

XTL BIOPHARMACEUTICALS LTD  
Form 20-F  
March 11, 2019

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 20-F**

(Mark One)

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

OR

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

For the fiscal year ended December 31, 2018

OR

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

OR

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

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

Commission file number: **000-36000**

**XTL BIOPHARMACEUTICALS LTD.**

(Exact name of registrant as specified in its charter)

**Israel**

(Jurisdiction of incorporation or organization)

5 Badner St.

Ramat Gan,  
4365603, Israel

(Address of principal executive offices)

Josh Levine

Chief Executive Officer

5 Badner St.

Ramat Gan,  
4365603, Israel

Tel: +972-3-6116600

Fax: +972-3-611-6605

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

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

American Depositary Shares, each representing

one hundred Ordinary Shares, par value NIS 0.1

**(Title of Class)**

The Nasdaq Capital Market

**(Name of each exchange on which registered)**

**Securities registered or to be registered pursuant to Section 12(g) of the Act:** None.

**Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:** None.

**Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.**

2,703,514 American Depositary Shares      514,205,799 Ordinary Shares

**Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.**

Yes    No

**If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.**

Yes    No

**Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.**

Yes    No

**Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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.)**

Yes    No

**Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of “large accelerated filer,” “accelerated filer,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.**

Large accelerated filer      Accelerated filer      Non-accelerated filer      Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards<sup>†</sup> provided pursuant to Section 13(a) of the Exchange Act.

<sup>†</sup> The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

US GAAP      International Financial Reporting Standards as issued by  
the International Accounting Standards Board      Other

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

Item 17      Item 18

**Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).**

Yes      No



**XTL BIOPHARMACEUTICALS LTD.**

**ANNUAL REPORT ON FORM 20-F**

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**SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS**

Certain matters discussed in this report, including matters discussed under the caption “Item 5. Operating and Financial Review and Prospects,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. In some instances, you can identify these forward-looking statements by words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plan,” “potential,” “will,” “should,” “would,” or similar including their negatives. These forward-looking statements include, without limitation, statements relating to our expectations and beliefs regarding:

fluctuations in the market price of our securities;

the possibility that our securities could be delisted from Nasdaq or the Tel-Aviv Stock Exchange (“TASE”);

potential dilution to the holders of our securities as a result of future issuances of our securities;

fluctuations in our results of operations;

the accuracy of our financial forecasts in our drug development activity and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;

the timing and cost of the in-licensing, partnering and acquisition of new product opportunities;

the timing of expenses associated with product development and manufacturing of the proprietary drug candidates that we have acquired - hCDR1 for the treatment of SLE and SS, and those that may be in-licensed, partnered or acquired;

the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

other risks and uncertainties described in this report.

Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under “Item 3. Key Information-Risk Factors,” “Item 4. Information on the Company,” “Item 5. Operating and Financial Review and Prospects,” and elsewhere in this report, as well as factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements.

Forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is filed. Therefore, you should not place undue reliance on any forward-looking statement as a prediction of future results. Forward-looking statements made in this report and the documents incorporated by reference are made as of the date of the respective documents, and we undertake no obligation to update them in light of new information or future results. Except as required by law, we assume no responsibility for updating any forward-looking statements.

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**PART I**

*Unless the context requires otherwise, references in this report to “XTL,” the “Company,” “we,” “us” and “our” refer to XTL Biopharmaceuticals Ltd, an Israeli company and our consolidated subsidiary. We have prepared our consolidated financial statements in United States, or US, dollars and in accordance with International Financial Reporting Standards, or IFRS. All references herein to “dollars” or “\$” are to US dollars, and all references to “Shekels” or “NIS” are to New Israeli Shekels.*

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

Not applicable

**ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE**

Not applicable

**ITEM 3. KEY INFORMATION**

**A. Selected Financial Data**

The tables below present selected financial data for the fiscal years ended and as of December 31, 2018, 2017, 2016, 2015 and 2014. We have derived the selected financial data for the fiscal years ended December 31, 2018, 2017 and 2016, and as of December 31, 2018 and 2017, from our audited consolidated financial statements, included elsewhere in this report and prepared in accordance with International Financial Reporting Standards (“IFRS”) issued by the International Accounting Standards Board (“IASB”) We have derived the selected financial data for the fiscal years ended December 31, 2015 and 2014, and as of December 31, 2016, 2015 and 2014, from our audited consolidated financial statements not included in this report. You should read the selected financial data in conjunction with “Item 5. Operating and Financial Review and Prospects,” “Item 8. Financial Information” and “Item 18. Consolidated Financial Statements.”



Table of Contents**Consolidated Statements of Comprehensive Income (Loss):**

	Year ended December 31,					
	2018	2017	2016	2015	2014	
	U.S Dollars in thousands (except for per share information)					
Research and development expenses	(38	) (43	) (443	) (578	) (278	)
General and administrative expenses	(755	) (1,203	) (1,270	) (1,419	) (1,744	)
Impairment of intangible assets	-	-	(848	) (1,604	) -	
Other gains, net	-	-	-	(10	) -	
Operating loss	(793	) (1,246	) (2,561	) (3,611	) (2,022	)
Issuance cost related to warrants to investors	-	(329	) -	-	-	
Revaluation of warrants to purchase ADS's	974	765	-	-	-	
Revaluation of marketable securities	2,753	-	-	-	-	
Other finance income	87	37	23	4	10	
Other finance expenses	(35	) (8	) (7	) (15	) (107	)
Financial income (expenses), net	3,779	465	16	(11	) (97	
Total income (loss) from continuing operations	2,986	(781	) (2,545	) (3,622	) (2,119	)
Other comprehensive income (loss):						
Items that might be classified to profit or loss:						
Changes in the fair value of available-for-sale financial assets	-	(116	) 163	-	-	
Total comprehensive income (loss) from continuing operations	2,986	(897	) (2,382	) (3,622	) (2,119	)
Total loss from discontinued operations	-	-	-	(689	) (746	)
Total comprehensive income (loss) for the year	2,986	(897	) (2,382	) (4,311	) (2,865	)
Income (loss) for the year attributable to:						
Equity holders of the Company	2,986	(781	) (2,545	) (4,313	) (2,527	)
Non-controlling interests	-	-	-	2	(338	)
	2,986	(781	) (2,545	) (4,311	) (2,865	)

Total comprehensive income (loss) for the year attributable to:

Equity holders of the Company	2,986	(897	) (2,382	) (4,313	) (2,527	)
Non-controlling interests	-	-	-	2	(338	)

	2,986	(897	) (2,382	) (4,311	) (2,865	)
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Basic and diluted earnings (loss) from continuing and discontinued operations (in US dollars)

From continuing operations	0.006	(0.002	) (0.009	) (0.014	) (0.009	)
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From discontinued operations	-	-	-	(0.003	) (0.002	)
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Basic and diluted earnings (loss) per share	0.006	(0.002	) (0.009	) (0.017	) (0.011	)
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Weighted average number of issued ordinary shares	514,205,799	470,188,629	274,035,533	263,730,467	231,224,512
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\* – less than one thousand.

