Opko Health, Inc.
Form 10-Q
November 07, 2016
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)
ý QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2016.
OR
¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to .
Commission file number 001-33528

OPKO Health, Inc.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	75-2402409
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

4400 Biscayne Blvd.
Miami, FL 33137
(Address of Principal Executive Offices) (Zip Code)

(305) 575-4100
(Registrant's Telephone Number, Including Area Code)

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. ý YES ¨ NO
Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). ý YES ¨ NO
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" (in Rule 12b-2 of the Exchange Act) (Check one):

Large accelerated filer x	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): ¨ YES ý NO

As of October 31, 2016, the registrant had 557,533,838 shares of Common Stock outstanding.

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EX-101.INS	XBRL Instance Document
EX-101.SCH	XBRL Taxonomy Extension Schema Document
EX-101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document

EX-101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
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EX-101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements," as that term is defined under the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements include statements about our expectations, beliefs or intentions regarding our product development efforts, business, financial condition, results of operations, strategies or prospects. You can identify forward-looking statements by the fact that these statements do not relate strictly to historical or current matters. Rather, forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements. These factors include those described below and in "Item 1A-Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2015, and described from time to time in our other reports filed with the Securities and Exchange Commission. We do not undertake an obligation to update forward-looking statements. We intend that all forward-looking statements be subject to the safe-harbor provisions of the PSLRA. These forward-looking statements are only predictions and reflect our views as of the date they are made with respect to future events and financial performance.

Risks and uncertainties, the occurrence of which could adversely affect our business, include the following:

- we have a history of losses and may not generate sustained positive cash flow sufficient to fund our operations and research and development programs;
- the risks inherent in funding, developing and obtaining regulatory approvals of new, commercially-viable and competitive products and treatments;
- our research and development activities may not result in commercially viable products;
- that earlier clinical results of effectiveness and safety may not be reproducible or indicative of future results;
- that the launch of commercial sales for Rayaldee may not be successful;
- that we may fail to obtain regulatory approval for or successfully commercialize our product candidates;
- that currently available over-the-counter and prescription products, as well as products under development by others, may prove to be as or more effective than our products for the indications being studied;
- our ability to develop a pharmaceutical sales and marketing infrastructure;
- our ability and our distribution and marketing partners' ability to comply with regulatory requirements regarding the sales, marketing and manufacturing of our products and product candidates and the operation of our laboratories;
- the performance of our third-party distribution partners, licensees and manufacturers over which we have limited control;
- our success is dependent on the involvement and continued efforts of our Chairman and Chief Executive Officer;
- integration challenges for Bio-Reference, EirGen, Transition Therapeutics and other acquired businesses;
- changes in regulation and policies in the United States and other countries, including increasing downward pressure on health care reimbursement;
- our ability to manage our growth and our expanded operations;
- increased competition, including price competition;
- changing relationships with payers, including the various state and multi-state Blues programs, suppliers and strategic partners;
- efforts by third-party payors to reduce utilization and reimbursement for clinical testing services;
- failure to timely or accurately bill for our services;
- failure to obtain and retain new clients and business partners, or a reduction in tests ordered or specimens submitted by existing clients;
- failure to establish, and perform to, appropriate quality standards to assure that the highest level of quality is observed in the performance of our testing services;
- failure to maintain the security of patient-related information;

- our ability to obtain and maintain intellectual property protection for our products;
- our ability to defend our intellectual property rights with respect to our products;
- our ability to operate our business without infringing the intellectual property rights of others;
- our ability to attract and retain key scientific and management personnel;
- our need for, and ability to obtain, additional financing;
- adverse results in material litigation matters or governmental inquiries;
- failure to obtain and maintain regulatory approval outside the U.S.; and
- legal, economic, political, regulatory, currency exchange, and other risks associated with international operations.

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PART I. FINANCIAL INFORMATION

Unless the context otherwise requires, all references in this Quarterly Report on Form 10-Q to the "Company", "OPKO", "we", "our", "ours", and "us" refer to OPKO Health, Inc., a Delaware corporation, including our wholly-owned subsidiaries.

Item 1. Financial Statements

OPKO Health, Inc. and Subsidiaries

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

(In thousands, except share and per share data)

	September 30, 2016	December 31, 2015
ASSETS		
Current assets:		
Cash and cash equivalents	$144,646	$ 193,598
Accounts receivable, net	223,827	193,875
Inventory, net	43,186	39,681
Other current assets and prepaid expenses	90,408	26,904
Total current assets	502,067	454,058
Property, plant and equipment, net	125,486	131,798
Intangible assets, net	781,890	638,152
In-process research and development	646,970	792,275
Goodwill	700,526	743,348
Investments	38,783	34,716
Other assets	4,305	4,841
Total assets	$2,800,027	$ 2,799,188
LIABILITIES AND EQUITY		
Current liabilities:		
Accounts payable	$58,544	$ 72,535
Accrued expenses	186,076	167,899
Current portion of lines of credit and notes payable	9,891	11,468
Total current liabilities	254,511	251,902
2033 Senior Notes and estimated fair value of embedded derivatives, net of discount	51,537	48,986
Deferred tax liabilities, net	184,493	226,036
Other long-term liabilities, principally deferred revenue and line of credit	204,094	292,470
Total long-term liabilities	440,124	567,492
Total liabilities	694,635	819,394
Equity:		
Common Stock - $0.01 par value, 750,000,000 shares authorized; 558,053,479 and 546,188,516 shares issued at September 30, 2016 and December 31, 2015, respectively	5,581	5,462
Treasury Stock - 586,760 and 1,120,367 shares at September 30, 2016 and December 31, 2015, respectively	(1,911)	(3,645)
Additional paid-in capital	2,834,300	2,705,385
Accumulated other comprehensive loss	(16,284)	(22,537)
Accumulated deficit	(716,294)	(704,871)
Total shareholders' equity	2,105,392	1,979,794
Total liabilities and equity	$2,800,027	$ 2,799,188

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)
(In thousands, except share and per share data)

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
Revenues:				
Revenue from services	$259,025	$ 103,919	$777,559	$ 107,929
Revenue from products	20,569	20,765	63,275	59,066
Revenue from transfer of intellectual property and other	18,441	18,350	105,338	48,552
Total revenues	298,035	143,034	946,172	215,547
Costs and expenses:				
Cost of service revenue	138,554	56,670	417,121	61,434
Cost of product revenue	12,626	10,658	35,033	30,650
Selling, general and administrative	124,845	55,246	370,358	93,629
Research and development	24,424	18,937	83,594	74,010
Contingent consideration	3,093	1,636	15,604	6,471
Amortization of intangible assets	18,116	8,110	47,337	14,011
Grant repayment	—	—	—	25,889
Total costs and expenses	321,658	151,257	969,047	306,094
Operating loss	(23,623)	(8,223)	(22,875)	(90,547)
Other income and (expense), net:				
Interest income	163	13	341	27
Interest expense	(2,018)	(2,745)	(6,022)	(6,296)
Fair value changes of derivative instruments, net	(5,701)	32,244	(5,889)	(34,100)
Other income (expense), net	(2,972)	17,482	3,543	16,734
Other income and (expense), net	(10,528)	46,994	(8,027)	(23,635)
Income (loss) before income taxes and investment losses	(34,151)	38,771	(30,902)	(114,182)
Income tax benefit	19,988	92,978	24,626	87,218
Income (loss) before investment losses	(14,163)	131,749	(6,276)	(26,964)
Loss from investments in investees	(814)	(3,502)	(5,147)	(6,067)
Net income (loss)	(14,977)	128,247	(11,423)	(33,031)
Less: Net loss attributable to noncontrolling interests	—	—	—	(1,400)
Net income (loss) attributable to common shareholders	$(14,977)	$ 128,247	$(11,423)	$ (31,631)
Earnings (loss) per share:				
Earnings (loss) per share, basic	$(0.03)	$ 0.26	$(0.02)	$ (0.07)
Earnings (loss) per share, diluted	$(0.03)	$ 0.18	$(0.02)	$ (0.07)
Weighted average common shares outstanding, basic	552,229,266	500,562,254	548,550,641	469,931,486
Weighted average common shares outstanding, diluted	552,229,266	715,512,850	548,550,641	469,931,486

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.
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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(Unaudited)
(In thousands)

	For the three months ended September 30,		For the nine months ended September 30,	
	2016	2015	2016	2015
Net income (loss)	$(14,977)	$128,247	$(11,423)	$(33,031)
Other comprehensive income (loss), net of tax:				
Change in foreign currency translation and other comprehensive income (loss)	2,796	(1,452)	5,306	(5,998)
Available for sale investments:				
Change in unrealized loss, net of tax	449	(661)	(2,955)	(2,602)
Less: reclassification adjustments for losses included in net loss, net of tax	3,902	—	3,902	—
Comprehensive income (loss)	(7,830)	126,134	(5,170)	(41,631)
Less: Comprehensive loss attributable to noncontrolling interest	—	—	—	(1,400)
Comprehensive income (loss) attributable to common shareholders	$(7,830)	$126,134	$(5,170)	$(40,231)

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)
(In thousands)

	For the nine months ended September 30,	
	2016	2015
Cash flows from operating activities:		
Net loss	$(11,423)	$(33,031)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	72,612	20,073
Non-cash interest	2,063	2,176
Amortization of deferred financing costs	175	1,175
Losses from investments in investees	5,147	6,067
Equity-based compensation – employees and non-employees	34,939	17,765
Revenue from receipt of equity	—	(140)
Realized loss (gain) on equity securities and disposal of fixed assets	943	(216)
Loss on conversion of 3.00% convertible senior notes	—	(943)
Change in fair value of derivative instruments	5,889	34,100
Change in fair value of contingent consideration	15,604	6,471
Gain on deconsolidation of SciVac	—	(17,340)
Deferred income tax benefit	(30,982)	(96,713)
Changes in assets and liabilities, net of the effects of acquisitions:		
Accounts receivable, net	(28,974)	(5,704)
Inventory, net	(2,726)	(5,724)
Other current assets and prepaid expenses	(24,310)	(4,225)
Other assets	(402)	1,262
Accounts payable	(16,141)	(35,504)
Foreign currency measurement	(433)	776
Deferred revenue	(56,256)	246,262
Accrued expenses and other liabilities	36,015	36,788
Net cash provided by operating activities	1,740	173,375
Cash flows from investing activities:		
Investments in investees	(9,171)	(3,000)
Acquisition of businesses, net of cash	15,878	(78,862)
Purchase of marketable securities	(15,631)	—
Maturities of short-term marketable securities	15,634	—
Proceeds from the sale of property, plant and equipment	1,082	—
Acquisition of intangible assets	(5,000)	(5,000)
Capital expenditures	(17,015)	(4,422)
Net cash used in investing activities	(14,223)	(91,284)
Cash flows from financing activities:		
Issuance of 2033 Senior Notes, net, including related parties	—	81
Proceeds from the exercise of Common Stock options and warrants	6,112	25,180
Cash from non-controlling interest	—	100
Borrowings on lines of credit	15,816	111,359
Repayments of lines of credit	(58,901)	(103,544)
Net cash (used in) provided by financing activities	(36,973)	33,176

Effect of exchange rate changes on cash and cash equivalents	504	(30)
Net (decrease) increase in cash and cash equivalents	(48,952)	115,237
Cash and cash equivalents at beginning of period	193,598	96,907
Cash and cash equivalents at end of period	$144,646	$212,144
SUPPLEMENTAL INFORMATION:		
Interest paid	$2,519	$2,917
Income taxes paid, net	$8,045	$1,383
Non-cash financing:		
Shares issued upon the conversion of:		
2033 Senior Notes	$—	$120,299
Common Stock options and warrants, surrendered in net exercise	$350	$14,241
Issuance of capital stock to acquire or contingent consideration settlement:		
Transition Therapeutics, Inc.	$58,530	$—
Bio-Reference Laboratories, Inc.	$—	$950,010
EirGen Pharma Limited	$—	$33,569
OPKO Health Europe	$313	$1,813
OPKO Renal	$25,986	$20,113
Issuance of stock for investment in Xenetic	$4,856	$—

The accompanying Notes to Condensed Consolidated Financial Statements are an integral part of these statements.

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OPKO Health, Inc. and Subsidiaries
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)
NOTE 1 BUSINESS AND ORGANIZATION

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes Bio-Reference Laboratories, Inc. ("Bio-Reference"), the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person sales and marketing department to drive growth and leverage new products, including the 4Kscore prostate cancer test and the Claros 1 in-office immunoassay platform (in development). Our pharmaceutical business features Rayaldee, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in patients with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency and VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO in November 2015 and PDUFA date for IV formulation is January 2017), TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and TT701, an androgen receptor modulator for androgen deficiency indications. Our pharmaceutical business also includes OPKO Biologics, which features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), a once-daily Factor VIIa drug for hemophilia (Phase 2a), and long-acting oxyntomodulin ("OXM") for diabetes and obesity (Phase 1). We are incorporated in Delaware and our principal executive offices are located in leased offices in Miami, Florida.

In August 2016, we completed the acquisition of Transition Therapeutics, Inc. ("Transition Therapeutics"), a clinical stage biotechnology company developing TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity, and TT701, an androgen receptor modulator for androgen deficiency indications. Holders of Transition Therapeutics common stock received 6,431,899 shares of OPKO Common Stock. The transaction was valued at approximately $58.5 million, based on a closing price per share of our Common Stock of $9.10 as reported by NASDAQ on the closing date.

In August 2015, we completed the acquisition of Bio-Reference, the third largest full service clinical laboratory in the United States, known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately $950.1 million, based on a closing price per share of our Common Stock of $12.38 as reported by the New York Stock Exchange on the closing date, or $34.05 per share of Bio-Reference common stock. Included in the transaction value is $2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

Through our acquisition of Bio-Reference, we provide laboratory testing services, primarily to customers in the larger metropolitan areas across New York, New Jersey, Maryland, Pennsylvania, Delaware, Washington DC, Florida, California, Texas, Illinois and Massachusetts as well as to customers in a number of other states. We offer a comprehensive test menu of clinical diagnostics for blood, urine, and tissue analysis. This includes hematology, clinical chemistry, immunoassay, infectious diseases, serology, hormones, and toxicology assays, as well as Pap smear, anatomic pathology (biopsies) and other types of tissue analysis. We perform cancer cytogenetic testing at our leased facilities in Elmwood Park, NJ, Clarksburg, MD, Milford, MA, and genetic testing at our leased facility in Gaithersburg, MD, as well as at our Elmwood Park facility. We perform cytology testing at our leased facilities in Frederick, MD, Milford, MA, Melbourne FL, Houston, TX and at our Elmwood Park facility. We market our laboratory testing services directly to physicians, geneticists, hospitals, clinics, correctional and other health facilities.

In May 2015, we acquired all of the issued and outstanding shares of EirGen Pharma Limited ("EirGen"), a specialty pharmaceutical company incorporated in Ireland focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products, for $133.8 million. We acquired the outstanding shares of EirGen for approximately $100.2 million in cash and delivered 2,420,487 shares of our Common Stock valued at approximately $33.6 million based on the closing price per share of our Common Stock as reported by the New York Stock Exchange on the closing date of the acquisition, $13.88 per share.

We operate established pharmaceutical platforms in Ireland, Chile, Spain, and Mexico, which are generating revenue and which we expect to facilitate future market entry for our products currently in development. In addition, we have a development and commercial supply pharmaceutical company and a global supply chain operation and holding

company in Ireland. We own a specialty active pharmaceutical ingredients (“APIs”) manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our molecular diagnostic and therapeutic products.

Our research and development activities are primarily performed at leased facilities in Miramar, Florida, Woburn, Massachusetts, Waterford, Ireland, Nes Ziona, Israel, and Barcelona, Spain.

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NOTE 2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation. The accompanying unaudited Condensed Consolidated Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all information and notes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of only normal recurring adjustments or otherwise disclosed herein) considered necessary to present fairly the Company's results of operations, financial position and cash flows have been made. The results of operations and cash flows for the three and nine months ended September 30, 2016, are not necessarily indicative of the results of operations and cash flows that may be reported for the remainder of 2016 or any future periods. The unaudited Condensed Consolidated Financial Statements should be read in conjunction with the Consolidated Financial Statements and the Notes to Consolidated Financial Statements included in our Annual Report on Form 10-K for the year ended December 31, 2015.

Principles of consolidation. The accompanying unaudited Condensed Consolidated Financial Statements include the accounts of OPKO Health, Inc. and of our wholly-owned subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

Use of estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from these estimates.

Cash and cash equivalents. Cash and cash equivalents include short-term, interest-bearing instruments with original maturities of 90 days or less at the date of purchase. We also consider all highly liquid investments with original maturities at the date of purchase of 90 days or less as cash equivalents. These investments include money markets, bank deposits, certificates of deposit and U.S. treasury securities.

Inventories. Inventories are valued at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost or market. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories. The provision for inventory obsolescence for the nine months ended September 30, 2016 and 2015 was $0.2 million and $0.7 million, respectively.

Pre-launch inventories. We may accumulate commercial quantities of certain product candidates prior to the date we anticipate that such products will receive final U.S. FDA approval. The accumulation of such pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, we may accumulate pre-launch inventories of certain products when such action is appropriate in relation to the commercial value of the product launch opportunity. In accordance with our policy, this pre-launch inventory is expensed. At September 30, 2016 and December 31, 2015, there were no pre-launch inventories.

Goodwill and intangible assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired accounted for by the acquisition method of accounting and arose from our acquisitions. Refer to Note 4. Goodwill, in-process research and development ("IPR&D") and other intangible assets acquired in business combinations, licensing and other transactions at September 30, 2016 and December 31, 2015 was $2.1 billion and $2.2 billion, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. We determined the fair value of intangible assets, including IPR&D, using the "income method."

Goodwill is tested at least annually for impairment, or when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value.

Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the

project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the IPR&D asset is charged to expense.

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We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was $47.3 million and $14.0 million for the nine months ended September 30, 2016 and 2015, respectively.

We reclassified $187.6 million of IPR&D related to Rayaldee from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheet upon the FDA's approval of Rayaldee in June 2016. The assets will be amortized on a straight-line basis over their estimated useful life of approximately 12 years.

Fair value measurements. The carrying amounts of our cash and cash equivalents, accounts receivable, accounts payable and short-term debt approximate their fair value due to the short-term maturities of these instruments. Investments that are considered available for sale as of September 30, 2016 and December 31, 2015 are carried at fair value. Our debt under the credit agreement with JPMorgan Chase Bank, N.A. approximates fair value due to the variable rate of interest.

In evaluating the fair value information, considerable judgment is required to interpret the market data used to develop the estimates. The use of different market assumptions and/or different valuation techniques may have a material effect on the estimated fair value amounts. Accordingly, the estimates of fair value presented herein may not be indicative of the amounts that could be realized in a current market exchange. Refer to Note 8.

Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain prior acquisitions to their fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as a reduction in contingent consideration expense. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as our development programs progress, revenue estimates evolve and additional data is obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value which may have a material impact on our results from operations and financial position.

Derivative financial instruments. We record derivative financial instruments on our Condensed Consolidated Balance Sheet at their fair value and recognize the changes in the fair value in our Condensed Consolidated Statement of Operations when they occur, the only exception being derivatives that qualify as hedges. For the derivative instrument to qualify as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2016 and December 31, 2015, our foreign currency forward contracts to economically hedge inventory purchases did not meet the documentation requirements to be designated as hedges. Accordingly, we recognize all changes in the fair values of our derivatives instruments, net, in our Condensed Consolidated Statement of Operations. Refer to Note 9.

