. and D.36.).*

**F- 92**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.24. PERSONNEL COSTS**

Total personnel costs include the following items:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Salaries	6,424	6,473	5,704
Social security charges (including defined-contribution pension plans)	1,948	1,951	1,776
Stock options and other share-based payment expense	250	206	206
Defined-benefit pension plans	273	280	282
Other employee benefits	224	224	195
<b>Total<sup>(a)</sup></b>	<b>9,119</b>	<b>9,134</b>	<b>8,163</b>

*(a) Excludes personnel costs for the Animal Health business of 0.6 billion for 2016, 0.6 billion for 2015 and 0.5 billion for 2014.*

The total number of registered employees, excluding those of the Animal Health business, was 106,859 as of December 31, 2016, compared with 109,089 as of December 31, 2015 and 107,387 as of December 31, 2014.

Employee numbers by function as of December 31 are shown below:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Production	41,867	42,754	41,717
Research and development	15,148	15,384	15,394
Sales force	30,815	32,771	32,766
Marketing and support functions	19,029	18,180	17,510
<b>Total<sup>(a)</sup></b>	<b>106,859</b>	<b>109,089</b>	<b>107,387</b>

*(a) Excludes workforce for the Animal Health business of 6,957 employees in 2016, 6,542 in 2015 and 6,109 in 2014.*

**D.25. OTHER OPERATING INCOME**

Other operating income totaled 355 million in 2016, versus 254 million in 2015 and 301 million in 2014.

This line item includes income arising under alliance agreements in the Pharmaceuticals segment ( 191 million in 2016, versus 59 million in 2015 and 47 million in 2014), and in particular 141 million arising under the agreement with Regeneron in 2016 ( 66 million in 2015), reflecting Regeneron's share of profits/losses from the commercialization of antibodies, amounting to 419 million in 2016 ( 216 million in 2015), net of the commercialization related expenses incurred by Regeneron of 278 million in 2016 ( 150 million in 2015).

*Other operating income* also includes 192 million received under arbitration settlements of contractual disputes; net

## Edgar Filing: Sanofi - Form 20-F

operating foreign exchange losses ( 146 million in 2016, 98 million in 2015 and 105 million in 2014); and proceeds from disposals relating to ongoing operations ( 40 million in 2016, 146 million in 2015 and 230 million in 2014).

### D.26. OTHER OPERATING EXPENSES

Other operating expenses totaled 482 million in 2016, compared with 462 million in 2015 and 157 million in 2014. In 2016, Sanofi recorded a foreign exchange loss of 102 million on the operations of its Venezuelan subsidiaries (see Note A.4.). This line item also includes shares of profits due to alliance partners (other than Warner Chilcott under the Actonel<sup>®</sup> agreement and BMS) under product marketing agreements ( 96 million in 2016, versus 52 million in 2015 and 23 million in 2014), and a payment of 90 million in settlement of litigation regarding generics of Cipro<sup>®</sup>.

### D.27. RESTRUCTURING COSTS AND SIMILAR ITEMS

Restructuring costs and similar items amounted to 879 million in 2016, 795 million in 2015 and 404 million in 2014, and comprise the following items:

( million)	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
Employee-related expenses	650	307	255
Expenses related to property, plant and equipment	139	132	89
Compensation for early termination of contracts (other than contracts of employment)	31	7	22
Decontamination costs	3	1	(1)
Other restructuring costs	56	348	39
<b>Total</b>	<b>879</b>	<b>795</b>	<b>404</b>

(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The restructuring costs recognized in 2016 related mainly to the implementation of an organizational transformation program in France and in the rest of the world as part of the 2020 strategic roadmap.

Costs relating to Sanofi transformation programs included within the Other restructuring costs line, as defined in Note B.20.1, amounted to 45 million in 2016. No costs of a comparable nature were recognized in 2015 or 2014.

In 2015, restructuring costs related mainly to (i) employee-related expenses arising from headcount adjustment plans in the United States, Japan, and the rest of the world and (ii) the reorganization of R&D activities, especially in France following signature of the agreement with Evotec. Expenses

related to property, plant and equipment mainly reflect impairment losses taken against industrial assets in Europe.

In 2014, restructuring costs related mainly to employee-related expenses arising under plans to realign Sanofi's resources in France and Europe.

**D.28. OTHER GAINS AND LOSSES, AND LITIGATION**

On December 30, 2016 Sanofi sold its interest in the Sanofi Pasteur MSD joint venture to MSD, generating a pre-tax gain on disposal of 211 million (see Note D.1.2.).

There were no other material transactions of this nature in 2015 or 2014, and no costs incurred as a result of major litigation.

**D.29. FINANCIAL INCOME AND EXPENSES**

An analysis of financial income and expenses is set forth below:

<i>( million)</i>	<b>2016<sup>(a)</sup></b>	<b>2015<sup>(a)</sup></b>	<b>2014<sup>(a)</sup></b>
Cost of debt <sup>(b)</sup>	(274)	(331)	(357)
Interest income	56	57	67
<b>Cost of debt, net of cash and cash equivalents</b>	<b>(218)</b>	<b>(274)</b>	<b>(290)</b>
Non-operating foreign exchange gains/(losses)	(21)	-	2
Unwinding of discount on provisions <sup>(c)</sup>	(33)	(44)	(74)
Net interest cost related to employee benefits	(114)	(114)	(140)
Gains/(losses) on disposals of financial assets	36	46	83 <sup>(d)</sup>
Impairment losses on financial assets, net of reversals	(487) <sup>(e)</sup>	(50)	(15)
Other	(19)	55	28 <sup>(f)</sup>
<b>Net financial income/(expenses)</b>	<b>(856)</b>	<b>(381)</b>	<b>(406)</b>
<b>comprising: Financial expenses</b>	<b>(924)</b>	<b>(559)</b>	<b>(598)</b>
<b>Financial income</b>	<b>68</b>	<b>178</b>	<b>192</b>