Table of Contents**Consolidated Statements of Financial Position Data:**

	As of December 31,				
	2018	2017	2016	2015	2014
	U.S Dollars in thousands				
Cash, cash equivalents and short-term bank deposits	5,275	5,796	2,019	3,817	2,159
Working capital*	7,942	5,906	2,424	3,829	2,081
Total assets	8,575	6,586	3,017	5,323	5,644
Long term liabilities	-	2,667	-	-	-
Total shareholders' equity	8,322	3,619	2,687	4,887	4,660
Non-controlling interests	-	-	-	-	19

\* Working capital is calculated as current assets less current liabilities.

**B. Capitalization And Indebtedness**

Not applicable.

**C. Reasons For Offer And Use Of Proceeds**

Not applicable.

**D. Risk Factors**

*Before you invest in our ordinary shares or American Depositary Shares, you should understand the high degree of risk involved. You should carefully consider the risks described below and other information in this report, including our consolidated financial statements and related notes included elsewhere in this report, before you decide to purchase our ordinary shares or American Depositary Shares ("ADSs"). If any of the following risks actually occur, our business, financial condition and operating results could be adversely affected. As a result, the trading price of our ordinary shares or ADSs could decline and you could lose part or all of your investment.*

**Risks Related to Our Financial Position and Capital Requirements**

***We have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future in our drug development activity and may never become profitable.***

You should consider our prospects in light of the risks and difficulties frequently encountered by development stage companies. We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future. We have not yet commercialized any of our drug candidates or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, consummate out-licensing agreements, obtain regulatory approval for our drug candidates and technologies and successfully commercialize them.



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We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we:

initiate and manage pre-clinical development and clinical trials for our current and new product candidates;

seek regulatory approvals for our product candidates;

implement internal systems and infrastructures;

seek to license additional technologies to develop;

hire management and other personnel; and

progress product candidates towards commercialization.

If our product candidates fail in clinical trials or do not gain regulatory clearance or approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows. Moreover, our prospects must be considered in light of the risks and uncertainties encountered by an early-stage company and in highly regulated and competitive markets, such as the biopharmaceutical market, where regulatory approval and market acceptance of our products are uncertain. There can be no assurance that our efforts will ultimately be successful or result in revenues or profits.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As December 31, 2018, we had approximately \$5,275 thousand in cash, cash equivalents and short-term bank deposits, working capital of approximately \$7,942 thousand and an accumulated deficit of approximately \$152,588 thousand. We have incurred continuing losses and depend on outside financing resources to continue our activities. Based on existing business plans, we estimate that our outstanding cash and cash equivalent balances will allow us to finance our activities for an additional period of at least 12 months from the date of this Report. In order to perform clinical trials aimed at developing our product until obtaining its marketing approval, we will need to raise additional financing by issuing securities. Should we fail to raise additional capital under terms acceptable to us, we will be required to reduce our development activities or sell or grant a sublicense to third parties to use all or part of our technologies.

We have expended and believe that, subject to receiving adequate financing and/or entering into a collaboration agreement, we will continue to expend significant operating and capital expenditures for the foreseeable future developing our product candidates. These expenditures will include, but are not limited to, costs associated with research and development, manufacturing, conducting preclinical experiments and clinical trials, contracting with contract manufacturing organizations and contract research organizations, hiring additional management and other personnel and obtaining regulatory approvals, as well as commercializing any products approved for sale. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates and any other future product. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we will require additional funds, through public or private equity or debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

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Our future capital requirements depend on many factors, including:

the number and characteristics of products we develop;

the scope, progress, results and costs of researching and developing our product candidates and conducting preclinical and clinical trials;

the timing of, and the costs involved in, obtaining regulatory approvals;

the cost of commercialization activities if any are approved for sale, including marketing, sales and distribution costs;

the cost of manufacturing any product candidate we successfully commercialize;

our ability to establish and maintain strategic partnerships, licensing, supply or other arrangements and the financial terms of such agreements;

the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;

hCDR1 patent expiration in 2024 and failure to obtain patent term extension, expand patent protection or obtain data exclusivity in the U.S. and Europe;

the costs of in-licensing further patents and technologies.

the cost of development of in-licensed technologies

the timing, receipt and amount of sales of, or royalties on, any future products;

the expenses needed to attract and retain skilled personnel; and

any product liability or other lawsuits related to existing and/or any future products.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates or any future products.

***Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.***

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect shareholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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**Risks Related to our Drug Development Business**

*We have not yet commercialized any products or technologies, and we may never become profitable.*

We have not yet commercialized any products or technologies, and we may never be able to do so. We do not know when or if we will complete any of our product development efforts, obtain regulatory approval for any product candidates incorporating our technologies or successfully commercialize any approved products. Even if we are successful in developing products that are approved for marketing, we will not be successful unless these products gain market acceptance for appropriate indications at favorable reimbursement rates. The degree of market acceptance of these products will depend on a number of factors, including:

the timing of regulatory approvals in the countries, and for the uses, we seek;

the competitive environment;

the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products;

our ability to enter into strategic agreements with pharmaceutical and biotechnology companies with strong marketing and sales capabilities;

the adequacy and success of distribution, sales and marketing efforts; and

the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, third-party payors or the medical community in general may be unwilling to accept, utilize or recommend, and in the case of third-party payors, cover any of our products or products incorporating our technologies. As a result, we are unable to predict the extent of future losses or the time required to achieve profitability, if at all. Even if we successfully develop one or more products that incorporate our technologies, we may not become profitable.

***If we are unable to successfully complete our clinical trial programs for our drug candidates, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.***

Whether or not and how quickly we complete clinical trials depends in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate at which we are able to collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases and stages as we are studying. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis.

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***We have limited experience in conducting and managing clinical trials necessary to obtain regulatory approvals. If our drug candidates and technologies do not receive the necessary regulatory approvals, we will be unable to commercialize our products.***

We have not received, and may never receive, regulatory approval for commercial sale for hCDR1. We currently do not have any drug candidates pending approval with the Food and Drug Administration, or FDA or with regulatory authorities of other countries. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. In order to obtain FDA approval to market a new drug product, we or our potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we and/or our potential partners will have to conduct “adequate and well-controlled” clinical trials.

Clinical development is a long, expensive and uncertain process. Clinical trials are very difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

obtaining regulatory approvals to commence a clinical trial;

reaching agreement on acceptable terms with prospective CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

slower than expected rates of patient recruitment due to narrow screening requirements and competing clinical studies;

the inability of patients to meet protocol requirements imposed by the FDA or other regulatory authorities;

the need or desire to modify our manufacturing process;

delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and

governmental or regulatory delays or “clinical holds” requiring suspension or termination of the trials.

Following the completion of a clinical trial, regulators may not interpret data obtained from pre-clinical and clinical tests of our drug candidates and technologies the same way that we do, which could delay, limit or prevent our receipt of regulatory approval. In addition, the designs of any clinical trials may not be reviewed or approved by the FDA prior to their commencement, and consequently the FDA could determine that the parameters of any studies are insufficient to demonstrate proof of safety and efficacy in humans. Failure to approve a completed study could also result from several other factors, including unforeseen safety issues, the determination of dosing, low rates of patient recruitment, the inability to monitor patients adequately during or after treatment, the inability or unwillingness of medical investigators to follow our clinical protocols, and the lack of effectiveness of the trials.