Property, plant and equipment. Property, plant and equipment are recorded at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets and includes amortization expense for assets capitalized under capital leases. The estimated useful lives by asset class are as follows: software - 3 years, machinery, medical and other equipment - 5-8 years, furniture and fixtures - 5-10 years, leasehold improvements - the lesser of their useful life or the lease term, buildings and improvements - 10-40 years, automobiles and aircraft - 3-15 years. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation expense was $25.3 million and $6.1 million for the nine months ended September 30, 2016 and 2015, respectively. Assets held under capital leases are included within Property, plant and equipment, net in our Condensed Consolidated Balance Sheet and are amortized over the shorter of their useful lives or the expected term of their related leases.

Impairment of long-lived assets. Long-lived assets, such as property and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted future cash flows expected to be generated by the asset. If the carrying amount of an asset exceeds its estimated future cash flows, then an impairment charge is recognized for the amount by which the carrying amount of the asset exceeds the fair value of the asset.

Income taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date.

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We operate in various countries and tax jurisdictions globally. For interim reporting purposes, we record income taxes based on the expected annual effective income tax rate taking into consideration global forecasted tax results. For the three and nine months ended September 30, 2016, the tax rate differed from the U.S. federal statutory rate of 35% primarily due to the relative mix in earnings and losses in the U.S. versus foreign tax jurisdictions, the impact of certain discrete tax events and operating results in tax jurisdictions which do not result in a tax benefit.

Income tax benefit for the three and nine months ended September 30, 2015 was primarily due to a $93.4 million release of a valuation allowance on our U.S. deferred tax assets as a result of the merger with Bio-Reference in August 2015.

We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment. On January 5, 2016, the Israeli Parliament officially published the Law for the Amendment of the Israeli Tax Ordinance (Amendment 216), that reduces the standard corporate income tax rate from 26.5% to 25%. The amendment was entered into force on January 1, 2016 and the 25% corporate tax rate will apply to income that was generated from that day onwards. The new rate has been used in determining Income tax benefit in 2016.

Revenue recognition. Revenue for laboratory services is recognized at the time test results are reported, which approximates when services are provided. Services are provided to patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in revenue net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue. For the nine months ended September 30, 2016 and 2015, approximately 10% and 9%, respectively, of our revenues from services were derived directly from the Medicare and Medicaid programs. The increase in revenues from laboratory services, including revenue from Medicare and Medicaid programs, is due to the acquisition of Bio-Reference in August 2015.

Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and management’s evaluation of specific factors that may increase or decrease the risk of product returns.

Revenue from transfer of intellectual property includes revenue related to the sale, license or transfer of intellectual property such as upfront license payments, license fees, milestone and royalty payments received through our license, and collaboration and commercialization agreements. We analyze our multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting.

Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and qualifies for treatment as a separate unit of accounting under multiple-element arrangement guidance. License fees with ongoing involvement or performance obligations that do not have standalone value are recorded as deferred revenue, included in Accrued expenses or Other long-term liabilities, when received and generally are recognized ratably over the period of such performance obligations only after both the license period has commenced and we have delivered the technology.

The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a periodic basis. For the three and nine months ended September 30, 2016, revenue from transfer of intellectual property includes $17.7 million and $53.0 million, respectively, of revenue related to the Pfizer Transaction. For the three and nine months ended September 30, 2015, revenue from transfer of intellectual property includes $17.7 million and $47.8 million, respectively, of revenue related to the Pfizer Transaction. Refer to Note 12.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Revenue from transfer of intellectual property upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; there was substantive uncertainty at the date of entering into the arrangement that the milestone would be achieved; the milestone is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item by us; the milestone relates solely to past performance; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are not considered to be substantive and are, therefore, deferred and recognized as Revenue from transfer of intellectual property over the term of the arrangement as we complete our performance obligations.

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Total deferred revenue included in Accrued expenses and Other long-term liabilities was $180.4 million and $232.9 million at September 30, 2016 and December 31, 2015, respectively. The deferred revenue balance at September 30, 2016 relates primarily to the Pfizer Transaction. Refer to Note 12.

Concentration of credit risk and allowance for doubtful accounts. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of accounts receivable. Substantially all of our accounts receivable are with either companies in the health care industry or patients. However, credit risk is limited due to the number of our clients as well as their dispersion across many different geographic regions.

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related health care programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. Accounts receivable balances (net of contractual adjustments) from Medicare and Medicaid were $31.1 million and $26.1 million at September 30, 2016 and December 31, 2015, respectively.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At September 30, 2016 and December 31, 2015, receivables due from patients represent approximately 6.6% and 7.5%, respectively, of our consolidated accounts receivable (prior to allowance for doubtful accounts).

We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer's ability to pay. Actual results could differ from those estimates. Our reported net income (loss) is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts was $41.1 million and $25.2 million at September 30, 2016 and December 31, 2015, respectively. The provision for bad debts for the nine months ended September 30, 2016 and 2015 was $62.5 million and $8.3 million, respectively.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow and as a reduction of taxes paid in cash flow from operations. Equity-based compensation arrangements to non-employees are recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. During the nine months ended September 30, 2016 and 2015, we recorded $34.9 million and $17.8 million, respectively, of equity-based compensation expense.

Research and development expenses. Research and development expenses include external and internal expenses, partially offset by third-party grants and fundings arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. Research and development employee-related expenses include salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities. We expense these costs in the period in which they are incurred. We estimate our liabilities for research and development expenses in order to match the recognition of expenses to the period in which the actual services are received. As such, accrued liabilities related to third party research and development activities are recognized based upon our estimate of services received and degree of completion of the services in accordance with the specific third party contract.

We record expense for in-process research and development projects acquired as asset acquisitions which have not reached technological feasibility and which have no alternative future use. For in-process research and development projects acquired in business combinations, the in-process research and development project is capitalized and evaluated for impairment until the development process has been completed. Once the development process has been completed the asset will be amortized over its remaining useful life.

Segment reporting. Our chief operating decision-maker ("CODM") is Phillip Frost, M.D., our Chairman and Chief Executive Officer. Our CODM reviews our operating results and operating plans and makes resource allocation

decisions on a Company-wide or aggregate basis. We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations we acquired in Chile, Mexico, Ireland, Israel and Spain and our pharmaceutical research and development. The diagnostics segment primarily consists of clinical laboratory operations we acquired through the acquisitions of Bio-Reference and OPKO Lab and our point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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Variable interest entities. The consolidation of variable interest entities ("VIE") is required when an enterprise has a controlling financial interest. A controlling financial interest in a VIE will have both of the following characteristics: (a) the power to direct the activities of a VIE that most significantly impact the VIE's economic performance and (b) the obligation to absorb losses of the VIE that could potentially be significant to the VIE. Refer to Note 5.

Investments. We have made strategic investments in development stage and emerging companies. We record these investments as equity method investments or investments available for sale based on our percentage of ownership and whether we have significant influence over the operations of the investees. Investments for which it is not practical to estimate fair value and which we do not have significant influence are accounted for as cost method investments. For investments classified under the equity method of accounting, we record our proportionate share of their losses in Losses from investments in investees in our Condensed Consolidated Statement of Operations. Refer to Note 5. For investments classified as available for sale, we record changes in their fair value as unrealized gain or loss in Other comprehensive income (loss) based on their closing price per share at the end of each reporting period. Refer to Note 5.

Recent accounting pronouncements. In May 2014, the FASB issued Accounting Standards Update ("ASU") No. 2014-09, "Revenue from Contracts with Customers." ASU 2014-09 clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP and International Financial Reporting Standards that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Companies can choose to apply the ASU using either the full retrospective approach or a modified retrospective approach. We are currently evaluating both methods of adoption and the impact that the adoption of this ASU will have on our Condensed Consolidated Financial Statements.

In June 2014, the FASB issued ASU No. 2014-12, "Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force)." ASU 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 was effective for the Company beginning after January 1, 2016. Our adoption of ASU 2014-12 in the first quarter of 2016 using the prospective application did not have a material impact on our Condensed Consolidated Financial Statements.

In August 2014, the FASB issued ASU No. 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 with early adoption permitted. We do not believe the impact of our pending adoption of ASU 2014-15 on our Condensed Consolidated Financial Statements will be material.

In February 2015, the FASB issued ASU No. 2015-02, "Consolidation (Topic 810): Amendments to the Consolidation Analysis," which amends current consolidation guidance including changes to both the variable and voting interest models used by companies to evaluate whether an entity should be consolidated. The requirements from ASU 2015-02 were effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-02 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs," which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU 2015-03 was effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-03 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

In July 2015, the FASB issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory," which changes the measurement principle for entities that do not measure inventory using the last-in, first-out ("LIFO")

or retail inventory method from the lower of cost or market to lower of cost and net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In September 2015, the FASB issued ASU No. 2015-16, “Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments,” which replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period’s financial statements, the effect on earnings

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of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. Our early adoption of ASU 2015-16 in 2015 did not have a significant impact on our Condensed Consolidated Financial Statements.

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes," which requires deferred tax liabilities and assets to be classified as noncurrent in a classified statement of financial position. We early adopted the provisions of this ASU prospectively in the fourth quarter of 2015, and did not retrospectively adjust the prior periods. The adoption of this ASU simplifies the presentation of deferred income taxes and reduces complexity without decreasing the usefulness of information provided to users of financial statements. The adoption of ASU 2015-17 did not have a significant impact on our Condensed Consolidated Financial Statements.

In January 2016, the FASB issued ASU No. 2016-01, "Financial Instruments - Overall (Subtopic 825-10)," which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The ASU requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. ASU 2016-01 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," which will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation - Stock Compensation (Topic 718)," which simplifies several aspects of the accounting for share-based payment award transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and accounting for forfeitures. ASU 2016-09 will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230)," which addresses the classification of eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

NOTE 3 EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing our net income (loss) by the weighted average number of shares outstanding during the period. For diluted earnings per share, the dilutive impact of stock options, warrants and bifurcated conversion options of the 2033 Senior Notes is determined by applying the "treasury stock" method. In the periods in which their effect would be antidilutive, no effect has been given to outstanding options, warrants or the potentially dilutive shares issuable pursuant to the 2033 Senior Notes (defined in Note 6) in the dilutive computation. The following table sets forth the computation of basic and diluted earnings (loss) per share:

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(Shares in thousands)	For the three months ended September 30, 2016	2015	For the nine months ended September 30, 2016	2015
Numerator				
Net income (loss) attributable to common shareholders, basic	$(14,977)	$128,247	$(11,423)	$(31,631)
Add: Interest on 2033 Senior Notes	—	945	—	—
Change in FV of embedded derivative income	—	(36,132)	—	—
Net income (loss) attributable to common shareholders, diluted	$(14,977)	$93,060	$(11,423)	$(31,631)
Denominator				
(Shares in thousands)				
Weighted average common shares outstanding, basic	552,229	500,562	548,551	469,931
Effect of dilutive securities:				
Stock options	—	6,349	—	—
Warrants	—	2,065	—	—
2033 Senior Notes	—	6,537	—	—
Dilutive potential shares	—	14,951	—	—
Weighted average common shares outstanding, diluted	552,229	515,513	548,551	469,931
Earnings (loss) per share, basic	$(0.03)	$0.26	$(0.02)	$(0.07)
Earnings (loss) per share, diluted	$(0.03)	$0.18	$(0.02)	$(0.07)

A total of 9,175,105 and 11,687,219 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the three and nine months ended September 30, 2016, respectively, because their inclusion would be antidilutive. A total of 12,348,652 potential shares of Common Stock have been excluded from the calculation of diluted net loss per share for the nine months ended September 30, 2015, because their inclusion would be antidilutive.

During the three months ended September 30, 2016, 660,921 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 658,357 shares of Common Stock. Of the 660,921 Common Stock options and Common Stock warrants exercised, 2,564 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the nine months ended September 30, 2016, 2,899,458 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 2,771,514 shares of Common Stock. Of the 2,899,458 Common Stock options and Common Stock warrants exercised, 127,944 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the three months ended September 30, 2015, 1,595,614 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 1,595,461 shares of Common Stock. Of the 1,595,614 Common Stock options and Common Stock warrants exercised, 153 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

During the nine months ended September 30, 2015, 25,437,929 Common Stock options and Common Stock warrants to purchase shares of our Common Stock were exercised, resulting in the issuance of 24,231,122 shares of Common Stock. Of the 25,437,929 Common Stock options and Common Stock warrants exercised, 1,206,807 shares of Common Stock were surrendered in lieu of a cash payment via the net exercise feature of the agreements.

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NOTE 4 COMPOSITION OF CERTAIN FINANCIAL STATEMENT CAPTIONS

(In thousands)	September 30, 2016	December 31, 2015
Accounts receivable, net		
Accounts receivable	$ 264,957	$ 219,043
Less: allowance for doubtful accounts	(41,130)	(25,168)
	$ 223,827	$ 193,875
Inventories, net		
Consumable supplies	$ 22,693	$ 22,265
Finished products	14,030	13,404
Work in-process	1,596	1,215
Raw materials	6,014	3,848
Less: inventory reserve	(1,147)	(1,051)
	$ 43,186	$ 39,681
Other current assets and prepaid expenses		
Taxes recoverable	56,566	3,076
Other receivables	16,020	11,946
Prepaid supplies	11,428	8,773
Prepaid insurance	5,520	2,206
Other	874	903
	$ 90,408	$ 26,904
Intangible assets, net:		
Customer relationships	$ 445,743	$ 449,972
Technologies	339,333	151,709
Trade names	50,476	50,416
Licenses	23,506	23,432
Covenants not to compete	16,361	8,612
Product registrations	7,911	7,512
Other	4,430	5,600
Less: accumulated amortization	(105,870)	(59,101)
	$ 781,890	$ 638,152
Accrued expenses:		
Deferred revenue	$ 72,559	$ 70,246
Employee benefits	33,608	29,751
Clinical trials	10,056	2,505
Taxes payable	16,733	7,605
Contingent consideration	5,211	22,164
Capital leases short-term	3,062	5,373
Milestone payment	4,966	5,000
Professional fees	2,259	1,506
Other	37,622	23,749
	$ 186,076	$ 167,899

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(In thousands)	September 30, 2016	December 31, 2015
Other long-term liabilities:		
Deferred revenue	$ 107,817	$ 162,634
Line of credit	38,444	72,107
Contingent consideration	38,532	32,258
Mortgages and other debts payable	2,243	2,523
Capital leases long-term	7,527	9,285
Other	9,531	13,663
	$ 204,094	$ 292,470

All of the intangible assets and goodwill acquired relate to our acquisitions of principally OPKO Renal, OPKO Biologics, EirGen and Bio-Reference. We do not anticipate capitalizing the cost of product registration renewals, rather we expect to expense these costs, as incurred. Our goodwill is not tax deductible for income tax purposes in any jurisdiction we operate in.

We reclassified $187.6 million of IPR&D related to Rayaldee from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheet upon the FDA's approval of Rayaldee in June 2016. In addition, we made certain purchase price allocation adjustments related to the Bio-Reference acquisition during the nine months ended September 30, 2016. Refer to Note 5. Other changes in value of the intangible assets and goodwill are primarily due to foreign currency fluctuations between the Chilean and Mexican pesos, the Euro and the Shekel against the U.S. dollar.

The following table reflects the changes in Goodwill during the nine months ended September 30, 2016.

(In thousands)	2016 Balance at January 1st	Purchase accounting adjustments	Foreign exchange	Balance at September 30th
Pharmaceuticals				
CURNA	$4,827	$ —	$ —	$ 4,827
EirGen	81,139	—	2,364	83,503
FineTech	11,698	—	—	11,698
OPKO Chile	4,517	—	343	4,860
OPKO Biologics	139,784	—	—	139,784
OPKO Health Europe	7,191	—	201	7,392
OPKO Renal	2,069	—	—	2,069
Transition Therapeutics	—	3,453	(16)	3,437
Diagnostics				
Bio-Reference	441,158	(49,167)	—	391,991
OPKO Diagnostics	17,977	—	—	17,977
OPKO Lab	32,988	—	—	32,988
	$743,348	$ (45,714)	$ 2,892	$ 700,526

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NOTE 5 ACQUISITIONS, INVESTMENTS AND LICENSES

Transition Therapeutics acquisition

In August 2016, we completed the acquisition of Transition Therapeutics, a clinical stage biotechnology company. Holders of Transition Therapeutics common stock received 6,431,899 shares of OPKO Common Stock. The transaction was valued at approximately $58.5 million, based on a closing price per share of our Common Stock of $9.10 as reported by NASDAQ on the closing date.

The following table summarizes the preliminary purchase price allocation and the estimated fair value of the net assets acquired and liabilities assumed at the date of acquisition. The purchase price allocation for Transition Therapeutics is preliminary pending completion of the fair value analysis of acquired assets and liabilities:

(In thousands)	Transition Therapeutics
Cash and cash equivalents	$ 15,878
IPR&D assets	41,000
Goodwill	3,453
Other assets	634
Accounts payable and other liabilities	(1,035)
Deferred tax liability	(1,400)
Total purchase price	$ 58,530

Goodwill from the acquisition of Transition Therapeutics principally relates to intangible assets that do not qualify for separate recognition (for instance, Transition Therapeutics' assembled workforce) and the deferred tax liability generated as a result of the transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the pharmaceutical reporting segment.

Revenue and Net income (loss) in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2016 includes revenue and net loss of Transition Therapeutics from the date of acquisition to September 30, 2016 of $0.0 million and $(0.5) million, respectively.

Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the IPR&D assets are then accounted for as finite-lived intangible assets and amortized on a straight-line basis over its estimated useful life.

Pro forma disclosure for Transition Therapeutics acquisition

The following table includes the pro forma results for the three and nine months ended September 30, 2016 and 2015 and combines the results of operations of OPKO and Transition Therapeutics as though the acquisition of Transition Therapeutics had occurred on January 1, 2015.

	For the three months ended September 30,		For the nine months ended September 30,	
(In thousands)	2016	2015	2016	2015
Revenues	$298,035	$143,034	$946,172	$215,547
Net income (loss)	(16,897)	124,942	(18,147)	(51,089)
Net income (loss) attributable to common shareholders	(16,897)	124,942	(18,147)	(49,689)

The unaudited pro forma financial information is presented for information purposes only. The unaudited pro forma financial information may not necessarily reflect our future results of operations or what the results of operations would have been had we owned and operated Transition Therapeutics as of the beginning of the period presented.

Bio-Reference acquisition

In August 2015, we completed the acquisition of Bio-Reference, the third largest full service clinical laboratory in the United States, known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding

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shares of Bio-Reference common stock. The transaction was valued at approximately $950.1 million, based on a closing price per share of our Common Stock of $12.38 as reported by the New York Stock Exchange, or $34.05 per share of Bio-Reference common stock. Included in the transaction value is $2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

The following table summarizes the final purchase price allocation and the fair value of the net assets acquired and liabilities assumed in the acquisition of Bio-Reference at the date of acquisition:

(In thousands)	Bio-Reference
Purchase price:	
Value of OPKO Common Stock issued to Bio-Reference shareholders	$ 947,889
Value of replacement stock options awards to holders of Bio-Reference stock options	2,259
Total purchase price	$ 950,148
Preliminary value of assets acquired and liabilities assumed:	
Current assets	
Cash and cash equivalents	$ 15,800
Accounts receivable	168,164
Inventory	19,674
Other current assets, principally deferred tax assets	100,052
Total current assets	303,690
Property, plant and equipment	112,457
Intangible assets:	
Trade name	47,100
Customer relationships	389,800
Technology	100,600
Other intangible assets	7,750
Total intangible assets	545,250
Goodwill	391,991
Investments	5,326
Other assets	13,265
Total assets	1,371,979
Accounts payable and accrued expenses	(108,217)
Income taxes payable	(1,014)
Lines of credit and notes payable	(65,701)
Capital lease obligations	(18,293)
Deferred tax liability (non-current)	(228,606)
Total purchase price	$ 950,148

During the nine months ended September 30, 2016, we finalized our purchase price allocation during the measurement period and obtained new fair value information related to certain assets acquired and liabilities assumed of Bio-Reference. As a result, for the nine months ended September 30, 2016 we adjusted the purchase price allocation by increasing Other current assets by $38.9 million, decreasing customer relationships by $5.4 million, increasing Other intangible assets by $7.8 million, decreasing Goodwill by $49.2 million, decreasing Accrued expenses by $0.5 million, increasing Income taxes payable by $0.6 million and decreasing Deferred tax liability (non-current) by $8.0 million. As a result of these adjustments, Amortization of intangible assets in our Condensed Consolidated Statement of Operations for the nine months ended September 30, 2016 increased $2.6 million.