## Edgar Filing: Sanofi - Form 20-F

- (a) *The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36.*
- (b) *Includes net gain on interest rate derivatives used to hedge debt: 86 million in 2016, 85 million in 2015 and 84 million in 2014.*
- (c) *Primarily on provisions for environmental risks, restructuring provisions, and provisions for product-related risks (see Note D.19.).*
- (d) *Mainly comprises a gain on the sale of an equity interest in Ionis Pharmaceuticals (formerly Isis Pharmaceuticals; refer to Note D.7.).*
- (e) *On October 5, 2016, Alnylam announced that it was terminating its revusiran development program, as a result of which its share price fell by 48% on October 6, 2016. Consequently, Sanofi recognized an impairment loss reflecting the difference between the historical acquisition cost of its shares in Alnylam and their market value. That impairment loss, which amounted to 457 million as of December 31, 2016, is included within the line Impairment losses on financial assets, net of reversals .*
- (f) *Includes a 35 million gain arising on the purchase of an equity interest in Alnylam, reflecting the difference between the value based on the quoted market price and the transaction price at the acquisition date (see Note D.7.).*
- In 2016, 2015 and 2014, the impact of the ineffective portion of hedging relationships was not material.

### F- 94

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.30. INCOME TAX EXPENSE**

Sanofi has elected for tax consolidations in a number of countries, principally France, Germany, the United Kingdom and the United States.

The table below shows the allocation of income tax expense between current and deferred taxes:

( million)	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
Current taxes	(1,869)	(1,978)	(2,345)
Deferred taxes	543	1,269	1,131
<b>Total</b>	<b>(1,326)</b>	<b>(709)</b>	<b>(1,214)</b>
<b>Income before tax and associates and joint ventures</b>	<b>5,678</b>	<b>5,243</b>	<b>5,658</b>

(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); see Notes D.2. and D.36.

The difference between the effective tax rate and the standard corporate income tax rate applicable in France is explained as follows:

(as a percentage)	2016 <sup>(a)</sup>	2015 <sup>(a)</sup>	2014 <sup>(a)</sup>
Standard tax rate applicable in France	34.4	34.4	34.4
Difference between the standard French tax rate and the rates applicable to the Sanofi group <sup>(b)</sup>	(10.1)	(17.7)	(12.2)
Tax rate differential on intragroup margin in inventory <sup>(c)</sup>	(0.6)	1.7	(0.5)
Tax effects of the share of profits reverting to BMS (see Note D.32.)	(0.5)	(0.6)	(0.7)
Contribution on distributed income (3%) <sup>(d)</sup>	2.0	2.1	1.9
CVAE tax in France <sup>(e)</sup>	1.1	1.3	0.9
Revisions to tax exposures and settlements of tax disputes	(4.8)	0.3	(2.8)
Fair value remeasurement of contingent consideration liabilities	0.4	(1.1)	0.4
Other items <sup>(f)</sup>	1.5	(6.9)	0.1
<b>Effective tax rate</b>	<b>23.4</b>	<b>13.5</b>	<b>21.5</b>

(a) The results of the Animal Health business are presented separately in accordance with IFRS 5 (Non-Current Assets Held for Sale and Discontinued Operations); refer to Notes D.2. and D.36.

(b) The difference between the French tax rate and tax rates applicable to foreign subsidiaries reflects the fact that Sanofi has operations in many countries, most of which have lower tax rates than France.

(c) When internal margin included in inventory is eliminated, a deferred tax asset is recognized on the basis of the tax rate applicable to the subsidiary that holds the inventory, which may differ from the tax rate of the subsidiary that generated the eliminated intragroup margin.

## Edgar Filing: Sanofi - Form 20-F

(d) *Entities liable to corporate income tax in France are also liable to pay an additional tax contribution in respect of amounts distributed by the entity.*

(e) *Net impact on the effective tax rate (current taxes, impact of the tax deduction, and deferred taxes).*

(f) *In 2016, the Other items line includes the effects of changes in tax rates in various countries, particularly in France, Hungary, Italy, Japan and the United States. In 2015, the Other items line includes the impact ( 161 million) of changes in the taxation of dividends in France following the ruling of the Court of Justice of the European Union in the Steria case and the resulting amendments to the 2015 Finance Act. It also includes (i) the net impact (current and deferred taxes) of the Contribution Exceptionnelle levy in France (10.7% in 2016, 2015 and 2014), which is immaterial at consolidated level and (ii) the net tax effect of taxable temporary differences associated with holdings in Sanofi subsidiaries. In determining the amount of the deferred tax liability for 2016 and 2015, Sanofi took into account changes in the ownership structure of certain subsidiaries.*

For the periods presented, the amount of deferred tax assets recognized in profit or loss that were initially subject to impairment losses on a business combination is immaterial.

The contribution on distributed income, for which the triggering event is the decision by the Annual General Meeting to approve the distribution, is not taken into account in the determination of deferred tax assets and liabilities.

### **D.31. SHARE OF PROFIT/LOSS OF ASSOCIATES AND JOINT VENTURES**

With effect from the beginning of April 2014, this line item includes Sanofi's share of the profits and losses of Regeneron, which represented a net profit of 126 million in 2016 (compared with net losses of 54 million in 2015 and 126 million in 2014). That amount includes the impact of amortization charged on the fair value remeasurement of Sanofi's share of the acquired intangible assets and inventories of Regeneron.

---

**Table of Contents**

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

This line item also includes the share of co-promotion profits attributable to Sanofi for territories covered by entities majority owned by BMS (see Note C.2.). The impact of the BMS alliance in 2016 was 25 million, before deducting the tax effect of 9 million (compared with 57 million in 2015 with a tax effect of 21 million, and 50 million in 2014 with a tax effect of 19 million).

The Sanofi Pasteur MSD joint venture ceased to be accounted for by the equity method on March 8, 2016, the date on which it was announced that the joint venture was to be dissolved (see Notes B.1. and D.1.2.).