Additionally, the regulators could determine that the studies indicate the drugs may have serious side effects. In the U.S., this is called a black box warning, which is a type of warning that appears on the package insert for prescription drugs indicating that they may cause serious adverse effects. A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects.



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If the clinical trials fail to satisfy the criteria required, the FDA and/or other regulatory agencies/authorities may request additional information, including additional clinical data, before approval of marketing a product. Negative or inconclusive results or medical events during a clinical trial could also cause us to delay or terminate our development efforts. If we experience delays in the testing or approval process, or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates and technologies may be materially impaired.

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after achieving promising results in earlier trials. It may take us many years to complete the testing of our drug candidates and technologies, and failure can occur at any stage of this process.

Even if regulatory approval is obtained, our products and their manufacture will be subject to continual review, and there can be no assurance that such approval will not be subsequently withdrawn or restricted. Changes in applicable legislation or regulatory policies, or discovery of problems with the products or their manufacture, may result in the imposition of regulatory restrictions, including withdrawal of the product from the market, or result in increased costs to us.

***If third parties on which we will have to rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our products.***

We will have to depend on independent clinical investigators, and other third-party service providers to conduct the clinical trials of our drug candidates and technologies. We also may, from time to time, engage a clinical research organization for the execution of our clinical trials. We will rely heavily on these parties for successful execution of our clinical trials, but we will not control many aspects of their activities. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the general investigational plan and protocol. Our reliance on these third parties that we do not control does not relieve us of our responsibility to comply with the regulations and standards of the FDA and/or other foreign regulatory agencies/authorities relating to good clinical practices. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trial's plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products, or could result in enforcement action against us.

***Our international clinical trials may be delayed or otherwise adversely impacted by social, political and economic factors affecting the particular foreign country.***

We may conduct clinical trials in different geographical locations. Our ability to successfully initiate, enroll and complete a clinical trial in any of these countries, or in any future foreign country in which we may initiate a clinical trial, are subject to numerous risks unique to conducting business in foreign countries, including:

difficulty in establishing or managing relationships with clinical research organizations and physicians;

different standards for the conduct of clinical trials and/or health care reimbursement;

our inability to locate qualified local consultants, physicians, and partners;

the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and

general geopolitical risks, such as political and economic instability, and changes in diplomatic and trade relations.

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Any disruption to our international clinical trial program could significantly delay our product development efforts.

***If the clinical data related to our drug candidates and technologies do not confirm positive early clinical data or preclinical data, our corporate strategy and financial results will be adversely impacted.***

Our drug candidates and technologies are in clinical stages. Specifically, our product candidate, hCDR1 is planned for and/or ready for advanced clinical studies. In order for our candidates to proceed to later stage clinical testing or marketing approval, they must show positive clinical results.

Preliminary results of pre-clinical, clinical observations or clinical tests do not necessarily predict the final results, and promising results in pre-clinical, clinical observations or early clinical testing might not be obtained in later clinical trials. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. Any negative results from future tests may prevent us from proceeding to later stage clinical testing or marketing approval, which would materially impact our corporate strategy, and our financial results may be adversely impacted.

***If we do not establish or maintain drug development and marketing arrangements with third parties, we may be unable to commercialize our drug candidates and technologies into products.***

We do not possess all of the capabilities to fully commercialize our drug candidates and technologies on our own. From time to time, we may need to contract with third parties to:

assist us in developing, testing and obtaining regulatory approval for some of our compounds and technologies;

manufacture our drug candidates; and

market and distribute our products.

We can provide no assurance that we will be able to successfully enter into agreements with such third-parties on terms that are acceptable to us. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of

our drug development programs or seek to develop or commercialize our drug candidates and technologies independently, which could result in delays. Further, such failure could result in the termination of license rights to one or more of our drug candidates and technologies. Moreover, if these development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we may be unable to control whether such products will be scientifically or commercially successful.

***Even if we or our collaborative/strategic partners or potential collaborative/strategic partners receive approval to market our drug candidates, if our products fail to achieve market acceptance, we will never record meaningful revenues.***

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our product candidates will depend on a number of factors, including:

perceptions by members of the health care community, including physicians, of the safety and efficacy of our products;

the rates of adoption of our products by medical practitioners and the target populations for our products;

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the potential advantages that our products offer over existing treatment methods or other products that may be developed;

the cost-effectiveness of our products relative to competing products including potential generic competition;

the availability of government or third-party pay or reimbursement for our products;

the side effects of our products which may lead to unfavorable publicity concerning our products or similar products; and

the effectiveness of our and/or our partners' sales, marketing and distribution efforts.

Specifically, hCDR1, if successfully developed and commercially launched for the treatment of systemic lupus erythematosus, or SLE, and Sjogren's syndrome, or SS, on the one hand, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our product candidates. Physicians and other prescribers may not be inclined to prescribe our products unless our products bring clear and demonstrable advantages over other products currently marketed for the same indications. Because we expect sales of our products to generate substantially all of our revenues in the long-term, the failure of our products to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

***If the third parties upon whom we rely to manufacture our products do not successfully manufacture our products, our business will be harmed.***

We do not currently have the ability to manufacture the compounds that we need to conduct our clinical trials and, therefore, rely upon, and intend to continue to rely upon, certain manufacturers to produce and supply our drug candidates for use in clinical trials and for future sales. In order to commercialize our products, such products will need to be manufactured in commercial quantities while adhering to all regulatory and other local requirements, all at an acceptable cost. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms, if at all.

If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or sources, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our drug candidates.

Our contract manufacturers will be required to produce our clinical drug candidates under strict compliance with current Good Manufacturing Practices, or cGMP, in order to meet acceptable regulatory standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our drug candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our drug candidates. Any difficulties or delays in our contractors' manufacturing and supply of drug candidates could increase our costs, cause us to lose revenue or make us postpone or cancel clinical trials.

In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign or local governmental agencies to ensure strict compliance with, among other things, cGMP, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. No assurance can be given that our third-party manufacturers will comply with these regulations or other regulatory requirements now or in the future.

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In the event that we are unable to obtain or retain third-party manufacturers, we will not be able to commercialize our products as planned. If third-party manufacturers fail to deliver the required quantities of our products on a timely basis and at commercially reasonable prices, our ability to develop and deliver products on a timely and competitive basis may be adversely impacted and our business, financial condition or results of operations will be materially harmed.

***If our competitors develop and market products that are less expensive, more effective or safer than our products, our revenues and results may be harmed and our commercial opportunities may be reduced or eliminated.***

The pharmaceutical industry is highly competitive. Our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our products. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are already commercialized or are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing safe, effective drugs, our products may not compete successfully with products produced by our competitors, who may be able to market their drugs more effectively.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields present substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop products that could render our technologies or our drug candidates obsolete or noncompetitive. Development of new drugs, medical technologies and competitive medical devices may damage the demand for our products without any certainty that we will successfully and effectively contend with those competitors.