The purchase price allocation adjustments are largely due to an approval we received from the Internal Revenue Service during 2016 on an application for a change in accounting method. As a result of the change, we recognized an additional $51.7

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million of income tax benefits, of which $39.4 million was recognized as taxes recoverable in Other current assets and $12.3 million was recognized as a reduction of our Deferred tax liability (non-current). In addition, Goodwill was reduced by $51.7 million.

Goodwill from the acquisition of Bio-Reference principally relates to intangible assets that do not qualify for separate recognition (for instance, Bio-Reference's assembled workforce), our expectation to develop and market new products, and the deferred tax liability generated as a result of the transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the diagnostics reporting segment.

Revenue and Net income (loss) in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2015 includes revenue and net loss of Bio-Reference from the date of acquisition to September 30, 2015 of $102.1 million and $6.8 million, respectively.

The weighted average amortization periods for intangible assets recognized in the Bio-Reference acquisition are 5 years for trade name, 19.3 years for customer relationships, 10.2 years for technology and 13.0 years in total.

EirGen Pharma Limited acquisition

In May 2015, we acquired all of the issued and outstanding shares of EirGen, a specialty pharmaceutical company incorporated in Ireland focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products, for $133.8 million. We acquired the outstanding shares of EirGen for approximately $100.2 million in cash and delivered 2,420,487 shares of our Common Stock valued at approximately $33.6 million based on the closing price per share of our Common Stock as reported by the New York Stock Exchange on the closing date of the acquisition, $13.88 per share.

The following table summarizes the final purchase price allocation and the fair value of the net assets acquired and liabilities assumed in the acquisition of EirGen at the date of acquisition:

(In thousands)	EirGen
Current assets [(1)]	$11,795
Intangible assets:	
IPR&D assets	560
Customer relationships	34,155
Currently marketed products	3,919
Total intangible assets	38,634
Goodwill	83,373
Property, plant and equipment	8,117
Other assets	1,232
Accounts payable and other liabilities	(6,254)
Deferred tax liability	(3,131)
Total purchase price	$133,766

(1)Current assets include cash, accounts receivable, inventory and other assets of $5.5 million, $2.7 million, $2.2 million and $1.4 million, respectively, related to the EirGen acquisition. The fair value of the accounts receivable equals the gross contractual amount at the date of acquisition.

Goodwill from the acquisition of EirGen principally relates to intangible assets that do not qualify for separate recognition (for instance, EirGen's assembled workforce), our expectation to develop and market new products, and the deferred tax liability generated as a result of this being a partial stock transaction. Goodwill is not tax deductible for income tax purposes and was assigned to the pharmaceutical reporting segment.

Revenue and Net income (loss) in the Condensed Consolidated Statement of Operations for the nine months ended September 30, 2015 includes revenue and net income of EirGen from the date of acquisition to September 30, 2015 of $7.6 million and $0.1 million, respectively.

Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval, the IPR&D assets are then accounted for as finite-lived intangible assets and amortized on a straight-line

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basis over its estimated useful life. The weighted average amortization periods for amortizing intangible assets recognized in the EirGen acquisition are 15.8 years for customer relationships, 10.0 years for currently marketed product and 15.0 years in total.

Investments

The following table reflects the accounting method, carrying value and underlying equity in net assets of our unconsolidated investments as of September 30, 2016:

(in thousands)

Investment type	Investment Carrying Value	Underlying Equity in Net Assets
Equity method investments	$ 30,338	$ 33,543
Variable interest entity, equity method	565	—
Available for sale investments	5,767	
Warrants and options	2,113	
Total carrying value of investments	$ 38,783	

Equity Method Investments

Our equity method investments consist of investments in Pharmsynthez (ownership 17%), Cocrystal Pharma, Inc. ("COCP") (8%), Sevion Therapeutics, Inc. ("Sevion") (3%), Non-Invasive Monitoring Systems, Inc. (1%), Neovasc (4%), VBI (17%) and InCellDx, Inc. (27%). The total assets, liabilities, and net losses of our equity method investees as of and for the nine months ended September 30, 2016 were $432.8 million, $(173.8) million, and $(132.3) million, respectively. We have determined that we and/or our related parties can significantly influence the success of our equity method investments through our board representation and/or voting power. Accordingly, we account for our investment in these entities under the equity method and record our proportionate share of their losses in Loss from investments in investees in our Condensed Consolidated Statement of Operations. The aggregate value of our equity method investments based on the quoted market price of their common stock and the number of shares held by us as of September 30, 2016 is $57.1 million.

Available for Sale Investments

Our available for sale investments consist of investments in RXi Pharmaceuticals Corporation ("RXi") (ownership 3%), ChromaDex Corporation (2%), MabVax Therapeutics Holdings, Inc. ("MabVax") (4%), ARNO Therapeutics, Inc. ("ARNO") (5%) and Xenetic Biosciences, Inc. ("Xenetic") (3%). We have determined that our ownership, along with that of our related parties, does not provide us with significant influence over the operations of our available for sale investments. Accordingly, we account for our investment in these entities as available for sale, and we record changes in these investments as an unrealized gain or loss in Other comprehensive income (loss) each reporting period.

Based on our evaluation of the value of our investments in RXi, including RXi's decreasing stock price during the nine months ended September 30, 2016, we determined that the decline in fair value of our RXi common shares was other-than-temporary and recorded an impairment charge of $0.4 million in Other income (expense), net in our Consolidated Statement of Operations for the nine months ended September 30, 2016 to write our investment in RXi common shares down to its fair value of $0.4 million as of September 30, 2016. Based on our evaluation of the value of our investments in Xenetic, including Xenetic's decreasing stock price during the nine months ended September 30, 2016, we determined that the decline in fair value of our Xenetic common shares was other-than-temporary and recorded an impairment charge of $3.5 million in Other income (expense), net in our Consolidated Statement of Operations for the nine months ended September 30, 2016 to write our investment in Xenetic common shares down to its fair value of $1.4 million as of September 30, 2016.

Sales of Investments

Gains (losses) included in earnings from sales of our investments are recorded in Other income (expense), net in our Condensed Consolidated Statement of Operations. We did not have any such activity in the nine months ended September 30, 2016 and 2015. The cost of securities sold is based on the specific identification method. Refer to Investment in SciVac below.

Warrants and Options

In addition to our equity method investments and available for sale investments, we hold options to purchase 0.1 million additional shares of Neovasc, which are fully vested as of December 31, 2015, and 1.0 million, 2.2 million, 0.5 million, 0.7 million and 0.7 million of warrants to purchase additional shares of COCP, ARNO, Sevion, MabVax and InCellDx, Inc., respectively. We

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recorded the changes in the fair value of the options and warrants in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations. We record the fair value of the options and warrants in Investments, net in our Condensed Consolidated Balance Sheets. See further discussion of the Company's options and warrants in Note 8 and Note 9.

Investments in Variable Interest Entities

We have determined that we hold variable interests in Zebra Biologics, Inc. ("Zebra"). We made this determination as a result of our assessment that Zebra does not have sufficient resources to carry out its principal activities without additional financial support.

We own 1,260,000 shares of Zebra Series A-2 Preferred Stock and 900,000 shares of Zebra restricted common stock (ownership 29% at September 30, 2016). Zebra is a privately held biotechnology company focused on the discovery and development of biosuperior antibody therapeutics and complex drugs. Dr. Richard Lerner, M.D., a member of our Board of Directors, is a founder of Zebra and, along with Dr. Frost, serves as a member of Zebra's Board of Directors. In order to determine the primary beneficiary of Zebra, we evaluated our investment and our related parties' investment, as well as our investment combined with the related party group's investment to identify if we had the power to direct the activities that most significantly impact the economic performance of Zebra. Based on the capital structure, governing documents and overall business operations of Zebra, we determined that, while a VIE, we do not have the power to direct the activities that most significantly impact Zebra's economic performance. We did determine, however, that we can significantly influence the success of Zebra through our board representation and voting power. Therefore, we have the ability to exercise significant influence over Zebra's operations and account for our investment in Zebra under the equity method.

Investment in SciVac

In June 2012, we acquired a 50% stock ownership in SciVac from FDS Pharma LLP ("FDS"). SciVac was a privately-held Israeli company that produced a third-generation hepatitis B-vaccine. From November 2012 through June 30, 2015, we loaned to SciVac a combined $7.9 million for working capital purposes. We determined that we held variable interests in SciVac based on our assessment that SciVac did not have sufficient resources to carry out its principal activities without financial support. We had also determined we were the primary beneficiary of SciVac through our representation on SciVac's board of directors. As a result of this conclusion, we consolidated the results of operations and financial position of SciVac through June 2015 and recorded a reduction of equity for the portion of SciVac we do not own.

On July 9, 2015, SciVac Therapeutics Inc., formerly Levon Resources Ltd. ("STI") completed a reverse takeover transaction (the "Arrangement") pursuant to which STI acquired all of the issued and outstanding securities of SciVac. As a result of this transaction, OPKO's ownership in STI decreased to 24.5%.

Upon completion of the Arrangement, we determined that STI was not a VIE. We also determined that we do not have the power to direct the activities that most significantly impact the economic performance of STI that would require us to consolidate STI. We recorded a $17.3 million gain on the deconsolidation of SciVac in Other income (expense), net in our Condensed Consolidated Statement of Operations for the nine months ended September 30, 2015. The recognized gain was primarily due to the fair value of the retained interest in STI based on Levon's cash contribution of approximately $21.2 million under the Arrangement.

Following the deconsolidation, we account for our investment in STI under the equity method as we have determined that we and/or our related parties can significantly influence STI through our voting power and board representation. STI is considered a related party as a result of our board representation in STI and executive management's ownership interests in STI.

In May 2016, STI completed a merger transaction pursuant to which a wholly-owned subsidiary of STI merged with and into VBI Vaccines Inc. with VBI Vaccines Inc. surviving the merger as a wholly-owned subsidiary of STI, and STI changed its name to VBI Vaccines Inc. ("VBI") . We recorded a $2.5 million gain in connection with the merger transaction in Other income (expense), net in our Condensed Consolidated Statement of Operations for the nine months ended September 30, 2016. In June 2016, we invested an additional $5.7 million in VBI for 1,362,370 shares of its common stock. As a result of these two transactions, OPKO's ownership in VBI changed to 17%.

We account for our investment in VBI under the equity method as we have determined that we can significantly influence VBI through our board representation.

Other

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On January 5, 2016, we completed a stock exchange agreement (the "Exchange Agreement") with Relative Core Cyprus Limited ("Relative Core") pursuant to which Relative Core agreed to transfer and sell to us that certain number of shares of Xenetic having a fair market value of $5.0 million in exchange for that number of shares of our common stock having a fair market value of $5.0 million. We issued 494,462 shares of our common stock to Relative Core and received 10,204,082 shares of Xenetic common stock from Relative Core. The number of shares exchanged in the transaction was calculated based on the average closing sale price for our common stock on the NYSE for the ten (10) consecutive trading day period ending on the second day prior to the closing and the average closing sale price for Xenetic's common stock on the OTC "Pink Sheet" for the ten (10) consecutive trading day period ending on the second day prior to the closing. We account for investment in Xenetic as an available for sale investment.

In March 2016, we entered into an agreement with Relative Core pursuant to which we delivered $5.0 million to Relative Core in exchange for a $5.0 million promissory note ("Relative Note") which bears interest at 10% and is due in March 2017. The Relative Note is secured by 4,000,000 shares of common stock of Xenetic and 494,462 shares of OPKO common stock. We recorded the Relative Note within Other current assets and prepaid expenses in our Condensed Consolidated Balance Sheet.

NOTE 6 DEBT

In January 2013, we entered into note purchase agreements (the "2033 Senior Notes") with qualified institutional buyers and accredited investors (collectively the "Purchasers") in a private placement in reliance on exemptions from registration under the Securities Act of 1933 (the "Securities Act"). The 2033 Senior Notes were issued on January 30, 2013. The 2033 Senior Notes, which totaled $175.0 million in original principal amount, bear interest at the rate of 3.00% per year, payable semiannually on February 1 and August 1 of each year. The 2033 Senior Notes will mature on February 1, 2033, unless earlier repurchased, redeemed or converted. Upon a fundamental change as defined in the Indenture, dated as of January 30, 2013, by and between the Company and Wells Fargo Bank N.A., as trustee, governing the 2033 Senior Notes (the "Indenture"), subject to certain exceptions, the holders may require us to repurchase all or any portion of their 2033 Senior Notes for cash at a repurchase price equal to 100% of the principal amount of the 2033 Senior Notes being repurchased, plus any accrued and unpaid interest to but not including the related fundamental change repurchase date.

The following table sets forth information related to the 2033 Senior Notes which is included our Condensed Consolidated Balance Sheets as of September 30, 2016:

(In thousands)	Embedded conversion option	2033 Senior Notes	Discount	Debt Issuance Cost	Total
Balance at December 31, 2015	$ 23,737	$32,200	$(6,525)	$ (426)	$48,986
Amortization of debt discount and debt issuance costs	—	—	1,379	111	1,490
Change in fair value of embedded derivative	1,061	—	—	—	1,061
Balance at September 30, 2016	$ 24,798	$32,200	$(5,146)	$ (315)	$51,537

The 2033 Senior Notes will be convertible at any time on or after November 1, 2032, through the second scheduled trading day immediately preceding the maturity date, at the option of the holders. Additionally, holders may convert their 2033 Senior Notes prior to the close of business on the scheduled trading day immediately preceding November 1, 2032, under the following circumstances: (1) conversion based upon satisfaction of the trading price condition relating to the 2033 Senior Notes; (2) conversion based on the Common Stock price; (3) conversion based upon the occurrence of specified corporate events; or (4) if we call the 2033 Senior Notes for redemption. The 2033 Senior Notes will be convertible into cash, shares of our Common Stock, or a combination of cash and shares of Common Stock, at our election unless we have made an irrevocable election of net share settlement. The initial conversion rate for the 2033 Senior Notes will be 141.48 shares of Common Stock per $1,000 principal amount of 2033 Senior Notes (equivalent to an initial conversion price of approximately $7.07 per share of Common Stock), and will be subject to adjustment upon the occurrence of certain events. In addition, we will, in certain circumstances, increase the conversion rate for holders who convert their 2033 Senior Notes in connection with a make-whole fundamental change (as defined in the Indenture) and holders who convert upon the occurrence of certain specific events prior to February 1, 2017 (other than in connection with a make-whole fundamental change). Holders of the

2033 Senior Notes may require us to repurchase the 2033 Senior Notes for 100% of their principal amount, plus accrued and unpaid interest, on February 1, 2019, February 1, 2023 and February 1, 2028, or following the occurrence of a fundamental change as defined in the indenture governing the 2033 Senior Notes.

We may not redeem the 2033 Senior Notes prior to February 1, 2017. On or after February 1, 2017 and before February 1, 2019, we may redeem for cash any or all of the 2033 Senior Notes but only if the last reported sale price of our

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Common Stock exceeds 130% of the applicable conversion price for at least 20 trading days during the 30 consecutive trading day period ending on the trading day immediately prior to the date on which we deliver the redemption notice. The redemption price will equal 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest to but not including the redemption date. On or after February 1, 2019, we may redeem for cash any or all of the 2033 Senior Notes at a redemption price of 100% of the principal amount of the 2033 Senior Notes to be redeemed, plus any accrued and unpaid interest up to but not including the redemption date.

The terms of the 2033 Senior Notes, include, among others: (i) rights to convert into shares of our Common Stock, including upon a fundamental change; and (ii) a coupon make-whole payment in the event of a conversion by the holders of the 2033 Senior Notes on or after February 1, 2017 but prior to February 1, 2019. We have determined that these specific terms are considered to be embedded derivatives. Embedded derivatives are required to be separated from the host contract, the 2033 Senior Notes, and carried at fair value when: (a) the embedded derivative possesses economic characteristics that are not clearly and closely related to the economic characteristics of the host contract; and (b) a separate, stand-alone instrument with the same terms would qualify as a derivative instrument. We have concluded that the embedded derivatives within the 2033 Senior Notes meet these criteria and, as such, must be valued separate and apart from the 2033 Senior Notes and recorded at fair value each reporting period.

For accounting and financial reporting purposes, we combine these embedded derivatives and value them together as one unit of accounting. At each reporting period, we record these embedded derivatives at fair value which is included as a component of the 2033 Senior Notes on our Condensed Consolidated Balance Sheets.

In August 2013, one of the conversion rights in the 2033 Senior Notes was triggered. Holders of the 2033 Senior Notes converted $16.9 million principal amount into 2,396,145 shares of the Company’s Common Stock. In June 2014, we entered into an exchange agreement with a holder of the Company’s 2033 Senior Notes pursuant to which such holder exchanged $70.4 million in aggregate principal amount of 2033 Senior Notes for 10,974,431 shares of the Company’s Common Stock and approximately $0.8 million in cash representing accrued interest through the date of completion of the exchange. During 2015, pursuant to a conversion right or through exchange agreements we entered with certain holders of our 2033 Senior Notes, holders of our 2033 Senior Notes converted or exchanged $55.4 million in aggregate principal amount of 2033 Senior Notes for 8,118,062 shares of the Company’s Common Stock. On April 1, 2015, we initially announced that our 2033 Senior Notes were convertible through June 2015 by holders of such notes. This conversion right was triggered because the closing price per share of our Common Stock exceeded $9.19, or 130% of the initial conversion price of $7.07, for at least 20 of 30 consecutive trading days during the applicable measurement period. We have elected to satisfy our conversion obligation under the 2033 Senior Notes in shares of our Common Stock. Our 2033 Senior Notes continued to be convertible by holders of such notes for the remainder of 2015 and 2016, and may be convertible thereafter, if one or more of the conversion conditions specified in the Indenture is satisfied during future measurement periods. Pursuant to the Indenture, a holder who elects to convert the 2033 Senior Notes will receive 141.4827 shares of our Common Stock plus such number of additional shares as is applicable on the conversion date per $1,000 principal amount of 2033 Senior Notes based on the early conversion provisions in the Indenture. See further discussion in Note 14.

We used a binomial lattice model in order to estimate the fair value of the embedded derivative in the 2033 Senior Notes. A binomial lattice model generates two probable outcomes — one up and another down —arising at each point in time, starting from the date of valuation until the maturity date. A lattice model was initially used to determine if the 2033 Senior Notes would be converted, called or held at each decision point. Within the lattice model, the following assumptions are made: (i) the 2033 Senior Notes will be converted early if the conversion value is greater than the holding value; or (ii) the 2033 Senior Notes will be called if the holding value is greater than both (a) the redemption price (as defined in the Indenture) and (b) the conversion value plus the coupon make-whole payment at the time. If the 2033 Senior Notes are called, then the holder will maximize their value by finding the optimal decision between (1) redeeming at the redemption price and (2) converting the 2033 Senior Notes.

Using this lattice model, we valued the embedded derivatives using the “with-and-without method,” where the value of the 2033 Senior Notes including the embedded derivatives is defined as the “with,” and the value of the 2033 Senior Notes excluding the embedded derivatives is defined as the “without.” This method estimates the value of the embedded derivatives by looking at the difference in the values between the 2033 Senior Notes with the embedded derivatives

and the value of the 2033 Senior Notes without the embedded derivatives.

The lattice model requires the following inputs: (i) price of our Common Stock; (ii) Conversion Rate (as defined in the Indenture); (iii) Conversion Price (as defined in the Indenture); (iv) maturity date; (v) risk-free interest rate; (vi) estimated stock volatility; and (vii) estimated credit spread for the Company.