Finally, this line item also includes the share of profits or losses from other associates and joint ventures, the amount of which was immaterial in 2016, 2015 and 2014.

**D.32. NET INCOME ATTRIBUTABLE TO NON-CONTROLLING INTERESTS**

This line item includes the share of co-promotion profits attributable to BMS for territories covered by entities majority owned by Sanofi (see Note C.2.). The amounts involved were 86 million in 2016, 94 million in 2015 and 109 million in 2014. There is no tax effect on these amounts because BMS receives its share before tax.

This line item also includes the share of net income attributable to other non-controlling interests: 5 million in 2016, 7 million in 2015 and 10 million in 2014.

**D.33. RELATED PARTY TRANSACTIONS**

The principal related parties are companies over which Sanofi has control or significant influence, joint ventures, key management personnel and principal shareholders.

Sanofi has not entered into any transactions with any key management personnel. Financial relations with Sanofi's principal shareholders fall within the ordinary course of business and were immaterial in the years ended December 31, 2016, 2015 and 2014.

A list of the principal companies controlled by Sanofi is presented in Note F.1. Those companies are fully consolidated as described in Note B.1. Transactions between those companies, and between the parent company and its subsidiaries, are eliminated when preparing the consolidated financial statements.

Transactions with companies over which Sanofi has significant influence, and with joint ventures, are presented in Note D.6.

Key management personnel include corporate officers (including one director holding office for four months in 2016 and two directors holding office during 2015 and 2014 who were covered by top-up pension plans: see Item 6.B. Compensation ) and the members of the Executive Committee (an average of 13 members in 2016, 11 members in 2015, and 12 members in 2014).

The table below shows, by type, the compensation paid to key management personnel:

## Edgar Filing: Sanofi - Form 20-F

( million)	2016	2015	2014
Short-term benefits <sup>(a)</sup>	32	32	29
Post-employment benefits <sup>(b)</sup>	9	20	10
Share-based payment	22	14	22
<b>Total recognized in profit or loss</b>	<b>63</b>	<b>66</b>	<b>61</b>

(a) Compensation, employer's social security contributions, directors' attendance fees, and any termination benefits (net of reversals of termination benefit obligations).

(b) The 2015 figure includes the expense arising from the award of a deemed ten years of service to Olivier Brandicourt.

The aggregate top-up pension obligation in favor of certain corporate officers and of members of the Executive Committee was 72 million as of December 31, 2016, versus 128 million as of December 31, 2015 and 124 million as of December 31, 2014. The reduction in the obligation to corporate officers as of December 31, 2016 was mainly due to directors ceasing to hold office, rather than to a general reduction in the obligation.

The aggregate amount of termination benefits and lump-sum retirement benefits payable to key management personnel was 8 million as of December 31, 2016, compared with 6 million as of December 31, 2015 and 9 million as of December 31, 2014.

### D.34. INFORMATION ABOUT MAJOR CUSTOMERS AND CREDIT RISK

Credit risk is the risk that customers (wholesalers, distributors, pharmacies, hospitals, clinics or government agencies) may fail to pay their debts. Sanofi manages credit risk by vetting customers in order to set credit limits and risk levels and asking for guarantees or insurance where necessary, performing controls, and monitoring qualitative and quantitative indicators of accounts receivable balances such as the period of credit taken and overdue payments.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Customer credit risk also arises as a result of the concentration of Sanofi's sales with its largest customers, in particular certain wholesalers in the United States. Sanofi's three largest customers respectively accounted for approximately 12%, 7% and 6% of net sales in 2016 (versus 10%, 6% and 5% in 2015, and 9%, 6% and 5% in 2014).

**D.35. SEGMENT INFORMATION**

As indicated in Note B.26., Sanofi now has two operating segments: Pharmaceuticals and Human Vaccines (Vaccines). The Animal Health business was no longer an operating segment as of December 31, 2016, following the exchange deal with Boehringer Ingelheim that was finalized at the start of January 2017 (see Note D.2.).

The Pharmaceuticals segment comprises the commercial operations of the following franchises: Speciality Care (Rare Diseases, Multiple Sclerosis, Oncology), Diabetes & Cardiovascular, Established Prescription Products, Consumer Healthcare and Generics; and dedicated research and development, production and marketing activities for all of Sanofi's pharmaceuticals operations. The Sanofi pharmaceuticals portfolio consists of flagship products, plus a broad range of prescription medicines, generic medicines, and consumer health products. This segment also includes all associates whose activities are related to pharmaceuticals, in particular Regeneron and the entities majority owned by BMS.

The Vaccines segment is wholly dedicated to vaccines and includes the commercial operations of Sanofi Pasteur and dedicated research and development, production and marketing activities for Sanofi's vaccines operations.

This segment included the Sanofi Pasteur MSD joint venture until December 30, 2016, the date on which the joint venture ended.

Each segment includes global support function costs as allocated for internal reporting purposes within Sanofi.

The Other segment includes all activities that do not qualify as reportable segments under IFRS 8. This segment includes the effects of retained commitments in respect of divested activities.

Inter-segment transactions are not material.

**D.35.1. Segment results**

Sanofi reports segment results on the basis of Business operating income. This indicator is used internally by the chief operating decision maker of the Company to measure the performance of each operating segments and to allocate resources, in accordance with IFRS8.