***If we lose our key personnel or are unable to attract and retain additional personnel, our business could be harmed.***

As of December 31, 2018, we have one part-time employee, our Chief Executive Officer, and five part-time service providers. To successfully develop our drug candidates and technologies, we must be able to attract and retain highly skilled personnel, including consultants and employees. The retention of their services cannot be guaranteed. Our failure to retain and/or recruit such professionals might impair our performance and materially affect our technological and product development capabilities and our product marketing ability.

***Our Chief Financial Officer is not required to work exclusively for us, which could materially and adversely affect us and our business.***

Itay Weinstein, our Chief Financial Officer, is not required to work exclusively for us and does not devote all of his time to our operations. Since serving as our Chief Financial Officer, he has devoted approximately 6 hours a week of his time to the operation of our business. He also serves as a Partner of the accounting firm Shimony C.P.A. It is possible that his pursuit of other activities may slow our operations and impact our ability to timely complete our financial statements.

***Any acquisitions or in-licensing transactions we make may dilute your equity or require a significant amount of our available cash and may not be scientifically or commercially successful.***

As part of our business strategy, we may effect acquisitions or in-licensing transactions to obtain additional businesses, products, technologies, capabilities and personnel. If we complete one or more such transactions in which the consideration includes our ordinary shares or other securities, your equity may be significantly diluted. If we complete one or more such transactions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions and in-licensing transactions also involve a number of operational risks, including:

difficulty and expense of assimilating the operations, technology or personnel of the business;

our inability to attract and retain management, key personnel and other employees necessary to conduct the business;



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our inability to maintain relationships with key third parties, such as alliance partners, associated with the business;

exposure to legal claims for activities of the business prior to the acquisition;

the diversion of our management's attention from our other drug development businesses; and

the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

In addition, the basis for completing the acquisition or in-licensing could prove to be unsuccessful as the drugs or processes involved could fail to be scientifically or commercially viable. We may also be required to pay third parties substantial transaction fees, in the form of cash or ordinary shares, in connection with such transactions.

If any of these risks occur, it could have an adverse effect on both the business we acquire or in-license and our existing operations.

***We face product liability risks and may not be able to obtain adequate insurance.***

The use of our drug candidates and technologies in clinical trials, and the sale of any approved products, exposes us to liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates and technologies or limit commercialization of any approved products.

We believe that we will be able to obtain sufficient product liability insurance coverage for our planned clinical trials. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for a product;

damage to our reputation;

inability to continue to develop a drug candidate or technology;

withdrawal of clinical trial volunteers; and

loss of revenues.

Consequently, a product liability claim or product recall may result in material losses.

### **Risks Related to Our Intellectual Property**

*Because all of our proprietary drug candidates and technologies are licensed to us by third parties, termination of these license agreements could prevent us from developing our drug candidates.*

We do not own any of our drug candidates and technologies. We have licensed the rights, patent or otherwise, to our drug candidates from third parties. We have licensed hCDR1 from Yeda Research and Development Company Ltd., or Yeda. We licensed a use patent for the use of rHuEPO from Yeda and Mor Research Applications Ltd., or Mor which we acquired from Bio-Gal Limited, or Bio-Gal.

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These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed drugs and technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. While we have the right to defend patent rights related to our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort. If we do not meet our obligations in a timely manner, or if we otherwise breach the terms of our agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates and technologies. From time to time, in the ordinary course of business, we may have disagreements with our licensors or collaborators regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development, collaboration and commercialization of our drug candidates, or could require or result in litigation or arbitration, which could be time-consuming and expensive.

***If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.***

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents and technologies against third-party challenges. As part of our business strategy, our policy is to actively file patent applications in the U.S. and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and composition and improvements in each of these. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage of the patent.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

Generally, patent applications in the U.S. are maintained in secrecy for a period of at least 18 months. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. We cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim compounds or technology also claimed by us, we may be required to challenge competing patent rights, which could

result in substantial cost, even if the eventual outcome is favorable to us. While we have the right to defend patent rights related to the licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort.

We also rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to protect our trade secrets or other proprietary information adequately. In addition, we share ownership and publication rights to data relating to some of our drug candidates and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to protect our proprietary information will be at risk.

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***Litigation or third-party claims of intellectual property infringement could require us to spend substantial time, money and other resources defending such claims and adversely affect our ability to develop and commercialize our products.***

Third parties may assert that we are using their proprietary technology without authorization. In addition, third parties may have or obtain patents in the future and claim that our products infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected products could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all. In addition, any legal action against us that seeks damages or an injunction relating to the affected activities could subject us to monetary liability and/or require us to discontinue the affected technologies or obtain a license to continue use thereof.

In addition, there can be no assurance that our patents or patent applications or those licensed to us will not become involved in opposition or revocation proceedings instituted by third parties. If such proceedings were initiated against one or more of our patents, or those licensed to us, the defense of such rights could involve substantial costs and the outcome could not be predicted.

Competitors or potential competitors may have filed applications for, may have been granted patents for, or may obtain additional patents and proprietary rights that may relate to compounds or technologies competitive with ours. If patents are granted to other parties that contain claims having a scope that is interpreted to cover any of our products (including the manufacture thereof), there can be no assurance that we will be able to obtain licenses to such patents at reasonable cost, if at all, or be able to develop or obtain alternative technology.

***Risks Related to our ADSs***

***We will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.***

Our net cash used in operating activities for the year ended December 31, 2018 was \$816 thousand. If we continue to use cash at this rate we will need significant additional financing, which we may seek to raise through, among other things, public and private equity offerings and debt financing. Any equity financings will likely be dilutive to existing

stockholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all.

***The ADSs are traded in small volumes, limiting ability to sell ADSs that represent ordinary shares at a desirable price, if at all.***

The trading volume of the ADSs has historically been low. Even if the trading volume of the ADSs increases, we can give no assurance that it will be maintained or will result in a desirable stock price. As a result of this low trading volume, it may be difficult to identify buyers to whom shareholders can sell ADSs in desirable volume and shareholders may be unable to sell your ADSs at an established market price, at a price that is favorable, or at all. A low volume market also limits shareholders' ability to sell large blocks of the ADSs at a desirable or stable price at any one time. Shareholders should be prepared to own the ADSs indefinitely.

***Our stock price can be volatile, which increases the risk of litigation and may result in a significant decline in the value of your investment.***

The trading price of the ADSs representing our ordinary shares is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

developments concerning our drug candidates;

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announcements of technological innovations by us or our competitors;

introductions or announcements of new products by us or our competitors;

developments in the markets of the field of activities and changes in customer attributes;

announcements by us of significant acquisitions, in/out license transactions, strategic partnerships, joint ventures or capital commitments;

changes in financial estimates by securities analysts;

actual or anticipated variations in interim operating results and near-term working capital as well as failure to raise required funds for the continued development and operations of the company;

expiration or termination of licenses, patents, research contracts or other collaboration agreements;

conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

failure to obtain orphan drug designation status for the relevant drug candidates in the relevant regions;

increase in costs and lengthy timing of the clinical trials according to regulatory requirements;

failure to increase awareness of our products;

changes in reimbursement policy by governments or insurers in markets we operate or may operate in the future;

any changes in the regulatory environment relating to our drug candidates;

changes in the market valuations of similar companies; and

additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of the ADSs, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources even if we prevail in the litigation, all of which could seriously harm our business.