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The following table sets forth the inputs to the lattice model used to value the embedded derivative:

	September 30, 2016
Stock price	$10.59
Conversion Rate	141.4827
Conversion Price	$7.07
Maturity date	February 1, 2033
Risk-free interest rate	0.81%
Estimated stock volatility	41%
Estimated credit spread	979 basis points

The following table sets forth the fair value of the 2033 Senior Notes with and without the embedded derivatives, and the fair value of the embedded derivatives at September 30, 2016. At September 30, 2016 the principal amount of the 2033 Senior Notes was $32.2 million:

(In thousands)	September 30, 2016
Fair value of 2033 Senior Notes:	
With the embedded derivatives	$ 52,206
Without the embedded derivatives	$ 27,408
Estimated fair value of the embedded derivatives	$ 24,798

Changes in certain inputs into the lattice model can have a significant impact on changes in the estimated fair value of the embedded derivatives. For example, a decrease in our estimated credit spread results in an increase in the estimated value of the embedded derivatives. Conversely, a decrease in the price of our Common Stock results in a decrease in the estimated fair value of the embedded derivatives. For the nine months ended September 30, 2016, we observed an increase in the market price of our Common Stock which primarily resulted in a $1.1 million increase in the estimated fair value of our embedded derivatives recorded in Fair value changes of derivative instruments, net in our Condensed Consolidated Statements of Operations.

On November 5, 2015, Bio-Reference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent, as amended (the “Credit Agreement”), which replaced Bio-Reference’s prior credit facility. The Credit Agreement provides for a $175.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0 million sub-facility for the issuance of letters of credit. Bio-Reference may increase the credit facility to up to $275.0 million on a secured basis, subject to the satisfaction of specified conditions. The Credit Agreement matures on November 5, 2020 and is guaranteed by all of Bio-Reference’s domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in Bio-Reference. Availability under the Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. Principal under the Credit Agreement is due upon maturity on November 5, 2020.

At Bio-Reference’s option, borrowings under the Credit Agreement (other than swingline loans) will bear interest at (i) the CB floating rate (defined as the higher of (a) the prime rate and (b) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) for an interest period of one month plus 2.50%) plus an applicable margin of 0.35% for the first 12 months and 0.50% thereafter or (ii) the LIBOR rate (adjusted for statutory reserve requirements for Eurocurrency liabilities) plus an applicable margin of 1.35% for the first 12 months and 1.50% thereafter. Swingline loans will bear interest at the CB floating rate plus the applicable margin. The Credit Agreement also calls for other customary fees and charges, including an unused commitment fee of 0.25% of the lending commitments.

The Credit Agreement contains customary covenants and restrictions, including, without limitation, covenants that require Bio-Reference and its subsidiaries to maintain a minimum fixed charge coverage ratio if availability under the new credit facility falls below a specified amount and to comply with laws, and restrictions on the ability of Bio-Reference and its subsidiaries to incur additional indebtedness or to pay dividends and make certain other distributions to the Company, subject to certain exceptions as specified therein. Failure to comply with these covenants would constitute an event of default under the Credit Agreement, notwithstanding the ability of Bio-Reference to meet its debt service obligations. The Credit Agreement also includes various customary remedies for the lenders following an event of default, including the acceleration of repayment of outstanding amounts under the Credit Agreement and execution upon the collateral securing obligations under the Credit Agreement. Substantially all the assets of Bio-Reference and its subsidiaries are restricted from sale, transfer, lease, disposal or

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distributions to the Company, subject to certain exceptions. Bio-Reference and its subsidiaries net assets as of September 30, 2016 were approximately $1.0 billion, which includes goodwill of $392.0 million and intangible assets of $498.3 million.

In addition to the Credit Agreement with CB, we have line of credit agreements with nine other financial institutions as of September 30, 2016 and ten other financial institutions as of December 31, 2015 in United States, Chile and Spain. These lines of credit are used primarily as a source of working capital for inventory purchases.

The following table summarizes the amounts outstanding under the Bio Reference, Chilean and Spanish lines of credit:

(Dollars in thousands)			Balance Outstanding	
Lender	Interest rate on borrowings at September 30, 2016	Credit line capacity	September 30, 2016	December 31, 2015
JPMorgan Chase	3.85%	$ 175,000	$ 38,444	$ 72,107
Itau Bank	5.50%	1,450	1,020	282
Bank of Chile	6.60%	2,500	1,935	2,313
BICE Bank	5.50%	2,000	1,115	1,502
BBVA Bank	5.50%	2,300	965	1,825
Security Bank	N/A	N/A	—	145
Estado Bank	5.50%	2,400	1,431	2,210
Santander Bank	5.50%	3,000	1,308	1,345
Scotiabank	5.00%	1,300	802	939
Corpbanca	5.00%	500	182	—
Banco Bilbao Vizcaya	2.90%	280	—	—
Total		$ 190,730	$ 47,202	$ 82,668

At September 30, 2016 and December 31, 2015, the weighted average interest rate on our lines of credit was approximately 4.8% and 4.3%, respectively.

At September 30, 2016 and December 31, 2015, we had notes payable and other debt (excluding the 2033 Senior Notes, the Credit Agreement and amounts outstanding under lines of credit) as follows:

(In thousands)	September 30, 2016	December 31, 2015
Current portion of notes payable	$ 1,343	$ 1,054
Other long-term liabilities	2,335	1,963
Total	$ 3,678	$ 3,017

The notes and other debt mature at various dates ranging from 2015 through 2024 bearing variable interest rates from 1.8% up to 6.3%. The weighted average interest rate on the notes and other debt at September 30, 2016 and December 31, 2015, was 2.9% and 4.3%, respectively. The notes payable are secured by our office space in Barcelona.

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NOTE 7 ACCUMULATED OTHER COMPREHENSIVE INCOME (LOSS)

For the nine months ended September 30, 2016, changes in Accumulated other comprehensive income (loss), net of tax, were as follows:

(In thousands)	Foreign currency	Unrealized gain (loss) in Accumulated OCI	Total
Balance at December 31, 2015	$(21,791)	$ (746)	$(22,537)
Other comprehensive income (loss) before reclassifications	5,306	(2,955)	2,351
Amounts reclassified from accumulated other comprehensive income, net of tax	—	3,902	3,902
Net other comprehensive loss	5,306	947	6,253
Balance at September 30, 2016	$(16,485)	$ 201	$(16,284)

NOTE 8 FAIR VALUE MEASUREMENTS

We record fair values at an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement determined based on assumptions that market participants would use in pricing an asset or liability. We utilize a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. These tiers include: Level 1, defined as observable inputs such as quoted prices in active markets; Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable; and Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions.

A summary of our investments classified as available for sale and carried at fair value, is as follows:

	As of September 30, 2016			
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Fair value
Common stock investments, available for sale	$4,194	$ 1,573	$ —	$5,767
Total assets	$4,194	$ 1,573	$ —	$5,767

	As of December 31, 2015			
(In thousands)	Amortized Cost	Gross unrealized gains in Accumulated OCI	Gross unrealized losses in Accumulated OCI	Fair value
Common stock investments, available for sale	$2,978	$ 904	$ (267)	$3,615
Total assets	$2,978	$ 904	$ (267)	$3,615

Any future fluctuation in fair value related to our available for sale investments that is judged to be temporary, and any recoveries of previous write-downs, will be recorded in Accumulated other comprehensive income (loss). If we determine that any future valuation adjustment was other-than-temporary, we will record a loss during the period such determination is made.

As of September 30, 2016, we have money market funds that qualify as cash equivalents, forward foreign currency exchange contracts for inventory purchases (Refer to Note 9) and contingent consideration related to the acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe, and OPKO Renal that are required to be measured at fair value on a recurring basis. In addition, in connection with our investment and our consulting agreement with Neovasc, we record the related Neovasc options at fair value as well as the warrants from COCP, ARNO, Sevion and MabVax.

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Our financial assets and liabilities measured at fair value on a recurring basis are as follows:

(In thousands)	Fair value measurements as of September 30, 2016 Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$12,312	$ —	$ —	$12,312
Common stock investments, available for sale	5,767	—	—	5,767
Common stock options/warrants	—	2,113	—	2,113
Total assets	$18,079	$ 2,113	$ —	$20,192
Liabilities:				
Embedded conversion option	$—	$ —	$ 24,798	$24,798
Forward contracts	—	100	—	100
Contingent consideration	—	—	43,743	43,743
Total liabilities	$—	$ 100	$ 68,541	$68,641

(In thousands)	Fair value measurements as of December 31, 2015 Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
Assets:				
Money market funds	$84,421	$ —	$ —	$84,421
Common stock investments, available for sale	3,615	—	—	3,615
Common stock options/warrants	—	5,338	—	5,338
Forward contracts	—	9	—	9
Total assets	$88,036	$ 5,347	$ —	$93,383
Liabilities:				
Embedded conversion option	$—	$ —	$ 23,737	$23,737
Contingent consideration	—	—	54,422	54,422
Total liabilities	$—	$ —	$ 78,159	$78,159

The carrying amount and estimated fair value of our 2033 Senior Notes without the embedded conversion option, as well as the applicable fair value hierarchy tiers, are contained in the table below. The fair value of the 2033 Senior Notes is determined using a binomial lattice approach in order to estimate the fair value of the embedded derivative in the 2033 Senior Notes. Refer to Note 6.

	September 30, 2016			
(In thousands)	Carrying	Total	Level 1	Level 2	Level 3

	Value	Fair Value			
2033 Senior Notes	$27,054	$ 27,408	$ —	—$	$27,408

There have been no transfers between Level 1 and Level 2 and no transfers to or from Level 3 of the fair value hierarchy.

As of September 30, 2016 and December 31, 2015, the carrying value of our other assets and liabilities approximates their fair value due to their short-term nature or variable rate of interest.

The following table reconciles the beginning and ending balances of our Level 3 assets and liabilities as of September 30, 2016:

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	September 30, 2016	
(In thousands)	Contingent consideration	Embedded conversion option
Balance at December 31, 2015	$54,422	$ 23,737
Total losses for the period:		
Included in results of operations	15,604	1,061
Foreign currency impact	16	—
Payments	(26,299)	—
Balance at September 30, 2016	$43,743	$ 24,798

The estimated fair values of our financial instruments have been determined by using available market information and what we believe to be appropriate valuation methodologies. We use the following methods and assumptions in estimating fair value:

Contingent consideration – We estimate the fair value of the contingent consideration utilizing a discounted cash flow model for the expected payments based on estimated timing and expected revenues. We use several discount rates depending on each type of contingent consideration related to OPKO Diagnostics, CURNA, OPKO Health Europe and OPKO Renal transactions. If estimated future sales were to decrease by 10%, the contingent consideration related to OPKO Renal, which represents the majority of our contingent consideration liability, would decrease by $2.4 million. As of September 30, 2016, of the $43.7 million of contingent consideration, $5.2 million is recorded in Accrued expenses and $38.5 million is recorded in Other long-term liabilities. As of December 31, 2015, of the $54.4 million of contingent consideration, $22.2 million is recorded in Accrued expenses and $32.2 million is recorded in Other long-term liabilities.

Embedded conversion option – We estimate the fair value of the embedded conversion option related to the 2033 Senior Notes using a binomial lattice model. Refer to Note 6 for detail description of the binomial lattice model and the fair value assumptions used.

NOTE 9 DERIVATIVE CONTRACTS

The following table summarizes the fair values and the presentation of our derivative financial instruments in the Condensed Consolidated Balance Sheets:

(In thousands)	Balance Sheet Component	September 30, 2016	December 31, 2015
Derivative financial instruments:			
Common Stock options/warrants	Investments, net	$ 2,113	$ 5,338
Embedded conversion option	2033 Senior Notes, net of discount and estimated fair value of embedded derivatives	$ 24,798	$ 23,737
Forward contracts	Unrealized gains on forward contracts are recorded in Other current assets and prepaid expenses. Unrealized (losses) on forward contracts are recorded in Accrued expenses.	$ (100)	$ 9

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We enter into foreign currency forward exchange contracts to cover the risk of exposure to exchange rate differences arising from inventory purchases on letters of credit. Under these forward contracts, for any rate above or below the fixed rate, we receive or pay the difference between the spot rate and the fixed rate for the given amount at the settlement date.

To qualify the derivative instrument as a hedge, we are required to meet strict hedge effectiveness and contemporaneous documentation requirements at the initiation of the hedge and assess the hedge effectiveness on an ongoing basis over the life of the hedge. At September 30, 2016 and December 31, 2015, our derivative financial instruments do not meet the documentation requirements to be designated as hedges. Accordingly, we recognize the changes in Fair value of derivative instruments, net in our Condensed Consolidated Statements of Operations. The following table summarizes the losses and gains recorded for the nine months ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
(In thousands)	2016	2015	2016	2015
Derivative gain (loss):				
Common Stock options/warrants	$(12)	$(4,070)	$(4,728)	$(2,645)
2033 Senior Notes	(5,795)	36,132	(1,061)	(31,818)
Forward contracts	106	182	(100)	363
Total	$(5,701)	$32,244	$(5,889)	$(34,100)

NOTE 10 RELATED PARTY TRANSACTIONS

We hold investments in Zebra (ownership 29%), Sevion (3%), Neovasc (4%), ChromaDex Corporation (2%), MabVax (4%), COCP (8%) and ARNO (5%). These investments were considered related party transactions as a result of our executive management's ownership interests and/or board representation in these entities. See further discussion of our investments in Note 5. In July 2015, we made an additional $0.5 million investment in a private placement transaction with Sevion pursuant to which we acquired 66,667 shares of Series C Convertible Preferred Stock convertible into 666,667 shares of common stock and warrants to purchase 333,333 shares of common stock. In October 2015, we made an additional $0.4 million investment in MabVax pursuant to which we acquired 340,909 shares of common stock at $1.10 and 170,454 warrants to purchase shares of common stock. In November 2015, we made an additional $1.0 million investment in Zebra pursuant to which we acquired 420,000 shares of Series A-2 Preferred Stock. In January 2016, we invested an additional $0.3 million in ARNO for 714,285 shares of its common stock and in August 2016 we invested an additional $0.3 million in ARNO for 714,285 shares of its common stock and warrants to purchase 357,142 shares of its common stock. In August 2016 we invested an additional $1.0 million in MabVax for 207,900 shares of its common stock and warrants to purchase 415,800 shares of its common stock. In September 2016 we invested an additional $2.0 million in COCP for 4,878,050 shares of its common stock.

We lease office space from Frost Real Estate Holdings, LLC ("Frost Holdings") in Miami, Florida, where our principal executive offices are located. Effective May 28, 2015, we entered into an amendment to our lease agreement with Frost Holdings. The lease, as amended, is for approximately 25,000 square feet of space. The lease provides for payments of approximately $66 thousand per month in the first year increasing annually to $75 thousand per month in the fifth year, plus applicable sales tax. The rent is inclusive of operating expenses, property taxes and parking. The rent was reduced by $0.2 million for the cost of tenant improvements.

Our wholly-owned subsidiary, Bio-Reference purchases and uses certain products acquired from InCellDx, Inc., a company in which we hold a 27% minority interest.

We reimburse Dr. Frost for Company-related use by Dr. Frost and our other executives of an airplane owned by a company that is beneficially owned by Dr. Frost. We reimburse Dr. Frost for out-of-pocket operating costs for the use of the airplane by Dr. Frost or Company executives for Company-related business. We do not reimburse Dr. Frost for personal use of the airplane by Dr. Frost or any other executive. For the three and nine months ended September 30, 2016, we recognized approximately $154 thousand and $274 thousand, respectively, for Company-related travel by Dr. Frost and other OPKO executives. For the three and nine months ended September 30, 2015, we recognized approximately $66 thousand and $359 thousand, respectively, for Company-related travel by Dr. Frost and other

OPKO executives.

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NOTE 11 COMMITMENTS AND CONTINGENCIES

In connection with our acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe, and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events. As a result, as of September 30, 2016, we recorded $43.7 million as contingent consideration, with $5.2 million recorded within Accrued expenses and $38.5 million recorded within Other long-term liabilities in the accompanying Condensed Consolidated Balance Sheets. Refer to Note 4.

On or around October 21, 2014, we received a Civil Investigative Demand ("Demand") from the U.S. Attorney's Office for the Middle District of Tennessee ("Attorney's Office"). The Demand concerns an investigation of allegations that the Company or one of its affiliated entities or other parties submitted false claims for payment related to services provided to government healthcare program beneficiaries in violation of the False Claims Act, 31 U.S.C. Section 3729. We entered into a settlement agreement resolving the matter in May 2016, and it did not have a financial impact on the Company.

Following the announcement of entry into an agreement and plan of merger with Bio-Reference, four putative class action complaints challenging the merger were filed in the Superior Court of New Jersey in Bergen County (the "Court"). In September 2015, the parties executed a stipulation and agreement of compromise, settlement and release resolving all matters between them. In January 2016, the Court entered an order finally approving the settlement. The settlement did not have a material impact on our business, financial condition, results of operations or cash flows.

Under a license agreement one of our subsidiaries has with Washington University in St. Louis, we are obligated to pay Washington University a single digit percentage of any sublicensing payment we receive in connection with a sublicense of our rights to Washington University patents subject to certain exceptions. In connection with the Pfizer Transaction, we sublicensed to Pfizer the sole remaining patent licensed to us by Washington University and paid to Washington University the sublicensing payment we believe is due under the license agreement. Washington University disagreed with the computation of the sublicense payment and notified us that it would like to review additional information relating to the sublicense and the Pfizer Transaction to determine whether additional amounts are owed to it. In May 2016, the parties entered into a settlement agreement resolving the matter. The settlement did not have a material impact on our business, financial condition, results of operations or cash flows.

On December 18, 2013, Bio-Reference filed an action in the Superior Court of New Jersey against Horizon, captioned Bio-Reference Laboratories, Inc. v. Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey, Docket No. BER L-009748-13 (N.J. Super. Ct. Bergen County). Bio-Reference has been an in-network provider with Horizon's PPO network for more than 20 years and filed the lawsuit after attempts to resolve its dispute with Horizon were unsuccessful. The parties have agreed to a full and final settlement of the matter with an effective date of March 31, 2016, based on an execution date of May 11, 2016. Among other consideration, under the terms of the settlement, Horizon paid Bio-Reference a negotiated settlement for the disputed claims and Bio-Reference's current PPO contract will remain in effect through December 31, 2018. The settlement was not material to Revenue from services in our Condensed Consolidated Statements of Operations for the three or nine months ended September 30, 2016.

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect ongoing negotiations, settlements, rulings, advice of legal counsel and other relevant information. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For the matters referenced in the paragraphs below, the amount of liability is not probable or the amount cannot be reasonably estimated; and, therefore, accruals have not been made. In addition, in accordance with the relevant authoritative guidance, for matters which the likelihood of material loss is at least reasonably possible, we provide disclosure of the possible loss or range of loss; however, if a reasonable estimate cannot be made, we will provide disclosure to that effect.

From time to time, we may receive inquiries, document requests, or subpoenas from the Department of Justice, the Office of Inspector General and Office for Civil Rights ("OCR") of the Department of Health and Human Services, the Centers for Medicare and Medicaid Services, various payors and fiscal intermediaries, and other state and federal

regulators regarding investigations, audits and reviews. In addition to the matters discussed in this note, we are currently responding to subpoenas or document requests for various matters relating to our laboratory operations. In addition, we are subject to other claims and lawsuits arising in the ordinary course of our business. Some pending or threatened proceedings against us may involve potentially substantial amounts as well as the possibility of civil, criminal, or administrative fines, penalties, or other sanctions, which could be material. Settlements of suits involving the types of issues that we routinely confront may require monetary payments as well as corporate integrity agreements. Additionally, qui tam or "whistleblower" actions initiated under the civil False Claims Act may be pending but placed under seal by the court to comply with the False Claims Act's requirements for filing such suits. Also, from time to time, we may detect issues of non-compliance with federal healthcare laws pertaining to

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claims submission and reimbursement practices and/or financial relationships with physicians, among other things. We may avail ourselves of various mechanisms to address these issues, including participation in voluntary disclosure protocols. Participating in voluntary disclosure protocols can have the potential for significant settlement obligations or even enforcement action. The Company generally has cooperated, and intends to continue to cooperate, with appropriate regulatory authorities as and when investigations, audits and inquiries arise.