Business operating income is derived from *Operating income*, adjusted as follows:

- the amounts reported in the line items *Restructuring costs and similar items*, *Fair value remeasurement of contingent consideration liabilities* and *Other gains and losses, and litigation* are eliminated;
- amortization and impairment losses charged against intangible assets (other than software and other rights of an industrial or operational nature) are eliminated;

## Edgar Filing: Sanofi - Form 20-F

- the share of profits/losses of associates and joint ventures is added;
- net income attributable to non-controlling interests is deducted;
- other acquisition-related effects (primarily the workdown of acquired inventories remeasured at fair value at the acquisition date, and the impact of acquisitions on investments in associates and joint ventures) are eliminated;
- restructuring costs relating to associates and joint ventures are eliminated;
- the non-recurring adjustment recognized in 2014 for the annual Branded Prescription Drug Fee in the United States (following publication by the US Internal Revenue Service in July 2014 of the final regulations on that fee) is eliminated;

**F- 97**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

Segment results are shown in the tables below:

( million)	December 31, 2016			
	Pharmaceuticals	Vaccines	Other	Total
<b>Net sales</b>	<b>29,244</b>	<b>4,577</b>	-	<b>33,821</b>
Other revenues	274	613	-	887
Cost of sales	(8,349)	(2,353)	-	(10,702)
Research and development expenses	(4,618)	(554)	-	(5,172)
Selling and general expenses	(8,743)	(743)	-	(9,486)
Other operating income and expenses	(1)	(14)	(112)	(127)
Share of profit/(loss) of associates and joint ventures	129	48	-	177
Net income attributable to non-controlling interests	(112)	(1)	-	(113)
<b>Business operating income</b>	<b>7,824</b>	<b>1,573</b>	<b>(112)</b>	<b>9,285</b>

( million)	December 31, 2015			
	Pharmaceuticals	Vaccines <sup>(a)</sup>	Other	Total
<b>Net sales</b>	<b>29,799</b>	<b>4,261</b>	-	<b>34,060</b>
Other revenues	288	513	-	801
Cost of sales	(8,788)	(2,131)	-	(10,919)
Research and development expenses	(4,530)	(552)	-	(5,082)
Selling and general expenses	(8,656)	(726)	-	(9,382)
Other operating income and expenses	(121)	27	(114)	(208)
Share of profit/(loss) of associates and joint ventures	146	23	-	169
Net income attributable to non-controlling interests	(125)	(1)	-	(126)
<b>Business operating income</b>	<b>8,013</b>	<b>1,414</b>	<b>(114)</b>	<b>9,313</b>

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).

( million)	December 31, 2014			
	Pharmaceuticals	Vaccines <sup>(a)</sup>	Other	Total
<b>Net sales</b>	<b>27,720</b>	<b>3,660</b>	-	<b>31,380</b>
Other revenues	272	347	-	619
Cost of sales	(8,282)	(1,948)	-	(10,230)
Research and development expenses	(4,174)	(493)	-	(4,667)
Selling and general expenses	(7,692)	(614)	(3)	(8,309)
Other operating income and expenses	194	2	(52)	144
Share of profit/(loss) of associates and joint ventures	106	40	-	146
Net income attributable to non-controlling interests	(126)	-	-	(126)
<b>Business operating income</b>	<b>8,018</b>	<b>994</b>	<b>(55)</b>	<b>8,957</b>

## Edgar Filing: Sanofi - Form 20-F

(a) *Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).*

**F- 98**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

The table below shows a reconciliation between total Business operating income for our operating segments and *Income before tax and associates and joint ventures* as required by IFRS 8:

( million)	2016	2015	2014
<b>Business operating income</b>	<b>9,285</b>	<b>9,313</b>	<b>8,957</b>
Share of (profit)/loss of associates and joint ventures <sup>(a)</sup>	(177)	(169)	(146)
Net income attributable to non-controlling interests <sup>(b)</sup>	113	126	126
Amortization of intangible assets	(1,692)	(2,137)	(2,081)
Impairment of intangible assets	(192)	(767)	31
Fair value remeasurement of contingent consideration liabilities	(135)	53	(303)
Expenses arising from the impact of acquisitions on inventories <sup>(c)</sup>	-	-	-
Restructuring costs and similar items	(879)	(795)	(404)
Additional year expense related to the US Branded Prescription Drug Fee <sup>(d)</sup>	-	-	(116)
Other gains and losses, and litigation <sup>(e)</sup>	211	-	-
<b>Operating income</b>	<b>6,534</b>	<b>5,624</b>	<b>6,064</b>
Financial expenses <sup>(f)</sup>	(924)	(559)	(598)
Financial income	68	178	192
<b>Income before tax and associates and joint ventures</b>	<b>5,678</b>	<b>5,243</b>	<b>5,658</b>

(a) Excluding restructuring costs of associates and joint ventures and expenses arising from the impact of acquisitions on associates and joint ventures, and after elimination of Sanofi's share of the business net income of Sanofi Pasteur MSD from the date when Sanofi and Merck announced their intention to end their joint venture ( \$ 52 million in 2016).

(b) Excluding restructuring costs and other adjustments attributable to non-controlling interests.

(c) This line records the impact of the workdown of acquired inventories remeasured at fair value at the acquisition date.

(d) Annual fee relating to 2013 sales: the IRS reforms of July 2014 altered the date on which the liability is recognized, such that the expense recognized during 2014 was based on both 2013 and 2014 sales.

(e) This line item consists of the pre-tax gain on divestment of Sanofi's interest in the Sanofi Pasteur MSD joint venture.

(f) In 2016, this line includes the impairment loss of \$ 457 million taken against the investment in Alnylam.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.35.2. Other segment information**

The tables below show the split by operating segment of (i) the carrying amount of investments in associates and joint ventures, (ii) acquisitions of property, plant and equipment, and (iii) acquisitions of other intangible assets.

The principal associates and joint ventures are: for the Pharmaceuticals segment, Regeneron Pharmaceuticals, Inc. (see Note D.1.), the entities majority owned by BMS (see Note C.2.), and Infraser GmbH & Co. Höchst KG; and for the Vaccines segment, Sanofi Pasteur MSD (until March 8, 2016; see Notes B.1. and D.1.2.).

Acquisitions of intangible assets and property, plant and equipment correspond to acquisitions paid for during the period.