***Future issuances or sales of the ADSs could depress the market for the ADSs.***

Future issuances of a substantial number of the ADSs, or the perception by the market that those issuances could occur, could cause the market price of our ordinary shares or ADSs to decline or could make it more difficult for us to raise funds through the sale of equity in the future. Also, if we make one or more significant acquisitions in which the consideration includes ordinary shares or other securities, your portion of shareholders' equity in us may be significantly diluted.



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***Concentration of ownership of our ordinary shares among our principal stockholders may prevent new investors from influencing significant corporate decisions.***

There are two shareholders (Mr. Alexander Rabinovitch, a director, and Mr. David Bassa, a former director), who each beneficially hold more than 5% of our outstanding ordinary shares (approximately 31.88% cumulative, as of March 10, 2019). As a result, these persons, either acting alone or together, may have the ability to significantly influence the outcome of all matters submitted to our shareholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting alone or together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of our ordinary shares or ADSs.

***Our ordinary shares and ADSs trade on two different markets, and this may result in price variations and regulatory compliance issues.***

ADSs representing our ordinary shares are listed for trading on the Nasdaq Capital Market, or Nasdaq, and our ordinary shares are traded on the TASE. Trading in our securities on these markets is made in different currencies and at different times, including as a result of different time zones, different trading days and different public holidays in the U.S. and Israel. Consequently, the effective trading prices of our securities on these two markets may differ. Any decrease in the trading price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

***Holders of our ordinary shares or ADSs who are U.S. citizens or residents may be required to pay additional income taxes.***

There is a risk that we will be classified as a passive foreign investment company, or PFIC, for certain tax years. If we are classified as a PFIC, a U.S. holder of our ordinary shares or ADSs representing our ordinary shares will be subject to special federal income tax rules that determine the amount of federal income tax imposed on income derived with respect to the PFIC shares. We will be a PFIC if either 75% or more of our gross income in a tax year is passive income or the average percentage of our assets (by value) that produce or are held for the production of passive income in a tax year is at least 50%. The risk that we will be classified as a PFIC arises because cash balances, even if held as working capital, are considered to be assets that produce passive income. Therefore, any determination of PFIC status will depend upon the sources of our income and the relative values of passive and non-passive assets, including goodwill. A determination as to a corporation's status as a PFIC must be made annually. We believe we may be a PFIC during 2018 and although we have not determined whether we will be a PFIC in 2019, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. Although we may not be a PFIC in any one year, the PFIC taint remains with respect to those years in which we were or are a PFIC and the special PFIC taxation regime will continue to apply.

In view of the complexity of the issues regarding our treatment as a PFIC, U.S. shareholders are urged to consult their own tax advisors for guidance as to our status as a PFIC.

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***As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic issuers.***

As a foreign private issuer, we will be permitted to follow certain home country corporate governance practices instead of those otherwise required under Nasdaq for domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition and function of the audit committee and other committees of our Board of Directors and certain general corporate governance matters. In addition, in certain instances we will follow our home country law, instead of the Nasdaq, which requires that we obtain shareholder approval for certain dilutive events, such as an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. We comply with the director independence requirements of the Nasdaq, including the requirement that a majority of the Board of Directors be independent. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on Nasdaq may provide less protection than is accorded to investors under Nasdaq applicable to domestic issuers.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

***ADS holders are not shareholders and do not have shareholder rights.***

The Bank of New York Mellon, as depositary, executes and delivers the ADSs on our behalf. Each ADS is a certificate evidencing a specific number of ADSs. The ADS holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying the ADSs. Holders of the ADSs will have ADS holder rights. A deposit agreement among us, the depositary and the ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. Our shareholders have shareholder rights prescribed by Israeli law. Israeli law and our Articles of Association, or Articles, govern such shareholder rights. The ADS holders do not have the same voting rights as our shareholders. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares. The ADS holders may instruct the depositary to vote the ordinary shares underlying their ADSs, but only if we ask the depositary to ask for

their instructions. If we do not ask the depository to ask for their instructions, the ADS holders are not entitled to receive our notices of general meeting or instruct the depository how to vote. The ADS holders will not be entitled to attend and vote at a general meeting unless they withdraw the ordinary shares from the depository. However, the ADS holders may not know about the meeting far enough in advance to withdraw the ordinary shares. If we ask for the ADS holders' instructions, the depository will notify the ADS holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depository will try, as far as is practical, subject to the provisions of the deposit agreement, to vote the shares as the ADS holders instruct. The depository will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADS holders. We cannot assure the ADS holders that they will receive the voting materials in time to ensure that they can instruct the depository to vote their shares. In addition, there may be other circumstances in which the ADS holders may not be able to exercise voting rights.

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The ADS holders do not have the same rights to receive dividends or other distributions as our shareholders. Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary stock and we do not anticipate paying any cash dividends in the foreseeable future). Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares will be paid to the depositary, which has agreed to pay to the ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. The ADS holders will receive these distributions in proportion to the number of shares their ADSs represent. In addition, there may be certain circumstances in which the depositary may not pay to the ADS holders amounts distributed by us as a dividend or distribution.

***There are circumstances where it may be unlawful or impractical to make distributions to the holders of the ADSs.***

The deposit agreement with the depositary allows the depositary to distribute foreign currency only to those ADS holders to whom it is possible to do so. If a distribution is payable by us in New Israeli Shekels, the depositary will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, the ADS holders may lose some of the value of the distribution.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. This means that the ADS holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for the depositary to make such distributions available to them.

***Shareholders' percentage ownership in us may be diluted by future issuances of share capital, which could reduce their influence over matters on which shareholders vote.***

Issuances of additional shares would reduce shareholders' influence over matters on which our shareholders vote.

***We may fail to remain in compliance with the continued listing standards of the Nasdaq Capital Market and a delisting of our ADSs could make it more difficult for investors to sell their shares***

Our ADSs were approved for listing on the Nasdaq Capital Market in July 2013 where they continue to be listed. We are required to meet certain qualitative and financial tests (including having stockholders' equity of at least \$2.5 million, a market value of listed securities of \$35 million or \$500,000 of net income from continuing operations for the most recently completed fiscal year or two of the most recently completed fiscal years, to maintain the listing of our ADSs on the Nasdaq Capital Market as set forth in Nasdaq listing rule 5550(b)(1) the ("Stockholders' Equity Requirement" or "Rule 5550(b)(1)"). If we do not maintain compliance with the continued listing requirements for Nasdaq within specified periods and subject to permitted extensions, our ADSs may be recommended for delisting (subject to any appeal we would file). If our ADSs were delisted, it could be more difficult to buy or sell our ADSs and to obtain accurate quotations, and the price of our stock could suffer a material decline. Delisting would also impair our ability to raise capital.