We are a party to other litigation in the ordinary course of business. We do not believe that any such litigation will have a material adverse effect on our business, financial condition, results of operations or cash flows.

We expect to continue to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure, particularly as we prepare for the launch of Rayaldee. We do not anticipate that we will generate substantial revenue from the sale of proprietary pharmaceutical products or certain of our diagnostic products for some time and we have generated only limited revenue from our pharmaceutical operations in Chile, Mexico, Israel, Spain, and Ireland, and from sale of the 4Kscore test. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions.

We have employment agreements with certain executives of Bio-Reference which provide for compensation and certain other benefits and for severance payments under certain circumstances. During the nine months ended September 30, 2016, we recognized $17.9 million of severance costs pursuant to these employment agreements as a component of Selling, general and administrative expense.

At September 30, 2016, we were committed to make future purchases for inventory and other items in 2016 that occur in the ordinary course of business under various purchase arrangements with fixed purchase provisions aggregating $71.9 million.

NOTE 12 STRATEGIC ALLIANCES

Vifor Fresenius Medical Renal Care Pharma Ltd

We plan to develop a portfolio of product candidates through a combination of internal development and external partnerships. In May 2016, EirGen, our wholly-owned subsidiary, and Vifor Fresenius Medical Renal Care Pharma Ltd (“VFMCRP”), entered into a Development and License Agreement (the “VFMCRP Agreement”) for the development and marketing of Rayaldee (the “Product”) worldwide, except for (i) the United States, (ii) any country in Central America or South America (excluding Mexico), (iii) Russia, (iv) China, (v) Japan, (vi) Ukraine, (vii) Belorussia, (viii) Azerbaijan, (ix) Kazakhstan, and (x) Taiwan (the “Territory”). The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the Product in human patients (the “Field”), provided that initially the license is for the use of the Product for the treatment or prevention of secondary hyperparathyroidism related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency/deficiency (the “Initial Indication”).

Under the terms of the VFMCRP Agreement, EirGen granted to VFMCRP an exclusive license in the Territory in the Field to use certain EirGen patents and technology to make, have made, use, sell, offer for sale, and import Products and to develop, commercialize, have commercialized, and otherwise exploit the Product. EirGen received a non-refundable and non-creditable initial payment of $50 million. EirGen is also eligible to receive up to an additional $37 million in regulatory milestones (“Regulatory Milestones”) and $195 million in launch and sales-based milestones (“Sales Milestones”), and will receive tiered, double digit royalty payments or a minimum royalty, whichever is greater, upon the commencement of sales of the Product within the Territory and in the Field.

As part of the arrangement, the companies will share responsibility for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. EirGen will lead the manufacturing activities within and outside the Territory and the commercialization activities outside the Territory and outside the Field in the Territory and VFMCRP will lead the commercialization activities in the Territory and the Field. For the initial development plan agreed to by the companies, the companies have agreed to certain cost sharing arrangements. VFMCRP will be responsible for all other development costs that VFMCRP considers necessary to develop the Product for the use of the Product for the Initial Indication in the Territory in the Field except as otherwise

provided in the VFMCRP Agreement.

The VFMCRP Agreement will remain in effect with respect to the Product in each country of the Territory, on a country by country basis, until the date on which VFMCRP shall have no further payment obligations to EirGen under the terms of the VFMCRP Agreement, unless earlier terminated pursuant to the VFMCRP Agreement. VFMCRP's royalty obligations expire on a country-by-country and product-by-product basis on the later of (i) expiration of the last to expire valid claim covering the

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Product sold in such country, (ii) expiration of all regulatory and data exclusivity applicable to the Product in the country of sale, and (c) ten (10) years after the Product first commercial sale in such country. In addition to termination rights for material breach and bankruptcy, VFMCRP is permitted to terminate the VFMCRP Agreement in its entirety, or with respect to one or more countries in the Territory, after a specified notice period, provided that VFMCRP shall not have the right to terminate the VFMCRP Agreement with respect to certain major countries without terminating the entire VFMCRP Agreement. If the VFMCRP Agreement is terminated by EirGen or VFMCRP, provision has been made for transition of product and product responsibilities to EirGen.

In connection with the VFMCRP Agreement, the parties entered into a letter agreement (the "Letter Agreement") pursuant to which EirGen granted to VFMCRP an exclusive option (the "Option") to acquire an exclusive license under certain EirGen patents and technology to use, import, offer for sale, sell, distribute and commercialize the Product in the United States solely for the treatment of secondary hyperparathyroidism in dialysis patients with chronic kidney disease and vitamin D insufficiency (the "Dialysis Indication"). Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs incurred by EirGen with respect to the Product for the Dialysis Indication in the United States. VFMCRP would also pay EirGen up to an additional aggregate amount of $555 million upon the achievement of certain milestones and would be obligated to pay certain double digit royalties on VFMCRP's sales in the United States for the Dialysis Indication.

The Option is exercisable until the earlier of (i) the date that EirGen submits a new drug application or supplemental new drug application or their then equivalents to the U.S. Food and Drug Administration for the Product for the Dialysis Indication in the United States, (ii) the parties mutually agree to discontinue development of Product for the Dialysis Indication, or (iii) VFMCRP provides notice to OPKO that it has elected not to exercise the Option.

OPKO has guaranteed the performance of certain of EirGen's obligations under the VFMCRP Agreement and the Letter Agreement.

For revenue recognition purposes, we evaluated the various agreements with Vifor to determine whether there were multiple deliverables in the arrangement. The VFMCRP Agreement provides for the following: (1) an exclusive license in the Territory in the Field to use certain patents and technology to make, have made, use, sell, offer for sale, and import Products and to develop, commercialize, have commercialized, and otherwise exploit the Product; (2) EirGen will supply Products to support the development, sale and commercialization of the Products to VFMCRP in the Territory (the "Manufacturing Services"); (3) the Option to acquire an exclusive license under certain EirGen patents and technology to use, import, offer for sale, sell, distribute and commercialize the Product in the United States solely for the Dialysis Indication. Based on our evaluation, the exclusive license is the only deliverable at the outset of the arrangement. We concluded the Manufacturing Services was a contingent deliverable dependent on the future regulatory and commercial action by VFMCRP and the Option was substantive and not considered a deliverable under the license arrangement.

We recognized the $50.0 million upfront license payment in Revenue from transfer of intellectual property in our Condensed Consolidated Statements of Operations for the nine months ended September 30, 2016. Revenues related to the Manufacturing Services will be recognized as Product is sold to VFMCRP. No revenue related to the Option will be recognized unless and until VFMCRP exercises its' Option under the Letter Agreement.

We determined that the cost sharing arrangement for development of the Dialysis Indication is not a deliverable in the VFMCRP Agreement. Payments for the Dialysis Indication will be recorded as Research and development expense as incurred.

EirGen is also eligible to receive up to an additional $37 million in Regulatory Milestones and $195 million in Sales Milestones. Payments received for Regulatory Milestones and Sales Milestones are non-refundable. The Regulatory Milestones are payable if and when VFMCRP obtains approval from certain regulatory authorities and will be recognized as revenue in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. We account for the Sales Milestones as royalties and Sales Milestones payments will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. To date, no revenue has been recognized related to the achievement of the milestones.

Pfizer Inc.

In December 2014, we entered into an exclusive worldwide agreement with Pfizer Inc. (“Pfizer”) for the development and commercialization of our long-acting hGH-CTP for the treatment of growth hormone deficiency (“GHD”) in adults and children, as well as for the treatment of growth failure in children born small for gestational age (“SGA”) (the “Pfizer Transaction”).

The Pfizer Transaction closed in January 2015 following the termination of the waiting period under the Hart-Scott-Rodino Act. Under the terms of the Pfizer Transaction, we received non-refundable and non-creditable upfront payments of

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$295.0 million and are eligible to receive up to an additional $275.0 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition to regional, tiered gross profit sharing for both hGH-CTP and Pfizer's Genotropin®.

The agreement with Pfizer will remain in effect until the last sale of the licensed product, unless earlier terminated as permitted under the agreement. In addition to termination rights for material breach and bankruptcy, Pfizer is permitted to terminate the Agreement in its entirety, or with respect to one or more world regions, without cause after a specified notice period. If the Agreement is terminated by us for Pfizer's uncured material breach, or by Pfizer without cause, provision has been made for transition of product and product responsibilities to us for the terminated regions, as well as continued supply of product by Pfizer or transfer of supply to us in order to support the terminated regions.

We will lead the clinical activities and will be responsible for funding the development programs for the key indications, which includes Adult and Pediatric GHD and Pediatric SGA. Pfizer will be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer will fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan.

For revenue recognition purposes, we viewed the Pfizer Transaction as a multiple-element arrangement. Multiple-element arrangements are analyzed to determine whether the various performance obligations, or elements, can be separated or whether they must be accounted for as a single unit of accounting. We evaluated whether a delivered element under an arrangement has standalone value and qualifies for treatment as a separate unit of accounting. Deliverables that do not meet these criteria are not evaluated separately for the purpose of revenue recognition. For a single unit of accounting, payments received are recognized in a manner consistent with the final deliverable. We determined that the deliverables under the Pfizer Transaction, including the licenses granted to Pfizer, as well as our obligations to provide various research and development services, will be accounted for as a single unit of account. This determination was made because the ongoing research and development services to be provided by us are essential to the overall arrangement as we have significant knowledge and technical know-how that is important to realizing the value of the licenses granted. The performance period over which the revenue will be recognized is expected to continue from the first quarter of 2015 through 2019, when we anticipate completing the various research and development services that are specified in the Pfizer Transaction and our performance obligations are completed. We will continue to review the timing of when our research and development services will be completed in order to assess that the estimated performance period over which the revenue is to be recognized is appropriate. Any significant changes in the timing of the performance period will result in a change in the revenue recognition period. We are recognizing the non-refundable $295.0 million upfront payments on a straight-line basis over the performance period. We recognized $53.0 million of revenue related to the Pfizer Transaction in Revenue from transfer of intellectual property in our Condensed Consolidated Statement of Operations during the nine months ended September 30, 2016, and had deferred revenue related to the Pfizer Transaction of $176.5 million at September 30, 2016. As of September 30, 2016, $70.6 million of deferred revenue related to the Pfizer Transaction was classified in Accrued expenses and $105.9 million was classified in Other long-term liabilities in our Condensed Consolidated Balance Sheet.

The Pfizer Transaction includes milestone payments totaling $275.0 million upon the achievement of certain milestones. The milestones range from $20.0 million to $90.0 million each and are based on achievement of regulatory approval in the U.S. and regulatory approval and price approval in other major markets. We evaluated each of these milestone payments and believe that all of the milestones are substantive as (i) there is substantive uncertainty at the close of the Pfizer Transaction that the milestones would be achieved as approval from a regulatory authority must be received to achieve the milestones which would be commensurate with the enhancement of value of the underlying intellectual property, (ii) the milestones relate solely to past performance and (iii) the amount of the milestone is reasonable in relation to the effort expended and the risk associated with the achievement of the

milestone. The milestone payments will be recognized as revenue in full in the period in which the associated milestone is achieved, assuming all other revenue recognition criteria are met. To date, no revenue has been recognized related to the achievement of the milestones.

In the first quarter of 2015, we made a payment of $25.9 million to the Office of the Chief Scientist of the Israeli Ministry of Economy ("OCS") in connection with repayment obligations resulting from grants previously made by the OCS to OPKO Biologics to support development of hGH-CTP and the outlicense of the technology outside of Israel. We recognized the $25.9 million payment in grant repayment expense in our Condensed Consolidated Statement of Operations during the nine months ended September 30, 2015.

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TESARO

In November 2009, we entered into an asset purchase agreement (the "NK-1 Agreement") under which we acquired VARUBI™ (rolapitant) and other neurokinin-1 ("NK-1") assets from Merck. In December 2010, we entered into an exclusive license agreement with TESARO, in which we out-licensed the development, manufacture, commercialization and distribution of our lead NK-1 candidate, VARUBI™ (the "TESARO License"). Under the terms of the license, we received a $6.0 million upfront payment from TESARO and are eligible to receive milestone payments of up to $30 million upon achievement of certain regulatory and commercial sale milestones (of which $20 million has been received to date) and additional commercial milestone payments of up to $85 million if specified levels of annual net sales are achieved. During the nine months ended September 30, 2016 and 2015, no revenue has been recognized related to the achievement of the milestones under the TESARO License. TESARO is also obligated to pay us tiered royalties on annual net sales achieved in the United States and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the United States and Europe at low double-digit percentage rates. TESARO assumed responsibility for clinical development and commercialization of licensed products at its expense. Under the Agreement, we will continue to receive royalties on a country-by-country and product-by-product basis until the later of the date that all of the patent rights licensed from us and covering VARUBI™ expire, are invalidated or are not enforceable and 12 years from the first commercial sale of the product.

If TESARO elects to develop and commercialize VARUBI™ in Japan through a third-party licensee, TESARO will share equally with us all amounts it receives in connection with such activities, subject to certain exceptions and deductions. In addition, we will have an option to market the products in Latin America.

The term of the license will remain in force until the expiration of the royalty term in each country, unless we terminate the license earlier for TESARO's material breach of the license or bankruptcy. TESARO has a right to terminate the license at any time during the term for any reason on three months' written notice.

TESARO's New Drug Application ("NDA") for approval of oral VARUBI™, a neurokinin-1 receptor antagonist in development for the prevention of chemotherapy-induced nausea and vomiting, was approved by the U.S. FDA in September 2015, and in November 2015, TESARO announced the commercial launch of VARUBI™ in the United States. Under the terms of the NK-1 Agreement, upon approval by the FDA of the TESARO's NDA for oral VARUBI™, we were required to pay Merck a $5.0 million milestone payment. In addition, $5.0 million will be due and payable each year thereafter for the next four (4) years on the anniversary date of the NDA approval. We recognized the present value of the milestone payments on FDA approval of $23.0 million as an intangible asset which will be amortized to expense over the expected useful life of the asset, which is approximately 13 years. The present value of the future payments to Merck of $13.9 million at September 30, 2016 is recorded as a liability in our Condensed Consolidated Balance Sheet with $4.8 million in Accrued expenses and $9.1 million in Other long-term liabilities.

Pharmsynthez

In April 2013, we entered into a series of concurrent transactions with Pharmsynthez, a Russian pharmaceutical company traded on the Moscow Stock Exchange pursuant to which we acquired an equity method investment in Pharmsynthez (ownership 17%). We also granted rights to certain technologies in the Russian Federation, Ukraine, Belarus, Azerbaijan and Kazakhstan (the "Territories") to Pharmsynthez and agreed to perform certain development activities. We will receive from Pharmsynthez royalties on net sales of products incorporating the technologies in the Territories, as well as a percentage of any sublicense income from third parties for the technologies in the Territories.

In July 2015, we entered into a Note Purchase Agreement with Pharmsynthez pursuant to which we delivered $3.0 million to Pharmsynthez in exchange for a $3.0 million note (the "Pharmsynthez Note Receivable"). The Pharmsynthez Note Receivable will be settled in the fourth quarter of 2016 and Pharmsynthez may satisfy the note either in cash or shares of its capital stock. We recorded the Pharmsynthez Note Receivable within Other current assets and prepaid expenses in our Condensed Consolidated Balance Sheet.

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RXi Pharmaceuticals Corporation

In March 2013, we completed the sale to RXi of substantially all of our assets in the field of RNA interference (the "RNAi Assets") (collectively, the "Asset Purchase Agreement"). Pursuant to the Asset Purchase Agreement, RXi will be required to pay us up to $50.0 million in milestone payments upon the successful development and commercialization of each drug developed by RXi, certain of its affiliates or any of its or their licensees or sublicensees utilizing patents included within the RNAi Assets (each, a "Qualified Drug"). In addition, RXi will also be required to pay us royalties equal to: (a) a mid single-digit percentage of "Net Sales" (as defined in the Asset Purchase Agreement) with respect to each Qualified Drug sold for an ophthalmologic use during the applicable "Royalty Period" (as defined in the Asset Purchase Agreement); and (b) a low single-digit percentage of net sales with respect to each Qualified Drug sold for a non-ophthalmologic use during the applicable Royalty Period.

Other

We have completed strategic deals with numerous institutioins and commercial partners. In connection with these agreements, upon the achievement of certain milestones we are obligated to make certain payments and have royalty obligations upon sales of products developed under the license agreements. At this time, we are unable to estimate the timing and amounts of payments as the obligations are based on future development of the licensed products.

NOTE 13 SEGMENTS

We manage our operations in two reportable segments, pharmaceutical and diagnostics. The pharmaceutical segment consists of our pharmaceutical operations we acquired in Chile, Mexico, Ireland, Israel and Spain and our pharmaceutical research and development. The diagnostics segment primarily consists of our clinical laboratory operations we acquired through the acquisitions of Bio-Reference and OPKO Lab and our point-of-care operations. There are no significant inter-segment sales. We evaluate the performance of each segment based on operating profit or loss. There is no inter-segment allocation of interest expense and income taxes.

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Information regarding our operations and assets for our operating segments and the unallocated corporate operations as well as geographic information are as follows:

	For the three months ended September 30,		For the nine months ended September 30,	
(In thousands)	2016	2015	2016	2015
Revenue from services:				
Pharmaceutical	$—	$160	$—	$192
Diagnostics	259,025	103,739	777,559	107,597
Corporate	—	20	—	140
	$259,025	$103,919	$777,559	$107,929
Product revenues:				
Pharmaceutical	$20,569	$20,765	$63,275	$59,066
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$20,569	$20,765	$63,275	$59,066
Revenue from transfer of intellectual property:				
Pharmaceutical	$18,441	$18,350	$105,338	$48,552
Diagnostics	—	—	—	—
Corporate	—	—	—	—
	$18,441	$18,350	$105,338	$48,552
Operating income (loss):				
Pharmaceutical	$(18,593)	$5,300	$15,422	$(36,861)
Diagnostics	3,098	(1,961)	11,117	(17,961)
Corporate	(8,128)	(11,562)	(49,414)	(34,444)
Less: Operating loss attributable to noncontrolling interests	—	—	—	(1,281)
	$(23,623)	$(8,223)	$(22,875)	$(90,547)
Depreciation and amortization:				
Pharmaceutical	$6,994	$2,775	$12,841	$6,902
Diagnostics	18,818	9,602	59,711	13,103
Corporate	20	22	60	68
	$25,832	$12,399	$72,612	$20,073
Net income (loss) from investment in investees:				
Pharmaceutical	$399	$(3,502)	$(5,643)	$(6,067)
Diagnostics	(1,213)	—	496	—
Corporate	—	—	—	—
	$(814)	$(3,502)	$(5,147)	$(6,067)
Revenues:				
United States	$259,221	$104,358	$777,703	$109,359
Ireland	20,594	22,308	114,526	53,807
Chile	9,936	7,779	26,516	22,929
Spain	3,910	3,447	12,257	12,303
Israel	3,699	4,154	12,862	14,309
Mexico	675	988	2,308	2,840
	$298,035	$143,034	$946,172	$215,547

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(In thousands)	September 30, 2016	December 31, 2015
Assets:		
Pharmaceutical	$ 1,318,377	$ 1,234,752
Diagnostics	1,412,726	1,421,034
Corporate	68,924	143,402
	$ 2,800,027	$ 2,799,188
Goodwill:		
Pharmaceutical	$ 257,570	$ 251,225
Diagnostics	442,956	492,123
Corporate	—	—
	$ 700,526	$ 743,348

During the three and nine months ended September 30, 2015, revenue recognized under the Pfizer Transaction represented 12% and 22%, respectively, of our total consolidated revenue. Refer to Note 12. No customer represented more than 10% of our total consolidated revenue during the three and nine months ended September 30, 2016. As of September 30, 2016 , no customer represented more than 10% of our accounts receivable balance. As of December 31, 2015, one customer represented more than 10% of our accounts receivable balance.