	2016		
	Pharmaceuticals	Vaccines	Total
( million)			
Investments in associates and joint ventures <sup>(a)</sup>	2,886	4	2,890
Acquisitions of property, plant and equipment	904	315	1,219
Acquisitions of other intangible assets	807	57	864

	2015		
	Pharmaceuticals	Vaccines	Total
( million)			
Investments in associates and joint ventures	2,422	254	2,676
Acquisitions of property, plant and equipment	945	258	1,203
Acquisitions of other intangible assets	1,533	36	1,569

	2014		
	Pharmaceuticals	Vaccines	Total
Investments in associates and joint ventures	2,115	264	2,379
Acquisitions of property, plant and equipment	787	217	1,004
Acquisitions of other intangible assets	435	49	484

**F- 100**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.35.3. Information by geographical region**

The geographical information on net sales provided below is based on the geographical location of the customer. In accordance with IFRS 8, the non-current assets reported below exclude financial instruments, deferred tax assets, and pre-funded pension obligations.

( million)	2016					
	Total	Europe	of which France	North America	of which United States	Other countries
<b>Net sales</b>	<b>33,821</b>	<b>8,679</b>	<b>2,206</b>	<b>12,963</b>	<b>12,391</b>	<b>12,179</b>
<b>Non-current assets:</b>						
· property, plant and equipment	10,019	6,068	3,413	2,850	2,447	1,101
· goodwill	40,287	-	-	-	-	-
· other intangible assets	10,879	3,612	-	5,430	-	1,837

( million)	2015					
	Total	Europe	of which France	North America	of which United States	Other countries
<b>Net sales<sup>(a)</sup></b>	<b>34,060</b>	<b>9,861</b>	<b>2,248</b>	<b>12,369</b>	<b>11,764</b>	<b>11,830</b>
<b>Non-current assets:</b>						
· property, plant and equipment	9,943	5,956	3,480	2,879	2,498	1,108
· goodwill	39,557	-	-	-	-	-
· other intangible assets	12,026	3,719	-	5,980	-	2,327

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).

( million)	2014					
	Total	Europe	of which France	North America	of which United States	Other countries
<b>Net sales<sup>(a)</sup></b>	<b>31,380</b>	<b>9,835</b>	<b>2,311</b>	<b>10,735</b>	<b>10,186</b>	<b>10,810</b>
<b>Non-current assets:</b>						
· property, plant and equipment	10,396	6,330	3,848	2,830	2,428	1,236
· goodwill <sup>(b)</sup>	37,841	-	-	-	-	-
· other intangible assets	14,543	2,907	-	8,600	-	3,036

(a) Due to a change in accounting presentation, VaxServe sales of non-Sanofi products are included in **Other revenues** from 2016 onwards. The presentation of prior period **Net sales** and **Other revenues** has been amended accordingly (see Note A.5.).

## Edgar Filing: Sanofi - Form 20-F

*(b) Excluding the goodwill allocated in full to the Animal Health cash generating unit (see Note D.5.).*

As stated in Note D.5. to the consolidated financial statements, goodwill is not allocated by geographical region.

**F- 101**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****D.36. HELD-FOR-EXCHANGE ANIMAL HEALTH BUSINESS**

In accordance with IFRS 5 (see Notes B.7. and D.2.), all assets of the Animal Health business and all liabilities directly related to those assets are classified as of December 31, 2016 in the line items *Assets held for sale or exchange* and *Liabilities related to assets held for sale or exchange*, respectively, in the consolidated balance sheet as of that date (see Note D.8.). An analysis of those line items is provided below:

	2016	2015
<b>Assets</b>		
Property, plant and equipment	811	657
Goodwill	1,560	1,510
Other intangible assets	2,227	2,147
Investments in associates and joint ventures	12	6
Other non-current assets	41	46
Deferred tax assets	180	177
Inventories	629	526
Accounts receivable	471	479
Other current assets	83	55
Cash and cash equivalents	362	23
<b>Total assets held for sale or exchange</b>	<b>6,376</b>	<b>5,626</b>
<b>Liabilities</b>		
Long-term debt	6	4
Non-current provisions	134	149
Deferred tax liabilities	198	163
Short-term debt	148	18
Accounts payable	241	218
Other current liabilities	438	431
<b>Total liabilities related to assets held for sale or exchange</b>	<b>1,165</b>	<b>983</b>

**Meriel acquisition (2009)**

When Sanofi took control of Meriel in 2009, intangible assets (other than goodwill) were recognized at a total of 3,980 million. This figure included 3,104 million for marketed products (in particular fipronil-based products), 674 million foim-process research and development projects, and 131 million for the Meriel brand.

During 2015, none of the assets derived from the acquired research and development was brought into commercial use.

During 2014, some of the Meriel acquired research and development ( 44 million) came into commercial use, and started being amortized from the date of marketing approval. The main such item was the Purevax® Feline Rabies 3Y vaccine.

In accordance with IFRS 5, the net income/loss of the Animal Health business is presented in a separate line item for 2016 and comparative periods (see Notes B.7. and D.2.). The table below provides an analysis of the main items included in the line item *Net income/(loss) of the held-for-exchange Animal Health business*:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Net sales</b>	<b>2,708</b>	<b>2,515</b>	<b>2,076</b>
Gross profit	1,850	1,671	1,311
Operating income	678	101	80
Income before tax and associates and joint ventures	672	92	74
Income tax expense	(359)	(216)	43
<b>Net income/(loss) of the held-for-exchange Animal Health business</b>	<b>314</b>	<b>(124)</b>	<b>117</b>

**F- 102**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In accordance with the policies described in Note B.7., transactions between companies belonging to the Animal Health business and other consolidated companies are eliminated. The amount of transactions eliminated from the income statement is immaterial for the periods presented. As

of December 31, 2016, short-term debt owed by Animal Health companies to other consolidated companies and eliminated from the balance sheet amounted to 954 million; the amount of accounts receivable and accounts payable eliminated was immaterial.