On October 17, 2017, Nasdaq informed the Company that it failed to maintain the Stockholders' Equity Requirement for the quarter ended June 30, 2017. In accordance with Nasdaq's rules, the Company had 45 calendar days, or until December 1, 2017, to submit a plan to regain compliance. On November 27, 2017, the Company reported in its report on Form 6-K (the "Report") that its stockholder' equity was approximately \$3.6 million for the period ended September 30, 2017. The increase of stockholders' equity from June 30, 2017 is mainly due to financial income from the revaluation of the Company's derivative securities (warrants to purchase ADSs). On December 5, 2017, Nasdaq informed the Company that, based on its review of the Company's Report, the Company regained compliance with the Stockholders' Equity Requirement. However, there is no guarantee that we will be able to maintain continued compliance with the Stockholders' Equity Requirement or other applicable requirements.

If we fail to maintain compliance with Nasdaq's continued listing standards, we may be delisted and our ADSs will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board or OTCQX market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our ADSs could depress the price of our ADSs, substantially limit liquidity of our ADSs and materially adversely affect our ability to raise capital on terms acceptable to us, or at all.

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Finally, delisting of our ADSs would likely result in our ADSs becoming a “penny stock” under the Securities Exchange Act. The principal result or effect of being designated a “penny stock” is that securities broker-dealers cannot recommend the shares but must trade it on an unsolicited basis. Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document prepared by the SEC, which specifies information about penny stocks and the nature and significance of risks of the penny stock market. A broker-dealer must also provide the customer with bid and offer quotations for the penny stock, the compensation of the broker-dealer and sales person in the transaction, and monthly account statements indicating the market value of each penny stock held in the customer’s account. In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from those rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s written agreement to the transaction. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for shares that become subject to those penny stock rules. Under such circumstances, shareholders may find it more difficult to sell, or to obtain accurate quotations, for our ADSs, and our ADSs would become substantially less attractive to certain purchasers such as financial institutions, hedge funds and other similar investors.

**Risks Relating to Operations in Israel**

*Conditions in the Middle East and in Israel may harm our operations.*

Our head executive office, our research and development facilities, as well as some of our planned clinical sites are or will be located in Israel. Our officers and most of our directors are residents of Israel. A significant asset of ours is the investment in the shares of InterCure Ltd., an Israeli company. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, and between Israel and the Hamas and Hezbollah militant groups. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. In recent years, the hostilities involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Our offices, located in Ramat Gan, Israel, are within the range of the missiles and rockets that have been fired sporadically at Israeli cities and towns from Gaza and South Lebanon since 2006, with escalations in violence during which there were a substantially larger number of rocket and missile attacks aimed at Israel. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. Since September 2015, there has been an increase in terrorist attacks on Israeli civilians including shootings, stabbings and car rammings which has impacted the general feeling of personal safety in the country. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom

we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.



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Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

***Our results of operations may be adversely affected by inflation and foreign currency fluctuations.***

We hold most of our cash, cash equivalents and bank deposits in U.S. dollars. As we are located in Israel, a significant portion of our expenses are in New Israeli Shekels, or NIS, mainly due to payment to Israeli employees and suppliers. Our investment in the shares of InterCure Ltd. is also in NIS. As a result, we could be exposed to the risk that the U.S. dollar will be devalued against the NIS or other currencies, and consequentially our financial results could be harmed. To protect against currency fluctuations we may decide to hold a significant portion of our cash, cash equivalents, bank deposits and marketable securities in NIS, as well as to enter into currency hedging transactions. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the U.S. dollar or that the timing of any devaluation may lag behind inflation in Israel.

***Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.***

As a company incorporated under the laws of the State of Israel, we are subject to Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the holder of a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital,

in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to those of our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

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***It may be difficult to enforce a U.S. judgment against us, our officers or our directors or to assert U.S. securities law claims in Israel.***

Service of process upon us, since we are incorporated in Israel, and upon our directors and officers, who reside outside the U.S., may be difficult to obtain within the U.S. In addition, because substantially all of our assets and most of our directors and officers are located outside the U.S., any judgment obtained in the U.S. against us or any of our directors and officers may not be collectible within the U.S. There is a doubt as to the enforceability of civil liabilities under the Securities Act or the Exchange Act pursuant to original actions instituted in Israel. Subject to particular time limitations and provided certain conditions are met, executory judgments of a U.S. court for monetary damages in civil matters may be enforced by an Israeli court.

***Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, employees may be entitled to seek compensation for their inventions irrespective of their agreements with us, which in turn could impact our future profitability.***

We generally enter into non-competition agreements with our employees and key consultants. These agreements prohibit our employees and key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

In addition, Chapter 8 to the Israeli Patents Law, 5727-1967, or the Patents Law, deals with inventions made in the course of an employee's service and during his or her term of employment, whether or not the invention is patentable, or service inventions. Section 134 of the Patents Law, sets forth that if there is no agreement which explicitly determines whether the employee is entitled to compensation for the service inventions and the extent and terms of such compensation, such determination will be made by the Compensation and Rewards Committee, a statutory committee of the Israeli Patents Office. As a result, it is unclear if, and to what extent, our research and development employees may be able to claim compensation with respect to our future revenue. As a result, we may receive less revenue from future products if such claims are successful, which in turn could impact our future profitability.

***Your rights and responsibilities as a shareholder will be governed by Israeli law which may differ in some respects from the rights and responsibilities of shareholders of U.S. companies.***

We are incorporated under Israeli law. The rights and responsibilities of the holders of our ordinary shares and ADSs are governed by our Articles of Association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and interested party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders' actions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares and ADSs that are not typically imposed on shareholders of U.S. corporations.

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**ITEM 4. INFORMATION ON THE COMPANY**

**A. History and Development of XTL**

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical drugs for the treatment of autoimmune diseases. Our current drug development program is focused on the development of hCDR1 for the treatment of SLE and SS.

*Company Information and History*

Our legal and commercial name is XTL Biopharmaceuticals Ltd. We were established as a private company limited by shares under the laws of the State of Israel on March 9, 1993, under the name Xenograft Technologies Ltd. We re-registered as a public company on June 7, 1993, in Israel, and changed our name to XTL Biopharmaceuticals Ltd. on July 3, 1995.

We commenced operations to use and commercialize technology developed at the Weizmann Institute, in Rehovot, Israel. Since 1993 we pursued therapeutic and pharmaceutical development programs for the treatment of a variety of indications including hepatitis B, hepatitis C, diabetic neuropathic pain, schizophrenia, SLE and multiple myeloma, most of which have terminated. Our current drug development program is currently focused on the treatment of SLE and multiple myeloma.

We currently have one subsidiary, Xtepo Ltd., a private company limited by shares under the laws of the State of Israel which holds a license for the exclusive use of rHuEPO for the treatment of multiple myeloma. As of December 31, 2018, we hold approximately 2.56% of the issued and outstanding share capital of InterCure Ltd., a related party and former subsidiary of ours.

The ADSs are listed for trading on the Nasdaq Capital Market under the symbol “XTLB.” Our ordinary shares are traded on the TASE under the symbol “XTLB.” We operate under the laws of the State of Israel under the Israeli Companies Law, and in the U.S., the Securities Act and the Exchange Act.