NOTE 14 SUBSEQUENT EVENTS

On October 3, 2016, we announced that our 2033 Senior Notes continue to be convertible by holders of such 2033 Senior Notes through December 31, 2016. We have elected to satisfy the conversion obligation in shares of our Common Stock. The conversion right has been extended because the closing price per share of our Common Stock has exceeded $9.19, or 130% of the applicable conversion price of $7.07, for at least 20 of 30 consecutive trading days during the quarter ended on September 30, 2016. We previously announced that this conversion right had been triggered during the quarters ended March 31, 2015, June 30, 2015, September 30, 2015, December 31, 2015, March 31, 2016 and June 30, 2016. The 2033 Senior Notes will continue to be convertible until December 31, 2016, and may be convertible thereafter, if one or more of the conversion conditions specified in the Indenture is satisfied during future measurement periods. Pursuant to the Indenture, a holder who elects to convert the 2033 Senior Notes will receive 141.4827 shares of our Common Stock plus such number of additional shares as is applicable on the conversion date per $1,000 principal amount of 2033 Senior Notes based on the early conversion provisions in the Indenture.

We have reviewed all subsequent events and transactions that occurred after the date of our September 30, 2016 Condensed Consolidated Balance Sheet date, through the time of filing this Quarterly Report on Form 10-Q.

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ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

OVERVIEW

You should read this discussion together with the unaudited Condensed Consolidated Financial Statements, related Notes, and other financial information included elsewhere in this report and in our Annual Report on Form 10-K for the year ended December 31, 2015 (the "Form 10-K"). The following discussion contains assumptions, estimates and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors," in Part II, Item 1A of our Form 10-K for the year ended December 31, 2015, and described from time to time in our other reports filed with the Securities and Exchange Commission. These risks could cause our actual results to differ materially from those anticipated in these forward-looking statements.

We are a diversified healthcare company that seeks to establish industry-leading positions in large and rapidly growing medical markets. Our diagnostics business includes Bio-Reference Laboratories, the nation's third-largest clinical laboratory with a core genetic testing business and a 420-person sales and marketing department to drive growth and leverage new products, including the 4Kscore prostate cancer test and the Claros 1 in-office immunoassay platform. Our pharmaceutical operations feature Rayaldee, an FDA-approved treatment for secondary hyperparathyroidism ("SHPT") in patients with stage 3 or 4 chronic kidney disease ("CKD") and vitamin D insufficiency, VARUBI™ for chemotherapy-induced nausea and vomiting (oral formulation launched by partner TESARO in November 2015 and IV formulation PDUFA Date: January 2017), TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity which is a clinically advanced drug candidate among the new class of GLP-1 glucagon receptor dual agonists, and TT701, an androgen receptor modulator for androgen deficiency indications. Our pharmaceutical business includes OPKO Biologics, which features hGH-CTP, a once-weekly human growth hormone injection (in Phase 3 and partnered with Pfizer), a once-daily Factor VIIa drug for hemophilia (Phase 2a), and long-acting oxyntomodulin ("OXM") for diabetes and obesity (Phase 1).

We operate established pharmaceutical platforms in Spain, Ireland, Chile and Mexico, which are generating revenue and from which we expect to generate positive cash flow and facilitate future market entry for our products currently in development. EirGen, our specialty pharmaceutical manufacturing and development site in Ireland, is focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products. In addition, we operate a specialty active pharmaceutical ingredients ("APIs") manufacturer in Israel, which we expect will facilitate the development of our pipeline of molecules and compounds for our proprietary products.

RECENT DEVELOPMENTS

In August 2016, we completed the acquisition of Transition Therapeutics, a clinical stage biotechnology company developing TT401, a once or twice weekly oxyntomodulin for type 2 diabetes and obesity, and TT701, an androgen receptor modulator for androgen deficiency indications. Holders of Transition Therapeutics common stock received 6,431,899 shares of OPKO Common Stock. The transaction was valued at approximately $58.5 million, based on a closing price per share of our Common Stock of $9.10 as reported by NASDAQ.

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RESULTS OF OPERATIONS

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015

Revenues. Revenues for the three months ended September 30, 2016 increased $155.0 million compared to the prior year period. Revenues for the three months ended September 30, 2016 and 2015 were as follows:

Revenues	For the three months ended September 30,		
(In thousands)	2016	2015	Change
Revenue from services	$259,025	$103,919	$155,106
Revenue from products	20,569	20,765	(196)
Revenue from transfer of intellectual property and other	18,441	18,350	91
Total revenues	$298,035	$143,034	$155,001

The increase in Revenue from services is attributable to the acquisition of Bio-Reference in August 2015. Revenue from products for the three months ended September 30, 2016 is consistent with the comparable 2015 period. Revenue from transfer of intellectual property principally reflects $17.7 million of revenue from the transfer of intellectual property related to the Pfizer Transaction for the three months ended September 30, 2016 and 2015.

Costs of revenue. Cost of revenue for the three months ended September 30, 2016 increased $83.9 million compared to the prior year period. Our acquisition of Bio-Reference in August 2015 accounted for $84.3 million of the increase in cost of service revenue. The increase in cost of product revenue is attributable to an increase in revenue from OPKO Chile. Costs of revenue for the three months ended September 30, 2016 and 2015 were as follows:

Cost of Revenue	For the three months ended September 30,		
(In thousands)	2016	2015	Change
Cost of service revenue	$138,554	$56,670	$81,884
Cost of product revenue	12,626	10,658	1,968
Total cost of revenue	$151,180	$67,328	$83,852

Selling, general and administrative expenses. Selling, general and administrative expenses for the three months ended September 30, 2016 and 2015, were $124.8 million and $55.2 million, respectively. The increase in selling, general and administrative expenses was primarily due to the acquisition of Bio-Reference in August 2015, which accounted for $100.3 million and $35.3 million of selling, general and administrative expenses in the third quarter of 2016 and 2015, respectively. In addition, the three months ended September 30, 2016 included costs related to the planned launch of Rayaldee. Selling, general and administrative expenses during the three months ended September 30, 2016 and 2015, include equity-based compensation expense of $6.4 million and $3.2 million, respectively. The increase in equity-based compensation expense is due to stock option grants made in 2015 and 2016.

Research and development expenses. Research and development expenses for the three months ended September 30, 2016 and 2015, were $24.4 million and $18.9 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and PMA (pre-market approval) for diagnostics tests, if any. Internal expenses include employee-related expenses including salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

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The following table summarizes the components of our research and development expenses:

Research and Development Expenses	For the three months ended September 30,	
	2016	2015
External expenses:		
Phase 3 clinical trials	$2,647	$3,218
Manufacturing expense for biological products	2,168	3,122
Earlier-stage programs	1,910	1,266
Research and development employee-related expenses	6,718	5,145
Other internal research and development expenses	11,580	6,792
Third-party grants and funding from collaboration agreements	(599)	(606)
Total research and development expenses	$24,424	$18,937

The increase in research and development expenses is primarily due to an increase in research and development expenses related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015, including manufacturing expense for biological products. In addition, during the three months ended September 30, 2016 and 2015, we recorded, as an offset to research and development expenses, $0.6 million in each period related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the three months ended September 30, 2016 and 2015 include equity-based compensation expense of $2.0 million and $0.2 million, respectively. We expect our research and development expense to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration expense for the three months ended September 30, 2016 and 2015, were $3.1 million and $1.6 million, respectively. The increase in contingent consideration was primarily attributable to an increase in the fair value of our contingent obligations for OPKO Renal due to the time value of money. The contingent consideration liabilities at September 30, 2016 relate to potential amounts payable to former stockholders of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $18.1 million and $8.1 million, respectively, for the three months ended September 30, 2016 and 2015. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the three months ended September 30, 2016 includes $4.0 million of amortization expense related to intangible assets for Rayaldee. Upon the FDA's approval of Rayaldee in June 2016, we reclassified $187.6 million of IPR&D related to Rayaldee from In-process research and development to Intangible assets, net in our Condensed Consolidated Balance Sheet and began to amortize that asset. Amortization of intangible assets for the three months ended September 30, 2016 and 2015 also includes $10.3 million and $4.9 million, respectively, from Bio-Reference assets which we acquired in August 2015. Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D assets will then be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Interest income. Interest income for the three months ended September 30, 2016 and 2015, was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the three months ended September 30, 2016 and 2015, was $2.0 million and $2.7 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes including amortization of related deferred financing costs and to interest incurred on Bio-Reference's outstanding debt under its credit facility. The decrease in interest expense for the three months ended September 30, 2016 was due to a lower average principal amount of the 2033 Senior Notes outstanding in 2016 compared to 2015.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the three months ended September 30, 2016 and 2015, were $5.7 million of expense and $32.2 million of income, respectively. Fair value changes of derivative instruments, net principally related to non-cash income (expense) related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes of $5.8 million of expense and $36.1

million of income for the three months ended September 30, 2016 and 2015, respectively. For the three months ended September 30, 2015, we observed a decrease in the market price of our Common Stock which resulted in the decrease in the estimated fair value of our embedded derivatives in the 2033 Senior Notes. Income for the three months ended September 30, 2015 was partially offset by expense of

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$4.1 million related to the change in the fair value of options and warrants to purchase additional shares of Neovasc and MabVax.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2016 and 2015, were $3.0 million of expense and $17.5 million of income, respectively. The change in other income (expense), net for the three months ended September 30, 2016 compared to the same period in 2015 is due to a $17.3 million gain recognized on the deconsolidation of STI in the third quarter of 2015. Other income (expense), net for the three months ended September 30, 2016 primarily consists of a $3.9 million other-than-temporary impairment charge to write our investments in Xenetic and RXi down to their respective fair values as of September 30, 2016.

Income tax benefit. Our income tax benefit for the three months ended September 30, 2016 and 2015 was $20.0 million and $93.0 million, respectively, and reflects quarterly results using our expected effective tax rate for the full year. The change in income taxes is primarily due a $93.4 million release of OPKO's valuation allowance in the third quarter of 2015 on our U.S. deferred tax assets as a result of the merger with Bio-Reference and to changes in the geographic mix of revenues and expenses.

Loss from investments in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will report a net loss. Loss from investments in investees was $0.8 million and $3.5 million for the three months ended September 30, 2016 and 2015, respectively.

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015

Revenues. Revenues for the nine months ended September 30, 2016 increased $730.6 million compared to the prior year period. Revenues for the nine months ended September 30, 2016 and 2015 were as follows:

Revenues	For the nine months ended September 30,		
(In thousands)	2016	2015	Change
Revenue from services	$777,559	$107,929	$669,630
Revenue from products	63,275	59,066	4,209
Revenue from transfer of intellectual property and other	105,338	48,552	56,786
Total revenues	$946,172	$215,547	$730,625

The increase in Revenue from services is attributable to the acquisition of Bio-Reference in August 2015. The increase in Revenue from products principally reflects $9.5 million of revenue from EirGen, which we acquired in May 2015, compared to $6.9 million for the comparable period in 2015, and an increase in revenue from OPKO Chile. Revenue from transfer of intellectual property principally reflects $50.0 million of revenue from the initial payment in the VFMCRP Agreement for the nine months ended September 30, 2016 and $53.0 million and $47.8 million of revenue from the transfer of intellectual property related to the Pfizer Transaction for the nine months ended September 30, 2016 and 2015, respectively. We are recognizing the non-refundable $295.0 million upfront payments received in the Pfizer Transaction on a straight-line basis over the expected performance period. The performance period is expected to continue through 2019, when we anticipate completing the various research and development services that are specified in the Pfizer Transaction.

Costs of revenue. Cost of revenue for the nine months ended September 30, 2016 increased $360.1 million compared to the prior year period. Our acquisition of Bio-Reference in August 2015 accounted for $359.1 million of the increase in cost of revenue. Costs of revenue for the nine months ended September 30, 2016 and 2015 were as follows:

Cost of Revenue	For the nine months ended September 30,		
(In thousands)	2016	2015	Change
Cost of service revenue	$417,121	$61,434	$355,687
Cost of product revenue	35,033	30,650	4,383

Total cost of revenue	$452,154	$92,084	$360,070

The increase in cost of service revenue is attributable to the acquisition of Bio-Reference. The increase in cost of product revenue principally reflects cost of revenue of $7.5 million from EirGen for the nine months ended September 30, 2016, which

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we acquired in May 2015, compared to $3.9 million for the comparable period in 2015, and an increase in revenue from OPKO Chile. This was partially offset by the deconsolidation of STI in July 2015.

Selling, general and administrative expenses. Selling, general and administrative expenses for the nine months ended September 30, 2016 and 2015, were $370.4 million and $93.6 million, respectively. The increase in selling, general and administrative expenses for the nine months ended September 30, 2016 was primarily due to the acquisition of Bio-Reference in August 2015, which accounted for $295.3 million of selling, general and administrative expenses in the 2016 period compared to $35.3 million for the comparable period of 2015. In addition, the nine months ended September 30, 2016 included costs related to the planned launch of Rayaldee. Included in selling, general and administrative expenses for the nine months ended September 30, 2016 are $17.9 million of severance costs for certain Bio-Reference executives.

Selling, general and administrative expenses during the nine months ended September 30, 2016 and 2015, include equity-based compensation expense of $27.7 million and $11.3 million, respectively. The increase in equity-based compensation expense is due to stock option grants made in 2015 and 2016 and $8.9 million of expense related to the acceleration of stock option vesting for certain Bio-Reference executives.

Research and development expenses. Research and development expenses for the nine months ended September 30, 2016 and 2015, were $83.6 million and $74.0 million, respectively. Research and development costs include external and internal expenses, partially offset by third-party grants and funding arising from collaboration agreements. External expenses include clinical and non-clinical activities performed by contract research organizations, lab services, purchases of drug and diagnostic product materials and manufacturing development costs. We track external research and development expenses by individual program for phase 3 clinical trials for drug approval and PMA's (pre-market approval) for diagnostics tests, if any. Internal expenses include employee-related expenses including salaries, benefits and equity-based compensation expense. Other internal research and development expenses are incurred to support overall research and development activities and include expenses related to general overhead and facilities.

The following table summarizes the components of our research and development expenses:

Research and Development Expenses	For the nine months ended September 30,	
	2016	2015
External expenses:		
Phase 3 clinical trials	$8,436	$9,243
Manufacturing expense for biological products	17,107	17,223
Earlier-stage programs	4,949	5,780
Research and development employee-related expenses	21,266	20,631
Other internal research and development expenses	33,902	22,760
Third-party grants and funding from collaboration agreements	(2,066)	(1,627)
Total research and development expenses	$83,594	$74,010

The increase in research and development expenses during the nine months ended September 30, 2016, is primarily due to a $9.8 million increase in research and development expenses related to hGH-CTP, a long acting human growth hormone which was outlicensed to Pfizer in 2015, including manufacturing expense for biological products. Research and development expenses for the nine months ended September 30, 2016 also include $6.4 million from the acquisitions of Bio-Reference and EirGen in August 2015 and May 2015, respectively, compared to $2.2 million for the comparative period of 2015. This was partially offset by decreased expenses incurred by OPKO Renal related to the development of Rayaldee. In addition, during the nine months ended September 30, 2016 and 2015, we recorded, as an offset to research and development expenses, $2.1 million and $1.6 million, respectively, related to research and development grants received from our collaboration and funding agreements. Research and development expenses for the nine months ended September 30, 2016 and 2015 include equity-based compensation expense of $6.0 million and $6.1 million, respectively. We expect our research and development expense to increase as we continue to expand our research and development of potential future products.

Contingent consideration. Contingent consideration expense for the nine months ended September 30, 2016 and 2015, were $15.6 million and $6.5 million, respectively. The increase in contingent consideration was attributable to OPKO Renal resulting from an increase in the fair value of our contingent obligations due to changes in assumptions regarding the timing of successful achievement of future milestones driven by the FDA approval of Rayaldee in June 2016. The contingent consideration liabilities at September 30, 2016 relate to potential amounts payable to former stockholders of CURNA, OPKO

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Diagnostics, OPKO Health Europe and OPKO Renal pursuant to our acquisition agreements in January 2011, October 2011, August 2012 and March 2013, respectively.

Amortization of intangible assets. Amortization of intangible assets was $47.3 million and $14.0 million, respectively, for the nine months ended September 30, 2016 and 2015. Amortization expense reflects the amortization of acquired intangible assets with defined useful lives. Amortization of intangible assets for the nine months ended September 30, 2016 includes $32.5 million and $1.9 million from Bio-Reference and EirGen which we acquired in August 2015 and May 2015, respectively compared to $4.9 million and $1.1 million, respectively, for the comparable period of 2015. Amortization of intangible assets for the nine months ended September 30, 2016 also includes $4.0 million of amortization expense related to intangible assets for Rayaldee. Our IPR&D assets will not be amortized until the underlying development programs are completed. Upon obtaining regulatory approval by the U.S. FDA, the IPR&D assets will be accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life.

Grant repayment. During the nine months ended September 30, 2015, we made a payment of $25.9 million to the Office of the Chief Scientist of the Israeli Ministry of Economy ("OCS") in connection with repayment obligations resulting from grants previously made by the OCS to OPKO Biologics to support development of hGH-CTP and the outlicense of the technology outside of Israel. We did not have any such activity for the nine months ended September 30, 2016.

Interest income. Interest income for the nine months ended September 30, 2016 and 2015, was not significant as our cash investment strategy emphasizes the security of the principal invested and fulfillment of liquidity needs.

Interest expense. Interest expense for the nine months ended September 30, 2016 and 2015, was $6.0 million and $6.3 million, respectively. Interest expense is principally related to interest incurred on the 2033 Senior Notes including amortization of related deferred financing costs and to interest incurred on Bio-Reference's outstanding debt under its credit facility. The decrease in interest expense for the nine months ended September 30, 2016 is due to a decrease in the average principal amount of the 2033 Senior Notes outstanding in 2016 compared to 2015. Interest expense for the nine months ended September 30, 2015 also reflects a non-cash write-off of deferred financing costs of $1.0 million as interest expense related to the exchange of $55.4 million principal of 2033 Senior Notes in 2015. This was partially offset by interest incurred on Bio-Reference's outstanding debt under its credit facility for the nine months ended September 30, 2016.

Fair value changes of derivative instruments, net. Fair value changes of derivative instruments, net for the nine months ended September 30, 2016 and 2015, were $5.9 million and $34.1 million of expense, respectively. Fair value changes of derivative instruments, net related to non-cash expense related to the changes in the fair value of the embedded derivatives in the 2033 Senior Notes of $1.1 million and $31.8 million of expense for the nine months ended September 30, 2016 and 2015, respectively. For the nine months ended September 30, 2015, we observed an increase in the average market price of our Common Stock during the period which primarily resulted in an increase in the estimated fair value of our embedded derivatives in the 2033 Senior Notes. Fair value changes of derivative instruments, net for the nine months ended September 30, 2016 also reflects $4.0 million of expense related to the change in the fair value of options to purchase additional shares of Neovasc.

Other income (expense), net. Other income (expense), net for the nine months ended September 30, 2016 and 2015, were $3.5 million of income and $16.7 million of income, respectively. Other income (expense), net for the nine months ended September 30, 2016 primarily consists of a $2.5 million gain recognized in connection with the merger of STI and VBI Vaccines Inc., a $2.9 million gain recognized in connection with the settlement of a legal matter and foreign currency transaction gains recognized during the period, which was partially offset by a $3.9 million other-than-temporary impairment charge to write our investments in Xenetic and RXi down to their respective fair values. Other income (expense), net for the nine months ended September 30, 2015 primarily consists of a $17.3 million gain recognized on the deconsolidation of STI in the third quarter of 2015.