The table below presents basic and diluted earnings per share for the held-for-exchange Animal Health business, in accordance with IAS 33 (Earnings Per Share):

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
Net income/(loss) of the held-for-exchange Animal Health business	314	(124)	117
Average number of shares outstanding (million)	1,286.6	1,306.2	1,315.8
Average number of shares outstanding after dilution (million)	1,296.0	1,320.7	1,331.1
Basic earnings per share (in euros)	0.24	(0.10)	0.09
Diluted earnings per share (in euros)	0.24	(0.09)	0.09

The table below provides a reconciliation between Business operating income for the Animal Health business and *Net income/(loss) of the held-for-exchange Animal Health business*:

<i>( million)</i>	<b>2016</b>	<b>2015</b>	<b>2014</b>
<b>Business operating income<sup>(a)</sup></b>	<b>707</b>	<b>635</b>	<b>492</b>
Discontinuation of depreciation and amortization <sup>(b)</sup>	65	1	-
Amortization of intangible assets	-	(499)	(401)
Impairment of intangible assets	-	(3)	(4)
Restructuring costs	4	(6)	(7)
Costs associated with the exchange transaction	(97)	(27)	-
Financial income and expenses	(6)	(9)	(6)
Income tax expense <sup>(c)</sup>	(359)	(216)	43
<b>Net income/(loss) of the held-for-exchange Animal Health business</b>	<b>314</b>	<b>(124)</b>	<b>117</b>

(a) See Note D.35.1.

(b) Discontinuation of depreciation and amortization from the date of reclassification of property, plant and equipment and intangible assets to *Assets held for sale or exchange*.

(c)

## Edgar Filing: Sanofi - Form 20-F

*Includes the net tax effect arising from taxable temporary differences relating to holdings in subsidiaries, insofar as it has become probable that those differences will reverse, and the tax effect related to the amortization and impairment of intangible assets in 2015 and 2014.*

Off balance sheet commitments relating to the operating activities of the Animal Health business break down as follows:

December 31, 2016 ( million)	Total	Payments due by period			
		Less than 1 year	1 to 3 years	3 to 5 years	More than 5 years
Operating lease obligations	36	13	12	6	5
Irrevocable purchase commitments <sup>(a)</sup>					
given	252	235	16	1	-
received	(2)	(2)	-	-	-
Commitments related to research & development licensing agreements	32	8	9	5	10
<b>Total</b>	<b>318</b>	<b>254</b>	<b>37</b>	<b>12</b>	<b>15</b>

(a) These comprise irrevocable commitments to suppliers of (i) property, plant and equipment, net of down payments and (ii) goods and services.

**F- 103**

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****E/ Principal accountants fees and services**

PricewaterhouseCoopers Audit and Ernst & Young et Autres served as independent auditors of Sanofi for the year ended December 31, 2016 and for all other reporting periods presented. The table below shows fees charged by those firms and member firms of their networks to Sanofi and consolidated subsidiaries in the years ended December 31, 2016 and 2015.

( million)	Ernst & Young				PricewaterhouseCoopers			
	2016		2015		2016		2015	
	Amount	%	Amount	%	Amount	%	Amount	%
<b>Audit:</b>								
Audit of statutory and consolidated financial statements <sup>(1)</sup>	16.7	92%	17.0	96%	16.8	97%	18.2	97%
Services other than audit of financial statements	1.4	8%	0.8	4%	0.6	3%	0.5	3%
<i>Audit-related services</i> <sup>(2)</sup>	0.6		0.8		0.6		0.3	
<i>Tax</i>	-		-		-		0.2	
<i>Other services</i>	0.8		-		-		-	
<b>Total</b>	<b>18.1</b>	<b>100%</b>	<b>17.8</b>	<b>100%</b>	<b>17.4</b>	<b>100%</b>	<b>18.7</b>	<b>100%</b>

(1) Includes the following amounts for the audit of the financial statements of the parent company and its French subsidiaries: Ernst & Young, 7.0 million in 2016 and 7.1 million in 2015; PricewaterhouseCoopers, 7.4 million in 2016 and 6.9 million in 2015.

(2) Includes the following amounts charged to the parent company and its French subsidiaries: Ernst & Young, 0.5 million in 2016 and 0.5 million in 2015; PricewaterhouseCoopers, 0.3 million in 2016 and 0.3 million in 2015.

**Audit Committee Pre-approval and Procedures**

The Sanofi Audit Committee has adopted a policy and established certain procedures for the approval of audit services and the pre-approval of other non-audit services to

be provided by the independent auditors. In 2016, the Sanofi Audit Committee established a budget showing audit services and other permitted non-audit services provided by the independent auditors by type of service, and the related fees.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****F/ List of principal companies included in the consolidation during the year ended December 31, 2016****F.1. PRINCIPAL FULLY CONSOLIDATED COMPANIES**

The table below shows the principal companies and their country of incorporation:

	<b>Financial interest % as of December 31, 2016</b>
<b>Europe</b>	
Hoechst GmbH	Germany 100
Zentiva Pharma GmbH	Germany 100
Zentiva Inhalationsprodukte GmbH	Germany 100
Sanofi-Aventis Deutschland GmbH	Germany 100
Aventis Beteiligungsverwaltung GmbH	Germany 100
Genzyme GmbH	Germany 100
Merial GmbH	Germany 100
Sanofi-Aventis GmbH	Austria 100
Sanofi Belgium	Belgium 100
Sanofi European Treasury Center	Belgium 100
Genzyme Flanders BVBA	Belgium 100
Sanofi-Aventis Denmark A/S	Denmark 100
Merial Norden A/S	Denmark 100
Sanofi-Aventis SA	Spain 100
Merial Laboratorios S.A.	Spain 100
Sanofi Oy	Finland 100
Sanofi	France 100
Sanofi-Aventis France	France 100
Sanofi Winthrop Industries	France 100
sanofi aventis Recherche et Développement	France 100
Sanofi-Aventis Groupe	France 100
Sanofi CLIR	France 50.1
Sanofi Chimie	France 100
Francopia	France 100
Sanofi-Aventis Europe SAS	France 100
Sanofi-Aventis Participations SAS	France 100
Genzyme SAS	France 100
Genzyme Polyclonals SAS	France 100
Sanofi Pasteur (France) SA	France 100
Merial S.A.S France	France 100
Aventis Pharma S.A. (France)	France 100
Sanofi-Aventis Am Nord S.A.S.	France 100
Winthrop Medicaments	France 100
Aventis Agriculture	France 100
Chattem Greece S.A.	Greece 100