Our principal offices are located at 5 Badner St., Ramat Gan 5218102, Israel, and our telephone number is (972) 3-6116600. Our primary internet address is [www.xtlbio.com](http://www.xtlbio.com). None of the information on our website is incorporated by reference herein.

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**B. Business Overview**

*Introduction*

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical drugs for the treatment of autoimmune diseases. Our current drug, hCDR1, is a potential treatment for (1) systemic lupus erythematosus, or SLE and (2) Sjogren's syndrome, or SS.

Our sole drug candidate is hCDR1, a Phase II-ready asset for the treatment of SLE, the most prominent type of lupus. There is currently no known cure for SLE. Only one new treatment, Benlysta, has been approved by the U.S. Food and Drug Administration, or FDA, in the last 50 years for SLE. Lupus is a chronic autoimmune disease involving many systems in the human body, including joints, kidneys, the central nervous system, heart, the hematological system and others. The biologic basis of the disease is a defect in the immune (defense) system, leading to production of self (auto) antibodies, attacking healthy organs and causing irreversible damage. According to research estimates of the Lupus Foundation of America, at least 1.5 million Americans have the disease (more than 5 million worldwide) with more than 16,000 new cases diagnosed each year in the United States.

hCDR1 is a peptide that is administered subcutaneously and acts as a disease-specific treatment to modify the SLE-related autoimmune process. It does so by specific upstream immunomodulation through the generation of regulatory T cells, reducing inflammation and resuming immune balance. More than 40 peer-reviewed papers have been published on hCDR1. Two placebo controlled Phase I trials and a placebo controlled Phase 2 trial, or the PRELUDE trial, were conducted on patients with SLE by Teva Pharmaceutical Industries, Ltd., or Teva, which had previously in-licensed hCDR1 from Yeda Research and Development, or Yeda. The studies consisted of over 400 patients and demonstrated that hCDR1 is well tolerated by patients and has a favorable safety profile. The PRELUDE trial did not achieve its primary efficacy endpoint based on the SLE Disease Activity Index, or SLEDAI scale, resulting in Teva returning the asset to Yeda. However, the PRELUDE trial showed encouraging results in its secondary clinical endpoint, the British Isles Lupus Activity Group index, or BILAG index, and, in fact, the 0.5 mg weekly dose showed a substantial effect. Multiple post-hoc analyses also showed impressive results for this dose using the BILAG index. Such dose will be the focus of the clinical development plan moving forward. Subsequent to Teva's return of the program to Yeda, the FDA directed that the primary endpoint in future trials for Lupus therapies, including those for hCDR1, should be based on either the BILAG index or the SLE Responder Index ("SRI"). The FDA has provided the Company with written guidance confirming the acceptability of BILAG as the primary endpoint in our planned study. Given the FDA's recommendation and the positive findings from the PRELUDE trial (which showed a substantial effect in the BILAG index), we intend to initiate a new advanced clinical trial, which will include the 0.5 mg dose.

hCDR1 is also Phase II-ready for the treatment of SS. SS is a chronic autoimmune disorder affecting lacrimal and salivary gland function (glandular) but may also affect other organs and systems (extraglandular) such as the kidneys, gastrointestinal system, blood vessels, lungs, liver, pancreas, and the nervous system. There is currently no known cure for SS. The only specific treatments available, such as Salagen and Evoxac, are symptomatic, aiming to alleviate dry eyes and dry mouth. A number of immunomodulatory agents including corticosteroids, hydroxychloroquine, cyclosporine, and other immunosuppressive agents are used to treat systemic manifestations of SS. The biologic basis of the disease is a defect in the immune system, leading to production of antibodies that attack healthy organs causing irreversible damage. Disease prevalence estimations vary from 2.5 million patients (Global Data Research 2016) to 4 million patients (Sjogren's Syndrome Foundation) in the US alone, with a worldwide estimate of up to an aggregate of 7.7 million in the United States, France, Germany, Italy, Spain, United Kingdom, and Japan by the year 2024 (Global Data Research).

In preclinical studies, blood mononuclear cells (PBMCs) obtained from blood samples of patients with primary SS (pSS) were incubated in vitro in the presence of hCDR1 and a control peptide. Following 48 hours of incubation, cells were collected and mRNA was prepared from all samples. The expression of various genes was determined using real-time -PCR. The results obtained to date indicate that in vitro incubation of PBMCs of pSS patients with hCDR1 resulted in a significant reduction of gene expression of four pathogenic cytokines known to be involved in SS and lupus (including B-lymphocyte stimulator or BLyS), as well as upregulation of two immunosuppressive genes, one of which is a marker for activity of regulatory T cells. The vast majority of such effects were previously seen in similar studies involving lupus patients. Because amelioration of SLE manifestations in murine models as well as in SLE patients was associated with down-regulation of pathogenic cytokines, it is likely that hCDR1 is capable of beneficially affecting SS patients. In addition, based on hCDR1's favorable safety profile in over 400 SLE patients (as noted above), as well as the same route of administration as in SLE and similar doses, we believe we can begin the clinical development of hCDR1 in SS with a Phase 2 trial.

The Company is exploring the expansion of its IP portfolio surrounding hCDR1 and at the same time has decided to reduce its research and development expenditures in connection with execution of its clinical trials. In parallel, the Company searches to identify additional assets to add to XTL's portfolio.



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**Our Strategy**

Our objective is to be a leading biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of autoimmune diseases.

The Company is expanding its IP portfolio surrounding hCDR1 and has decided to reduce its research and development expenditures in connection with execution of its clinical trials until full funding for the trials or cooperation with a strategic partner is secured. In parallel, the Company will look to identify additional assets to add to XTL's portfolio.

Subject to receiving adequate financing and/or entering into a collaboration agreement, we plan to:

initiate an international, prospective advanced clinical study intended to assess the safety and efficacy of hCDR1 when given to patients with SLE;

initiate a prospective Phase 2 study intended to assess the safety and efficacy of hCDR1 when given to patients with pSS; and

continually build our pipeline of therapeutic candidates.

**Recent Developments**

On May 22, 2018 the shareholders approved the reelection of Oded Nagar and Osnat Hillel Fien to serve as outside directors. Also on December 27, 2018, our shareholders approved the re-appointment of Kesselman & Kesselman, Israel CPAs, a member firm of PricewaterhouseCoopers International Limited, as the Company's independent registered public accounting firm for the year ending December 31, 2018, the re-election of Alexander Rabinovitch, Dr. Jonathan Schapiro, Shlomo Shalev, Doron Turgeman and Dr. Dobroslav Melamed to our board of directors, and approved the employment terms of Mr. Turgeman, our Chairman. Mr. Turgeman was appointed chairman on July 5, 2018.