Income tax benefit. Our income tax benefit for the nine months ended September 30, 2016 and 2015 was $24.6 million and $87.2 million, respectively, and reflects nine-month results using our expected effective tax rate for the full year. The change in income taxes is primarily due a $93.4 million release of OPKO's valuation allowance in 2015 on our U.S. deferred tax assets as a result of the merger with Bio-Reference and to changes in the geographic mix of

revenues and expenses. In addition, income taxes in 2016 benefited from a favorable corporate tax rate reduction in Israel.

Loss from investments in investees. We have made investments in other early stage companies that we perceive to have valuable proprietary technology and significant potential to create value for us as a shareholder or member. We account for these investments under the equity method of accounting, resulting in the recording of our proportionate share of their losses until our share of their loss exceeds our investment. Until the investees' technologies are commercialized, if ever, we anticipate they will continue to report a net loss. Loss from investments in investees was $5.1 million and $6.1 million for the nine months ended September 30, 2016 and 2015, respectively.

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LIQUIDITY AND CAPITAL RESOURCES

At September 30, 2016, we had cash and cash equivalents of approximately $144.6 million. Cash provided by operations during 2016 principally reflects a $50.0 million upfront payment received from the VFMCRP Agreement and our operations at Bio-Reference, partially offset by expenses related to selling, general and administrative activities related to our corporate operations, research and development activities and our operations at OPKO Biologics, OPKO Renal and OPKO Diagnostics. Cash used in investing activities primarily reflects capital expenditures of $17.0 million, investments of $9.2 million and acquisitions of intangible assets of $5.0 million, partially offset by cash acquired in the acquisition of Transition Therapeutics of $15.9 million. Cash used in financing activities primarily reflects net repayments on lines of credit of $43.1 million, partially offset by $6.1 million received from Common Stock option and Common Stock warrant exercises. We have not generated sustained positive cash flow sufficient to offset our operating and other expenses and our primary source of cash has been from the public and private placement of stock, the issuance of the 2033 Senior Notes and credit facilities available to us.

In August 2016, we completed the acquisition of Transition Therapeutics, a clinical stage biotechnology company. Holders of Transition Therapeutics common stock received 6,431,899 shares of OPKO Common Stock. The transaction was valued at approximately $58.5 million, based on a closing price per share of our Common Stock of $9.10 as reported by NASDAQ on the closing date.

In June 2016, the FDA approved Rayaldee for the treatment for SHPT in patients with stage 3 or 4 CKD and vitamin D insufficiency. We expect to launch Rayaldee in the U.S. through our dedicated renal sales force in the fourth quarter of 2016.

In May 2016, EirGen, our wholly-owned subsidiary, partnered with VFMCRP through a Development and License Agreement for the development and marketing of Rayaldee in Europe, Canada, Mexico, Australia, South Korea and certain other international markets. The license to VFMCRP potentially covers all therapeutic and prophylactic uses of the Product in human patients, provided that initially the license is for the use of the Product for the treatment or prevention of secondary hyperparathyroidism related to patients with stage 3 or 4 chronic kidney disease and vitamin D insufficiency/deficiency. We received a non-refundable and non-creditable upfront payment of $50 million and are eligible to receive up to an additional $232 million upon the achievement of certain regulatory and sales-based milestones. In addition, we are eligible to receive tiered, double digit royalty payments or a minimum royalty, whichever is greater, upon commencement of sales of the Product within the Territory and in the Field.

As part of the arrangement, the companies will share responsibility for the conduct of trials specified within an agreed-upon development plan, with each company leading certain activities within the plan. For the initial development plan agreed to by the companies, the companies have agreed to certain cost sharing arrangements. VFMCRP will be responsible for all other development costs that VFMCRP considers necessary to develop the Product for the use of the Product for the Initial Indication in the Territory in the Field except as otherwise provided in the VFMCRP Agreement.

In connection with the VFMCRP Agreement, the parties entered into a Letter Agreement pursuant to which EirGen granted to VFMCRP an Option to acquire an exclusive license under certain EirGen patents and technology to use, import, offer for sale, sell, distribute and commercialize the Product in the United States solely for the Dialysis Indication. Upon exercise of the Option, VFMCRP will reimburse EirGen for all of the development costs incurred by EirGen with respect to the Product for the Dialysis Indication in the United States. VFMCRP would also pay EirGen up to an additional aggregate amount of $555 million upon the achievement of certain milestones and would be obligated to pay certain double digit royalties on VFMCRP’s sales in the United States for the Dialysis Indication.

In January 2015, we partnered with Pfizer through a worldwide agreement for the development and commercialization of our long-acting hGH-CTP for the treatment of GHD in adults and children, as well as for the treatment of growth failure in children born SGA. Under the terms of the agreements with Pfizer, we received non-refundable and non-creditable upfront payments of $295.0 million in the first quarter of 2015 and are eligible to receive up to an additional $275 million upon the achievement of certain regulatory milestones. Pfizer received the exclusive license to commercialize hGH-CTP worldwide. In addition, we are eligible to receive initial tiered royalty payments associated with the commercialization of hGH-CTP for Adult GHD with percentage rates ranging from the high teens to mid-twenties. Upon the launch of hGH-CTP for Pediatric GHD in certain major markets, the royalties will transition

to regional, tiered gross profit sharing for both hGH-CTP and Pfizer's Genotropin®.
We will lead the clinical activities and will be responsible for funding the development programs for the key indications, which includes Adult and Pediatric GHD and Pediatric SGA. Pfizer will be responsible for all development costs for additional indications as well as all post-marketing studies. In addition, Pfizer will fund the commercialization activities for all indications and lead the manufacturing activities covered by the global development plan.

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In August 2015, we completed the acquisition of Bio-Reference, the third largest full service clinical laboratory in the United States, known for its innovative technological solutions and pioneering leadership in the areas of genomics and genetic sequencing. Holders of Bio-Reference common stock received 76,566,147 shares of OPKO Common Stock for the outstanding shares of Bio-Reference common stock. The transaction was valued at approximately $950.1 million, based on a closing price per share of our Common Stock of $12.38 as reported by the New York Stock Exchange on the closing date, or $34.05 per share of Bio-Reference common stock. Included in the transaction value is $2.3 million related to the value of replacement stock option awards attributable to pre-merger service.

In May 2015, we entered into a series of purchase agreements to acquire all of the issued and outstanding shares of EirGen, a specialty pharmaceutical company incorporated in Ireland focused on the development and commercial supply of high potency, high barrier to entry pharmaceutical products, for $133.8 million. We acquired the outstanding shares of EirGen for approximately $100.2 million in cash and delivered 2,420,487 shares of our Common Stock valued at approximately $33.6 million based on the closing price per share of our Common Stock as reported by the New York Stock Exchange on the closing date of the acquisition, $13.88 per share.

We plan to construct a research, development and manufacturing center in Waterford, Ireland, for which we expect to incur between $25 million and $35 million for the construction and validation of the facility with expenditures beginning in the fourth quarter of 2016 and expected completion in 2019. Currently, we plan to fund the project from cash on hand or from third party funding sources that may be available to us.

Our licensee, TESARO, received approval by the U.S. FDA in September 2015 for oral VARUBI™, a neurokinin-1 receptor antagonist for the prevention of chemotherapy-induced nausea and vomiting. In November 2015, TESARO announced the commercial launch of VARUBI™ in the United States. We are eligible to receive milestone payments of up to $30.0 million (of which $20.0 million has been received to date) upon achievement of certain regulatory and commercial sale milestones and additional commercial milestone payments of up to $85.0 million if specified levels of annual net sales are achieved. During the nine months ended September 30, 2016 and 2015, no revenue has been recognized related to the achievement of the milestones under the TESARO License. TESARO is also obligated to pay us tiered royalties on annual net sales achieved in the United States and Europe at percentage rates that range from the low double digits to the low twenties, and outside of the United States and Europe at low double-digit percentage rates.

Under the terms of our agreement with Merck, upon approval by the FDA of the TESARO's NDA for oral VARUBI™, which occurred in September 2015, we were required to pay Merck a $5.0 million milestone payment. In addition, $5.0 million will be due and payable each year thereafter for the next four (4) years on the anniversary date of the NDA approval. We recognized the present value of the milestone payments on FDA approval of $23.0 million as an intangible asset which will be amortized to expense over the expected useful life of the asset, which is approximately 13 years. The present value of the future payments to Merck of $13.9 million at September 30, 2016 is recorded as a liability in our Condensed Consolidated Balance Sheet with $4.8 million in Accrued expenses and $9.1 million in Other long-term liabilities.

2033 Senior Notes. In January 2013, we issued $175.0 million of the 2033 Senior Notes. The 2033 Senior Notes were sold in a private placement in reliance on exemptions from registration under the Securities Act. At September 30, 2016, $32.2 million principal amount of 2033 Senior Notes was outstanding.

On October 3, 2016, we announced that our 2033 Senior Notes continue to be convertible by holders of such notes. We have elected to satisfy our conversion obligation under the 2033 Senior Notes in shares of our Common Stock. This conversion right has been triggered because the closing price per share of our Common Stock has exceeded $9.19, or 130% of the initial conversion price of $7.07, for at least 20 of 30 consecutive trading days during the period ending on September 30, 2016. The 2033 Senior Notes will continue to be convertible until December 31, 2016, and may be convertible thereafter, if one or more of the conversion conditions specified in the Indenture is satisfied during future measurement periods. Pursuant to the Indenture, a holder who elects to convert the 2033 Senior Notes will receive 141.4827 shares of our Common Stock plus such number of additional shares as is applicable on the conversion date per $1,000 principal amount of 2033 Senior Notes based on the early conversion provisions in the Indenture.

In connection with our acquisitions of CURNA, OPKO Diagnostics, OPKO Health Europe and OPKO Renal, we agreed to pay future consideration to the sellers upon the achievement of certain events, including up to an additional $19.1 million in shares of our Common Stock to the former stockholders of OPKO Diagnostics upon and subject to the achievement of certain milestones; and up to an additional $125.0 million in either shares of our Common Stock or cash, at our option subject to the achievement of certain milestones, to the former shareholders of OPKO Renal.
On November 5, 2015, Bio-Reference and certain of its subsidiaries entered into a credit agreement with JPMorgan Chase Bank, N.A. (“CB”), as lender and administrative agent, as amended (the “Credit Agreement”). The Credit Agreement provides for a $175.0 million secured revolving credit facility and includes a $20.0 million sub-facility for swingline loans and a $20.0

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million sub-facility for the issuance of letters of credit. Bio-Reference may increase the credit facility to up to $275.0 million on a secured basis, subject to the satisfaction of specified conditions. The Credit Agreement matures on November 5, 2020 and is guaranteed by all of Bio-Reference's domestic subsidiaries. The Credit Agreement is also secured by substantially all assets of Bio-Reference and its domestic subsidiaries, as well as a non-recourse pledge by us of our equity interest in Bio-Reference. Availability under the Credit Agreement is based on a borrowing base comprised of eligible accounts receivables of Bio-Reference and certain of its subsidiaries, as specified therein. The proceeds of the new credit facility were used to refinance existing indebtedness, to finance working capital needs and for general corporate purposes of Bio-Reference and its subsidiaries.

As of September 30, 2016, the total availability under our Credit Agreement with CB and our lines of credit with financial institutions in Chile and Spain was $152.3 million, of which $47.2 million was used and outstanding as of September 30, 2016. The weighted average interest rate on these lines of credit is approximately 4.8%. These lines of credit are short-term and are used primarily as a source of working capital. The highest balance at any time during the nine months ended September 30, 2016, was $83.5 million. We intend to continue to enter into these lines of credit as needed. There is no assurance that these lines of credit or other funding sources will be available to us on acceptable terms, or at all, in the future.

We expect to continue to incur substantial research and development expenses, including expenses related to the hiring of personnel and additional clinical trials. We expect that selling, general and administrative expenses will also increase as we expand our sales, marketing and administrative staff and add infrastructure, particularly as we prepare for the launch of Rayaldee in the fourth quarter of 2016.

We believe that the cash and cash equivalents on hand at September 30, 2016, and the amounts available to be borrowed under our lines of credit are sufficient to meet our anticipated cash requirements for operations and debt service beyond the next 12 months. We based this estimate on assumptions that may prove to be wrong or are subject to change, and we may be required to use our available cash resources sooner than we currently expect. If we acquire additional assets or companies, accelerate our product development programs or initiate additional clinical trials, we will need additional funds. Our future cash requirements will depend on a number of factors, including our relationship with Pfizer, preparations for the commercial launch of Rayaldee, our merger with Bio-Reference, possible acquisitions, the continued progress of research and development of our product candidates, the timing and outcome of clinical trials and regulatory approvals, the costs involved in preparing, filing, prosecuting, maintaining, defending, and enforcing patent claims and other intellectual property rights, the status of competitive products, the availability of financing, and our success in developing markets for our product candidates. If we are not able to secure additional funding when needed, we may have to delay, reduce the scope of, or eliminate one or more of our clinical trials or research and development programs or possible acquisitions.

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The following table provides information as of September 30, 2016, with respect to the amounts and timing of our known contractual obligation payments due by period.

Contractual obligations (In thousands)	Remaining three months ending December 31, 2016	2017	2018	2019	2020	Thereafter	Total
Open purchase orders	$ 63,471	$6,186	$1,248	$1,028	$10	$ —	$71,943
Operating leases	4,940	34,412	10,677	8,530	3,878	7,670	70,107
Capital leases	821	2,968	2,538	2,005	1,264	1,008	10,604
2033 Senior Notes	—	—	—	32,200	—	—	32,200
Deferred payments	—	5,000	5,000	5,000	—	—	15,000
Mortgages and other debts payable	447	433	385	379	379	1,047	3,070
Lines of credit	8,758	—	—	—	38,444	—	47,202
Severance payments	6,327	—	—	—	—	—	6,327
Interest commitments	612	1,033	1,022	208	1,325	56	4,256
Total	$ 85,376	$50,032	$20,870	$49,350	$45,300	$ 9,781	$260,709

The preceding table does not include information where the amounts of the obligations are not currently determinable, including the following:

- Contractual obligations in connection with clinical trials, which span over two years, and that depend on patient enrollment. The total amount of expenditures is dependent on the actual number of patients enrolled and as such, the contracts do not specify the maximum amount we may owe.
- Product license agreements effective during the lesser of 15 years or patent expiration whereby payments and amounts are determined by applying a royalty rate on uncapped future sales.
- Contingent consideration that includes payments upon achievement of certain milestones including meeting development milestones such as the completion of successful clinical trials, NDA approvals by the FDA and revenue milestones upon the achievement of certain revenue targets all of which are anticipated to be paid within the next 7 years and are payable in either shares of our Common Stock or cash, at our option, and that may aggregate up to $164.4 million.

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CRITICAL ACCOUNTING POLICIES AND ESTIMATES

Accounting estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ significantly from these estimates.

Goodwill and Intangible Assets. Goodwill represents the difference between the purchase price and the estimated fair value of the net assets acquired accounted for by the acquisition method of accounting and arose from our acquisitions. Goodwill and other intangible assets, including IPR&D, acquired in business combinations, licensing and other transactions at September 30, 2016 and December 31, 2015 was $2.1 billion and $2.2 billion, respectively, representing approximately 76% and 78% of total assets, respectively.

Assets acquired and liabilities assumed in business combinations, licensing and other transactions are generally recognized at the date of acquisition at their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recognized as goodwill. We determined the fair value of intangible assets, including IPR&D, using the "income method." This method starts with a forecast of net cash flows, risk adjusted for estimated probabilities of technical and regulatory success (for IPR&D) and adjusted to present value using an appropriate discount rate that reflects the risk associated with the cash flow streams. All assets are valued from a market participant view which might be different than our specific views. The valuation process is very complex and requires significant input and judgment using internal and external sources. Although the valuations are required to be finalized within a one-year period, it must consider all and only those facts and evidence which existed at the acquisition date. The most complex and judgmental matters applicable to the valuation process are summarized below:

- Unit of account – Most intangible assets are valued as single global assets rather than multiple assets for each jurisdiction or indication after considering the development stage, expected levels of incremental costs to obtain additional approvals, risks associated with further development, amount and timing of benefits expected to be derived in the future, expected patent lives in various jurisdictions and the intention to promote the asset as a global brand.
- Estimated useful life – The asset life expected to contribute meaningful cash flows is determined after considering all pertinent matters associated with the asset, including expected regulatory approval dates (if unapproved), exclusivity periods and other legal, regulatory or contractual provisions as well as the effects of any obsolescence, demand, competition, and other economic factors, including barriers to entry.
- Probability of Technical and Regulatory Success ("PTRS") Rate – PTRS rates are determined based upon industry averages considering the respective program's development stage and disease indication and adjusted for specific information or data known at the acquisition date. Subsequent clinical results or other internal or external data obtained could alter the PTRS rate and materially impact the estimated fair value of the intangible asset in subsequent periods leading to impairment charges.
- Projections – Future revenues are estimated after considering many factors such as initial market opportunity, pricing, sales trajectories to peak sales levels, competitive environment and product evolution. Future costs and expenses are estimated after considering historical market trends, market participant synergies and the timing and level of additional development costs to obtain the initial or additional regulatory approvals, maintain or further enhance the product. We generally assume initial positive cash flows to commence shortly after the receipt of expected regulatory approvals which typically may not occur for a number of years. Actual cash flows attributed to the project are likely to be different than those assumed since projections are subjected to multiple factors including trial results and regulatory matters which could materially change the ultimate commercial success of the asset as well as significantly alter the costs to develop the respective asset into commercially viable products.
- Tax rates – The expected future income is tax effected using a market participant tax rate. Our recent valuations typically use a U.S. tax rate (and applicable state taxes) after considering the jurisdiction in which the intellectual property is held and location of research and manufacturing infrastructure. We also considered that any repatriation of earnings would likely have U.S. tax consequences.
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Discount rate – Discount rates are selected after considering the risks inherent in the future cash flows; the assessment of the asset's life cycle and the competitive trends impacting the asset, including consideration of any technical, legal, regulatory, or economic barriers to entry, as well as expected changes in standards of practice for indications addressed by the asset.

Goodwill was $700.5 million and $743.3 million, respectively, at September 30, 2016 and December 31, 2015. Goodwill is tested at least annually for impairment or when events or changes in circumstances indicate that the carrying amount of such

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assets may not be recoverable, by assessing qualitative factors or performing a quantitative analysis in determining whether it is more likely than not that its fair value exceeds the carrying value. Examples of qualitative factors include our share price, our financial performance compared to budgets, long-term financial plans, macroeconomic, industry and market conditions as well as the substantial excess of fair value over the carrying value of net assets from the annual impairment test previously performed.

The estimated fair value of a reporting unit is highly sensitive to changes in projections and assumptions; therefore, in some instances changes in these assumptions could potentially lead to impairment. We perform sensitivity analyses around our assumptions in order to assess the reasonableness of the assumptions and the results of our testing. Ultimately, future potential changes in these assumptions may impact the estimated fair value of a reporting unit and cause the fair value of the reporting unit to be below its carrying value. We believe that our estimates are consistent with assumptions that marketplace participants would use in their estimates of fair value. However, if actual results are not consistent with our estimates and assumptions, we may be exposed to an impairment charge that could be material.

Intangible assets were $1.4 billion, including IPR&D of $647.0 million and $792.3 million, respectively, at September 30, 2016 and December 31, 2015. Intangible assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable, although IPR&D is required to be tested at least annually until the project is completed or abandoned. Upon obtaining regulatory approval, the IPR&D asset is then accounted for as a finite-lived intangible asset and amortized on a straight-line basis over its estimated useful life. If the project is abandoned, the IPR&D asset is charged to expense.