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>Financial interest % as of December 31, 2016</b>
<b>Europe</b>	
Sanofi-Aventis A.E.B.E.	Greece 100
Sanofi-Aventis Private Co, Ltd	Hungary 99.6
Chinoïn Private Co, Ltd	Hungary 99.6
Carraig Insurance DAC	Ireland 100
Sanofi-Aventis Ireland Ltd	Ireland 100
Genzyme Ireland Limited	Ireland 100
Sanofi Spa	Italy 100
Merial Italia S.p.A.	Italy 100
Genzyme Global Sarl	Luxembourg 100
Sanofi-Aventis Norge AS	Norway 100
Sanofi-Aventis Netherlands B.V.	Netherlands 100
Genzyme Europe BV	Netherlands 100
Sanofi-Aventis Sp. z.o.o.	Poland 100
Winthrop Farmaceutica Portugal Lda	Portugal 100
Sanofi Produtos Farmaceuticos Lda	Portugal 100
Zentiva, k.s.	Czech Republic 100
Zentiva Group, a.s.	Czech Republic 100
Sanofi-Aventis, s.r.o.	Czech Republic 100
Sanofi-Aventis Romania SRL	Romania 100
Sanofi-Synthelabo Ltd	United Kingdom 100
Sanofi Pasteur Holding Limited	United Kingdom 100
Chattem Limited (UK)	United Kingdom 100
Sanofi-Aventis UK Holdings Limited	United Kingdom 100
Genzyme Limited	United Kingdom 100
Merial Limited	United Kingdom 100
Merial Animal Health Ltd UK	United Kingdom 100
May and Baker Limited	United Kingdom 100
Aventis Pharma Limited	United Kingdom 100
Fisons Limited	United Kingdom 100
Limited Liability Zentiva Pharma	Russia 100
CJSC Sanofi-Aventis Vostok	Russia 74
AO Sanofi Russia	Russia 100
Zentiva a.s.	Slovakia 98.9
Sanofi-Aventis Pharma Slovakia s.r.o.	Slovakia 100
Sanofi AB	Sweden 100
Sanofi SA (Sanofi AG)	Switzerland 100
Sanofi-Aventis (Suisse) SA	Switzerland 100
Sanofi-Synthelabo Ilac As	Turkey 100

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

	<b>Financial interest % as of December 31, 2016</b>
<b>Europe</b>	
Zentiva Saglik Urunleri Sanayi ve Ticaret A.S.	Turkey 100
Sanofi-Aventis Ilaclari Limited Sirketi	Turkey 100
Sanofi Pasteur Asi Ticaret A.S	Turkey 100
Sanofi-Aventis Ukraine	Ukraine 100
	<b>Financial interest % as of December 31, 2016</b>
<b>United States</b>	
Sanofi US Services Inc	United States 100
Sanofi-Aventis US LLC	United States 100
Sanofi Pasteur Biologics, LLC	United States 100
TargeGen Inc.	United States 100
Chattem, Inc.	United States 100
Sanofi Pasteur VaxDesign Corporation	United States 100
BMP Sunstone Corporation	United States 100
Sanofi-Topaz, Inc.	United States 100
Carderm Capital L.P.	United States 100
Aventisub LLC	United States 100
Genzyme Corporation	United States 100
Merial, Inc.	United States 100
Armour Pharmaceutical Company	United States 100
Sanofi Pasteur Inc.	United States 100
Aventis Inc.	United States 100
VaxServe, Inc.	United States 100
	<b>Financial interest % as of December 31, 2016</b>
<b>Other Countries</b>	
Sanofi-Aventis South Africa (Pty) Ltd	South Africa 100
Zentiva South Africa (Pty) Ltd	South Africa 100
Sanofi-Aventis Algérie	Algeria 100
Winthrop Pharma Sidal SPA	Algeria 70
Sanofi-Aventis Argentina S.A.	Argentina 100
Genzyme de Argentina SA	Argentina 100
Merial Argentina	Argentina 100
Sanofi-Aventis Healthcare Pty Ltd	Australia 100
Sanofi-Aventis Australia Pty Ltd	Australia 100
Merial Australia Pty Ltd	Australia 100
Medley Farmaceutica Ltda	Brazil 100
Sanofi-Aventis Farmaceutica Ltda	Brazil 100
Merial Saude Animal Ltda Brazil	Brazil 100
Sanofi-Aventis Canada Inc.	Canada 100