Intangible assets are highly vulnerable to impairment charges, particularly newly acquired assets for recently launched products or IPR&D. These assets are initially measured at fair value and therefore any reduction in expectations used in the valuations could potentially lead to impairment. Some of the more common potential risks leading to impairment include competition, earlier than expected loss of exclusivity, pricing pressures, adverse regulatory changes or clinical trial results, delay or failure to obtain regulatory approval and additional development costs, inability to achieve expected synergies, higher operating costs, changes in tax laws and other macro-economic changes. The complexity in estimating the fair value of intangible assets in connection with an impairment test is similar to the initial valuation.

Considering the high risk nature of research and development and the industry’s success rate of bringing developmental compounds to market, IPR&D impairment charges are likely to occur in future periods. IPR&D is closely monitored and assessed each period for impairment.

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 3 to 20 years. We use the straight-line method of amortization as there is no reliably determinable pattern in which the economic benefits of our intangible assets are consumed or otherwise used up. Amortization expense was $47.3 million and $14.0 million for the nine months ended September 30, 2016 and 2015, respectively.

Revenue recognition. Revenue for laboratory services is recognized at the time test results are reported, which approximates when services are provided. Services are provided to patients covered by various third-party payer programs including various managed care organizations, as well as the Medicare and Medicaid programs. Billings for services under third-party payer programs are included in revenue net of allowances for contractual discounts and allowances for differences between the amounts billed and estimated program payment amounts. Adjustments to the estimated payment amounts based on final settlement with the programs are recorded upon settlement as an adjustment to revenue. For the three months ended September 30, 2016 and 2015, approximately 10% and 9%, respectively, of our revenues were derived directly from the Medicare and Medicaid programs. The increase in revenues from laboratory services, including revenue from Medicare and Medicaid programs, is due to the acquisition of Bio-Reference in August 2015.

Generally, we recognize revenue from product sales when goods are shipped and title and risk of loss transfer to our customers. Our estimates for sales returns and allowances are based upon the historical patterns of product returns and allowances taken, matched against the sales from which they originated, and management’s evaluation of specific factors that may increase or decrease the risk of product returns.

Revenue from transfer of intellectual property includes revenue related to the sale, license or transfer of intellectual property such as upfront license payments, license fees, milestone and royalty payments received through our license, and collaboration and commercialization agreements. We analyze our multiple-element arrangements to determine whether the elements can be separated and accounted for individually as separate units of accounting.
Non-refundable license fees for the out-license of our technology are recognized depending on the provisions of each agreement. We recognize non-refundable upfront license payments as revenue upon receipt if the license has standalone value and qualifies for treatment as a separate unit of accounting under multiple-element arrangement guidance. License fees with

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ongoing involvement or performance obligations that do not have standalone value are recorded as deferred revenue, included in Accrued expenses or Other long-term liabilities, when received and generally are recognized ratably over the period of such performance obligations only after both the license period has commenced and we have delivered the technology.

The assessment of our obligations and related performance periods requires significant management judgment. If an agreement contains research and development obligations, the relevant time period for the research and development phase is based on management estimates and could vary depending on the outcome of clinical trials and the regulatory approval process. Such changes could materially impact the revenue recognized, and as a result, management reviews the estimates related to the relevant time period of research and development on a periodic basis.

Revenue from milestone payments related to arrangements under which we have continuing performance obligations are recognized as Revenue from transfer of intellectual property upon achievement of the milestone only if all of the following conditions are met: the milestone payments are non-refundable; there was substantive uncertainty at the date of entering into the arrangement that the milestone would be achieved; the milestone is commensurate with either our performance to achieve the milestone or the enhancement of the value of the delivered item by us; the milestone relates solely to past performance; and the amount of the milestone is reasonable in relation to the effort expended or the risk associated with the achievement of the milestone. If any of these conditions are not met, the milestone payments are not considered to be substantive and are, therefore, deferred and recognized as Revenue from transfer of intellectual property over the term of the arrangement as we complete our performance obligations.

Concentration of credit risk and allowance for doubtful accounts. Financial instruments that potentially subject us to concentrations of credit risk consist primarily of accounts receivable. Substantially all of our accounts receivable are with either companies in the health care industry or patients. However, credit risk is limited due to the number of our clients as well as their dispersion across many different geographic regions.

While we have receivables due from federal and state governmental agencies, we do not believe that such receivables represent a credit risk since the related health care programs are funded by federal and state governments, and payment is primarily dependent upon submitting appropriate documentation. Accounts receivable balances (net of contractual adjustments) from Medicare and Medicaid were $31.1 million and $26.1 million at September 30, 2016 and December 31, 2015, respectively.

The portion of our accounts receivable due from individual patients comprises the largest portion of credit risk. At September 30, 2016 and December 31, 2015, receivables due from patients represent approximately 6.6% and 7.5% of our consolidated accounts receivable (prior to allowance for doubtful accounts and net of contractual adjustments). We assess the collectability of accounts receivable balances by considering factors such as historical collection experience, customer credit worthiness, the age of accounts receivable balances, regulatory changes and current economic conditions and trends that may affect a customer’s ability to pay. Actual results could differ from those estimates. Our reported net income (loss) is directly affected by our estimate of the collectability of accounts receivable. The allowance for doubtful accounts was $41.1 million and $25.2 million at September 30, 2016 and December 31, 2015, respectively.

Income Taxes. Income taxes are accounted for under the asset-and-liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and the respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. We periodically evaluate the realizability of our net deferred tax assets. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment.

Equity-based compensation. We measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized in the Condensed Consolidated Statement of Operations over the period during which an employee is required to provide service in exchange for the award. We record excess tax benefits, realized from the exercise of stock options as a financing cash inflow and as a reduction of taxes paid in cash flow from operations. Equity-based compensation arrangements to non-employees are

recorded at their fair value on the measurement date. The measurement of equity-based compensation to non-employees is subject to periodic adjustment as the underlying equity instruments vest. We estimate the grant-date fair value of our stock option grants using a valuation model known as the Black-Scholes-Merton formula or the "Black-Scholes Model." The Black-Scholes Model requires the use of several variables to estimate the grant-date fair value of stock options including expected term, expected volatility, expected dividends and risk-free interest rate. We perform analyses to calculate and select the appropriate variable assumptions used in the Black-Scholes Model and to estimate forfeitures of equity-based awards. We are required to adjust our forfeiture estimates

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on at least an annual basis based on the number of share-based awards that ultimately vest. The selection of assumptions and estimated forfeiture rates is subject to significant judgment and future changes to our assumptions and estimates which may have a material impact on our Condensed Consolidated Financial Statements.

Inventories. Inventories are valued at the lower of cost or market (net realizable value). Cost is determined by the first-in, first-out method. We consider such factors as the amount of inventory on hand, estimated time required to sell such inventories, remaining shelf-life, and current market conditions to determine whether inventories are stated at the lower of cost or market. Inventories at our diagnostics segment consist primarily of purchased laboratory supplies, which is used in our testing laboratories.

Pre-launch inventories. We may accumulate commercial quantities of certain product candidates prior to the date we anticipate that such products will receive final U.S. FDA approval. The accumulation of such pre-launch inventories involves the risk that such products may not be approved for marketing by the FDA on a timely basis, or ever. This risk notwithstanding, we may accumulate pre-launch inventories of certain products when such action is appropriate in relation to the commercial value of the product launch opportunity. In accordance with our policy, this pre-launch inventory is expensed.

Contingent consideration. Each period we revalue the contingent consideration obligations associated with certain prior acquisitions to their fair value and record increases in the fair value as contingent consideration expense and decreases in the fair value as a reduction in contingent consideration expense. Changes in contingent consideration result from changes in the assumptions regarding probabilities of successful achievement of related milestones, the estimated timing in which the milestones are achieved and the discount rate used to estimate the fair value of the liability. Contingent consideration may change significantly as our development programs progress, revenue estimates evolve and additional data is obtained, impacting our assumptions. The assumptions used in estimating fair value require significant judgment. The use of different assumptions and judgments could result in a materially different estimate of fair value which may have a material impact on our results from operations and financial position.

RECENT ACCOUNTING PRONOUNCEMENTS

In May 2014, the FASB issued Accounting Standards Update (“ASU”), ASU No. 2014-09, “Revenue from Contracts with Customers.” ASU 2014-09 clarifies the principles for recognizing revenue and develops a common revenue standard for GAAP and International Financial Reporting Standards that removes inconsistencies and weaknesses in revenue requirements, provides a more robust framework for addressing revenue issues, improves comparability of revenue recognition practices across entities, industries, jurisdictions, and capital markets, provides more useful information to users of financial statements through improved disclosure requirements and simplifies the preparation of financial statements by reducing the number of requirements to which an entity must refer. ASU 2014-09 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2017. Companies can choose to apply the ASU using either the full retrospective approach or a modified retrospective approach. We are currently evaluating both methods of adoption and the impact that the adoption of this ASU will have on our Condensed Consolidated Financial Statements.

In June 2014, the FASB issued ASU No. 2014-12, “Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period (a consensus of the FASB Emerging Issues Task Force).” ASU 2014-12 requires that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 was effective for the Company beginning after January 1, 2016. Our adoption of ASU 2014-12 in the first quarter of 2016 using the prospective application did not have a material impact on our Condensed Consolidated Financial Statements.

In August 2014, the FASB issued ASU No. 2014-15, “Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern,” to provide guidance on management’s responsibility in evaluating whether there is substantial doubt about a company’s ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for annual periods ending after December 15, 2016 with early adoption permitted. We do not believe the impact of our pending adoption of ASU 2014-15 on our Condensed Consolidated Financial Statements will be material.

In February 2015, the FASB issued ASU No. 2015-02, “Consolidation (Topic 810): Amendments to the Consolidation Analysis,” which amends current consolidation guidance including changes to both the variable and voting interest

models used by companies to evaluate whether an entity should be consolidated. The requirements from ASU 2015-02 were effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-02 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

In April 2015, the FASB issued ASU No. 2015-03, “Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs,” which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. ASU

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2015-03 was effective for the Company beginning January 1, 2016. Our adoption of ASU 2015-03 in the first quarter of 2016 did not have a material impact on our Condensed Consolidated Financial Statements.

In July 2015, the FASB issued ASU No. 2015-11, "Inventory (Topic 330): Simplifying the Measurement of Inventory," which changes the measurement principle for entities that do not measure inventory using the last-in, first-out ("LIFO") or retail inventory method from the lower of cost or market to lower of cost and net realizable value. ASU 2015-11 is effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In September 2015, the FASB issued ASU No. 2015-16, "Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments," which replaces the requirement that an acquirer in a business combination account for measurement period adjustments retrospectively with a requirement that an acquirer recognize adjustments to the provisional amounts that are identified during the measurement period in the reporting period in which the adjustment amounts are determined. ASU 2015-16 requires that the acquirer record, in the same period's financial statements, the effect on earnings of changes in depreciation, amortization, or other income effects, if any, as a result of the change to the provisional amounts, calculated as if the accounting had been completed at the acquisition date. Our early adoption of ASU 2015-16 in 2015 did not have a significant impact on our Condensed Consolidated Financial Statements.

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes," which requires deferred tax liabilities and assets to be classified as noncurrent in a classified statement of financial position. We early adopted the provisions of this ASU prospectively in the fourth quarter of 2015, and did not retrospectively adjust the prior periods. The adoption of this ASU simplifies the presentation of deferred income taxes and reduce complexity without decreasing the usefulness of information provided to users of financial statements. The adoption of ASU 2015-17 did not have a significant impact on our Condensed Consolidated Financial Statements.

In January 2016, the FASB issued ASU No. 2016-01, "Financial Instruments - Overall (Subtopic 825-10)," which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The ASU requires equity investments (except those accounted for under the equity method of accounting or those that result in consolidation of the investee) to be measured at fair value with changes in fair value recognized in net income. ASU 2016-01 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In February 2016, the FASB issued ASU No. 2016-02, "Leases (Topic 842)," which will require organizations that lease assets with lease terms of more than 12 months to recognize assets and liabilities for the rights and obligations created by those leases on their balance sheets. The ASU will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing, and uncertainty of cash flows arising from leases. ASU 2016-02 will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In March 2016, the FASB issued ASU No. 2016-09, "Compensation - Stock Compensation (Topic 718)," which simplifies several aspects of the accounting for share-based payment award transactions, including the income tax consequences, classification of awards as either equity or liabilities, classification on the statement of cash flows and accounting for forfeitures. ASU 2016-09 will be effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

In August 2016, the FASB issued ASU No. 2016-15, "Statement of Cash Flows (Topic 230)," which addresses the classification of eight specific cash flow issues with the objective of reducing the existing diversity in practice. ASU 2016-15 will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the impact of this new guidance on our Condensed Consolidated Financial Statements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk

In the normal course of doing business, we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

Foreign Currency Exchange Rate Risk – We operate globally and, as such, we are subject to foreign exchange risk in our commercial operations as a significant portion of our revenues are exposed to changes in foreign currency exchange rates, primarily the Chilean peso, the Mexican peso, the Euro and the New Israeli shekel.

Although we do not speculate in the foreign exchange market, we may from time to time manage exposures that arise in the normal course of business related to fluctuations in foreign currency exchange rates by entering into offsetting positions through the use of foreign exchange forward contracts. Certain firmly committed transactions may be hedged with foreign exchange forward contracts. As exchange rates change, gains and losses on the exposed transactions are partially offset by gains and losses related to the hedging contracts. Both the exposed transactions and the hedging contracts are translated and fair valued, respectively, at current spot rates, with gains and losses included in earnings.

Our derivative activities, which consist of foreign exchange forward contracts, are initiated to hedge forecasted cash flows that are exposed to foreign currency risk. The foreign exchange forward contracts generally require us to exchange local currencies for foreign currencies based on pre-established exchange rates at the contracts' maturity dates. As exchange rates change, gains and losses on these contracts are generated based on the change in the exchange rates that are recognized in the Condensed Consolidated Statement of Operations and offset the impact of the change in exchange rates on the foreign currency cash flows that are hedged. If the counterparties to the exchange contracts do not fulfill their obligations to deliver the contracted currencies, we could be at risk for currency related fluctuations. If Chilean pesos were to strengthen or weaken in relation to the U.S. dollar, our loss or gain on hedged foreign currency cash-flows would be offset by the derivative contracts, with a net effect of zero.

We do not engage in trading market risk sensitive instruments or purchasing hedging instruments or "other than trading" instruments that are likely to expose us to significant market risk, whether interest rate, foreign currency exchange, commodity price, or equity price risk.

Interest Rate Risk – Our exposure to interest rate risk relates to our cash and investments and to our borrowings. We maintain an investment portfolio of money market funds and marketable securities. The securities in our investment portfolio are not leveraged, and are, due to their very short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that a change in market interest rates would have a significant negative impact on the value of our investment portfolio except for reduced income in a low interest rate environment.

At September 30, 2016, we had cash and cash equivalents of $144.6 million. The weighted average interest rate related to our cash and cash equivalents for the nine months ended September 30, 2016 was less than 1%. As of September 30, 2016, the principal outstanding balance under our Credit Agreement with JPMorgan Chase Bank, N.A. and our Chilean and Spanish lines of credit was $47.2 million in the aggregate at a weighted average interest rate of approximately 4.8%.

Our $32.2 million aggregate principal amount of our 2033 Senior Notes has a fixed interest rate, and therefore is not subject to fluctuations in market interest rates.

The primary objective of our investment activities is to preserve principal while at the same time maximizing yields without significantly increasing risk. To achieve this objective, we may invest our excess cash in debt instruments of the U.S. Government and its agencies, bank obligations, repurchase agreements and high-quality corporate issuers, and money market funds that invest in such debt instruments, and, by policy, restrict our exposure to any single corporate issuer by imposing concentration limits. To minimize the exposure due to adverse shifts in interest rates, we maintain investments at an average maturity of generally less than three months.

Equity Price Risk – We are subject to equity price risk related to the (i) rights to convert into shares of our Common Stock, including upon a fundamental change; and (ii) a coupon make-whole payment in the event of a conversion by the holders of the 2033 Senior Notes on or after February 1, 2017 but prior to February 1, 2019. These terms are considered to be embedded derivatives. On a quarterly basis, we are required to record these embedded derivatives at fair value with the changes being recorded in our Condensed Consolidated Statement of Operations. Accordingly, our

results of operations are subject to exposure associated with increases or decreases in the estimated fair value of our embedded derivatives.

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Item 4. Controls and Procedures

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q. Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on this evaluation, management concluded that our disclosure controls and procedures were effective as of September 30, 2016.

Changes to the Company's Internal Control Over Financial Reporting

In connection with the acquisitions of EirGen in May 2015, Bio-Reference in August 2015 and Transition Therapeutics in August 2016, we began implementing standards and procedures at EirGen, Bio-Reference and Transition Therapeutics, including establishing controls over accounting systems and establishing controls over the preparation of financial statements in accordance with generally accepted accounting principles to ensure that we have in place appropriate internal control over financial reporting at EirGen, Bio-Reference and Transition Therapeutics. We are continuing to integrate the acquired operations of EirGen, Bio-Reference and Transition Therapeutics into our overall internal control over financial reporting process.

We are in the process of implementing a new comprehensive enterprise resource planning ("ERP") system on a company wide basis, which is one of the systems used for financial reporting. The implementation of the ERP system involves changes to our financial systems and other systems and accordingly, will necessitate changes to our internal controls over financial reporting.

These changes to the Company's internal control over financial reporting that occurred during the most recent quarter ended September 30, 2016 have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

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PART II. OTHER INFORMATION

Item 1. Legal Proceedings

We are, from time to time party to various legal proceedings arising out of our business. During the reporting period, there have been no material changes to the description of legal proceedings set forth in our Annual Report on Form 10-K for the year ended December 31, 2015, as updated by the information set forth in our quarterly reports on Form 10-Q for the quarters ended during 2016.

Item 1A. Risk Factors

Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2015, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2015.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On August 4, 2016, we issued 50,000 shares of our Common Stock (the “Settlement Shares”) pursuant to a settlement agreement in connection with a pending litigation matter with a Company stockholder. The Settlement Shares were issued in reliance upon an exemption from the registration requirements under the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

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Item 6. Exhibits

Exhibit 3.1[1]	Amended and Restated Certificate of Incorporation.
Exhibit 3.2[2]	Amended and Restated By-Laws.
Exhibit 3.3[3]	Certificate of Designation of Series D Preferred Stock.
Exhibit 4.3[4]	Indenture, dated as of January 30, 2013, between OPKO Health, Inc. and Wells Fargo Bank, National Association.
Exhibit 31.1	Certification by Phillip Frost, Chief Executive Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2016.
Exhibit 31.2	Certification by Adam Logal, Chief Financial Officer, pursuant to Rule 13a-14(a) and 15d-14(a) of the Securities and Exchange Act of 1934 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2016.
Exhibit 32.1	Certification by Phillip Frost, Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2016.
Exhibit 32.2	Certification by Adam Logal, Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 for the quarterly period ended September 30, 2016.
Exhibit 101.INS	XBRL Instance Document
Exhibit 101.SCH	XBRL Taxonomy Extension Schema Document
Exhibit 101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
Exhibit 101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
Exhibit 101.LAB	XBRL Taxonomy Extension Label Linkbase Document
Exhibit 101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Filed with the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2013 for the Company's three month period ended September 30, 2013, and incorporated herein by reference.

(2) Filed with the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 31, 2008, and incorporated herein by reference.

(3) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on September 24, 2009, and incorporated herein by reference.

(4) Filed with the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2013, and incorporated herein by reference.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Date: November 7, 2016 OPKO Health, Inc.

/s/ Adam Logal
Adam Logal
Senior Vice President, Chief Financial Officer,
Chief Accounting Officer and Treasurer

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Exhibit Index

Exhibit Number	Description
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