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

<b>Other Countries</b>	<b>Financial interest % as of December 31, 2016</b>
Sanofi Consumer Health Inc	Canada 100
Merial Canada, Inc.	Canada 100
Sanofi Pasteur Limited (Canada)	Canada 100
Sanofi-Aventis de Chile SA	Chile 100
Sanofi (Hangzhou) Pharmaceuticals Co., Ltd	China 100
Hangzhou Sanofi Minsheng Consumer Healthcare Co., Ltd	China 60
Sanofi (China) Investment Co., Ltd	China 100
Merial Animal Health Co Ltd China	China 99
Sanofi Beijing Pharmaceuticals Co.Ltd	China 100
Shenzhen Sanofi Pasteur Biological Products Co, Ltd	China 100
Winthrop Pharmaceuticals de Colombia SA	Colombia 100
Genfar S.A.	Colombia 100
Sanofi-Aventis de Colombia S.A	Colombia 100
Sanofi-Aventis Korea Co. Ltd	South Korea 100
Genzyme Korea Co Ltd	South Korea 100
Sanofi-Aventis Gulf FZE	United Arab Emirates 100
Sanofi Aventis del Ecuador S.A	Ecuador 100
Sanofi Egypt S.A.E	Egypt 99.8
Sanofi-Aventis de Guatemala S.A.	Guatemala 100
Sunstone China limited	Hong Kong 100
Sanofi-Aventis Hong-Kong Limited	Hong Kong 100
Sanofi-Synthelabo (India) Private Ltd	India 100
Sanofi India Limited	India 60.4
Shantha Biotechnics Private Ltd	India 98.2
PT Aventis Pharma	Indonesia 75
PT sanofi-aventis Indonesia	Indonesia 100
Sanofi-Aventis Israël Ltd	Israel 100
Sanofi K.K.	Japan 100
Genzyme Japan K.K. <sup>(a)</sup>	Japan -
Merial Japan Ltd	Japan 100
Winthrop Pharmaceuticals (Malaysia) SDN. BHD.	Malaysia 100
Sanofi-Aventis (Malaysia) SDN. BHD.	Malaysia 100
Sanofi-Aventis de Mexico S.A de CV	Mexico 100
Sanofi-Aventis Winthrop SA de CV	Mexico 100
Merial de Mexico SA de CV	Mexico 100
Sanofi Pasteur SA de CV (Mexico)	Mexico 100
Maphar	Morocco 99.3

(a) Merged into Sanofi K.K. in 2016.

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

<b>Other Countries</b>	<b>Financial interest % as of December 31, 2016</b>	
Sanofi-Aventis Maroc	Morocco	100
Sanofi-Aventis Pakistan Ltd	Pakistan	52.9
Sanofi-Aventis de Panama S.A.	Panama	100
Sanofi-Aventis Latin America SA	Panama	100
Sanofi-Aventis del Peru SA	Peru	100
Genfar Peru S.A.	Peru	100
Sanofi-Aventis Philippines Inc	Philippines	100
Sanofi-Aventis de la Republica Dominicana S.A.	Dominican Republic	100
Sanofi-Aventis Singapore Pte Ltd	Singapore	100
Aventis Pharma (Manufacturing) PTE LTD	Singapore	100
Sanofi Taiwan Co Ltd	Taiwan	100
Zentiva (Thailand) limited	Thailand	100
Sanofi-Aventis Thailand Ltd	Thailand	100
Sanofi-Aventis Pharma Tunisie	Tunisia	100
Winthrop Pharma Tunisie	Tunisia	100
Sanofi-Aventis de Venezuela SA	Venezuela	100
Sanofi-Synthelabo Vietnam	Vietnam	70
Sanofi Vietnam Shareholding Company	Vietnam	100

**F.2. PRINCIPAL ASSOCIATES AND JOINT VENTURES**

	<b>Financial interest % as of December 31, 2016</b>	
Infraserv GmbH & Co. Höchst KG	Germany	31.2
Bristol-Myers Squibb / Sanofi Canada Partnership	Canada	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Holding Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi Pharmaceuticals Partnership Puerto Rico	United States	49.9
Bristol-Myers Squibb / Sanofi-Synthelabo Partnership	United States	49.9
Bristol-Myers Squibb / Sanofi-Synthelabo Puerto Rico Partnership	United States	49.9
Regeneron Pharmaceuticals, Inc.	United States	22.1
Onduo LLC	United States	50
Sanofi Pasteur MSD S.N.C (France) <sup>(a)</sup>	France	-

(a) On December 30, 2016 Sanofi sold its interests in Sanofi Pasteur MSD S.N.C. (see Note D.1.2.).

**Table of Contents****NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (Continued)****G/ Events subsequent to December 31, 2016****Closing of the exchange of Sanofi's Animal Health business for Boehringer Ingelheim's Consumer Healthcare business**

Further to the exclusivity agreement of December 2015, and the subsequent negotiations that led to the announcement of June 27, 2016 that contracts had been signed to secure the deal, Sanofi closed the exchange of its Animal Health business (Merial) for Boehringer Ingelheim's Consumer Healthcare business on January 1, 2017.

This exchange deal gives Sanofi an opportunity to build a solid and innovative Consumer Healthcare unit, and enhances its position in a core strategic business and a promising market.

After taking account of preliminary enterprise value adjustments, the exchange values of the two businesses have been provisionally determined at 10.3 billion for Sanofi's Animal Health business and 6.2 billion for Boehringer Ingelheim's Consumer Healthcare business. Those values exclude business swaps in certain countries that have been delayed.

**Divestment of the Animal Health business**

The divestment of the Animal Health business will generate a pre-tax gain in the region of 4.3 billion in 2017, excluding the effect of price adjustments and delayed business swaps.

**Acquisition of Boehringer Ingelheim's Consumer Healthcare business**

The provisional purchase price allocation for the acquisition of Boehringer Ingelheim's Consumer Healthcare (CHC) business is as follows:

( billion)	
Property, plant and equipment	0.1
Other intangible assets	4
Inventories	0.2
Other assets and liabilities	(0.1)
Deferred taxes	(0.2)
<b>Net assets of the CHC business acquired from Boehringer Ingelheim</b>	<b>4</b>
Goodwill	2.2
<b>Purchase price</b>	<b>6.2</b>

The goodwill represents the ability to refresh the product portfolio using a dedicated structure, the skills base of the transferred staff, the advantages of creating new growth platforms and of expected future synergies, and the other beneficial effects of combining Boehringer Ingelheim's CHC activities with those of Sanofi.

## Edgar Filing: Sanofi - Form 20-F

Because the purchase price allocation for each acquirer entity has not yet been completed, the portion of this goodwill that is tax-deductible has not been determined at this stage.

The costs incurred in connection with the acquisition of Boehringer Ingelheim's CHC business will be no more than 20 million.

**F- 110**