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**Products Under Development**

**hCDR1 for the Treatment of Systemic Lupus Erythematosus**

*Market Opportunity*

hCDR1 (edratide) is a Phase 2-ready asset for the treatment of SLE, the most prominent type of lupus. SLE is a heterogenous, chronic, debilitating inflammatory autoimmune disease characterized by the production of an array of autoantibodies, including antibodies to double-stranded DNA, to other nuclear antigens, and to ribonucleoproteins. Although SLE can affect any part of the body, most patients experience systemic symptoms including fever, fatigue and malaise along with symptoms in one or only a few organs. The most common signs and symptoms are arthralgia, arthritis, fatigue, fever, skin rashes, including a characteristic butterfly-shaped rash across the cheeks and nose, anemia and pleurisy. The clinical course of SLE may also include periods in which few, if any, symptoms are evident and other times when the disease becomes more active.

According to research estimates of the Lupus Foundation of America, at least 1.5 million Americans have the disease (more than 5 million worldwide) with more than 16,000 new cases diagnosed each year in the United States. The Lupus Foundation of America reports that lupus affects mostly women of childbearing age (15-44). SLE is one of the most common forms of lupus, affecting over 70% of lupus patients.

SLE treatment is highly individualized and is based on a patient's disease severity, organ involvement and previous response. Mild forms of SLE may be treated with antimalarial medications, non-steroidal anti-inflammatory drugs, and topical and/or low-dose glucocorticoids, although treatment with methotrexate may be needed. In addition, low-dose oral steroids or intramuscular injections of depot steroid preparations can be used for mild disease. More severe cases of SLE may be treated with high-dose glucocorticoids and immunosuppressive or cytotoxic drugs to suppress the immune system. GlaxoSmithKline's Benlysta (belimumab), a monoclonal antibody, is a newer medication that is FDA-approved for patients with mild to moderate SLE currently taking standard therapy who have not yet experienced an adequate response. Benlysta is the first product to gain marketing approval for patients with SLE in more than 50 years, paving the way for the introduction of new disease-modifying therapies and reigniting the interest of pharmaceutical developers in this therapy area. GlaxoSmithKline reported that its 2016 sales of Benlysta were £306 million, up 19% on the prior year.

Decision Resources estimates the drug sales for SLE in 2012 were approximately \$900 million across the markets covered in its forecast. By the end of the forecast period of 2022, sales are estimated to grow to \$4.0 billion with a CAGR of 16.1%. This growth is expected to be driven by improved uptake of Benlysta, the introduction of new

biological therapies and the overall increase in prevalent cases of SLE, mainly due to the increasing population in these markets.

*hCDR1: General & Mechanism of Action*

hCDR1 is a synthetic peptide composed of 19 amino-acid residues. It was developed by Teva in collaboration with Prof. Edna Mozes of the Weizmann Institute of Science, Rehovot, Israel. The sequence of the peptide is based on the complementarity determining region 1 (CDR1) of a pathogenic human anti-dsDNA mAb that bears the 16/6 idiotype. The idiotype was found to have clinical relevance in SLE patients.

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Accumulating data from *in vivo* and *in vitro* studies demonstrate that hCDR1 functions by inducing regulatory T cell function through multiple pathways. Administration of hCDR1 to mice has been shown to induce CD4 + CD25 + cells using regulatory and suppressor characteristics such as CD45RB LOW , TGF-, CTLA-4 and Foxp3. This induction suppresses autoreactive CD4 + cell activation, indicated by the reduced expression of CD69 and Fas ligand; ultimately, resulting in reduced rates of activation-induced apoptosis. Inhibition by hCDR1-induced CD4 + CD25 + cells is mediated through the immunosuppressive cytokine TGF-. TGF- secretion is up regulated and activated autoreactive cells are decreased; both are associated with a decrease of pathogenic cytokines such as interferon gamma (IFN-), interleukin-10 (IL-10), interleukin-1 beta (IL-1), and tumor necrosis factor-alpha (TNF-). Effects on TGF- and Foxp3 have been shown to correlate with a significant decrease in SLEDAI-2K and BILAG scores in patients treated with hCDR1 in comparison with patients treated with placebo. Another subset of T cells (CD8 + CD28 - ) expresses Foxp3 and has been shown to be essential for the induction and the optimal suppressive function of CD4 + CD25 + cells. The function of hCDR1-induced subsets of regulatory T cells result in the effective suppression, ultimately leading to the modulation of the underlying aberrancy of the immune system, which culminates in the diminished activity of the disease.

hCDR1 is currently under investigation for its ability to down-regulate the autoimmune response elicited by the pathogenic antibodies and autoreactive T cells in SLE and up-regulate the expression of gene markers, such as TGF- and FoxP3. hCDR1 may attenuate the general SLE-associated autoimmune process and provide effective treatment for many clinical manifestations of SLE. The clinical development plan is thus designed to demonstrate the efficacy of hCDR1 in the systemic disease.

### *Clinical Trial History*

Prior to being licensed to us by Yeda, hCDR1 was licensed to Teva which performed two placebo controlled Phase I trials and a placebo controlled Phase 2 trial, or the PRELUDE trial. The Phase I and Phase 2 studies consisted of over 400 patients, demonstrating that hCDR1 is well tolerated by patients and has a favorable safety profile.

The PRELUDE trial was a 26-week study conducted at 48 centers in 12 countries: Canada, France, Germany, Holland, Hungary, Israel, Italy, Mexico, Russia, Spain, UK and U.S. enrolling 340 patients with mild to moderate SLE. The PRELUDE trial did not achieve its primary efficacy endpoint based on the SLEDAI scale, resulting in Teva returning the asset to Yeda in 2009. However, the PRELUDE trial showed encouraging results in its secondary clinical endpoint, the BILAG index, and, in fact, the 0.5 mg weekly dose showed a substantial effect. Multiple post-hoc analyses also showed impressive results for this dose using the BILAG index. Such dose will be the focus of clinical development moving forward. Subsequent to Teva's return of the program to Yeda, in 2010 the FDA directed that the primary endpoint in future trials for lupus therapies, including those for hCDR1, should be based on either the BILAG index or the Systemic Lupus Erythematosus Responder Index. The FDA has provided the Company with written guidance confirming the acceptability of BILAG as the primary endpoint in our planned study, subject to receipt of adequate financing.

*Planned Clinical Trial*

Given the FDA's recommendation and the positive findings from the PRELUDE trial (which showed a substantial effect in the BILAG index), subject to receipt of adequate financing and/or entry into a collaboration agreement, we intend to initiate a multinational, randomized, double blind, placebo-controlled, multiple dose, parallel group study to assess the efficacy, tolerability and safety of hCDR1 administered subcutaneously to patients with active SLE. We estimate that the trial will take over one year to enroll patients, 26 weeks for the treatment phase, and additional time to analyze the results for a total of approximately two years. We intend to include an interim analysis which will provide a read-out of data prior to the end date of the study.

The Company submitted a pre-Investigational New Drug ("IND") meeting package, including a draft protocol for our planned clinical trial, to the FDA in December 2015. In January 2016, the Company received a written response to its pre-IND meeting package in which the FDA provided guidance on several key aspects of its proposed clinical trial including: acceptance of the primary efficacy endpoint to be based on the BILAG index, a measure of lupus disease activity which was the secondary efficacy endpoint in the PRELUDE trial and confirmation of the appropriate patient population and total number of patients required to prove safety for a new drug application (NDA) for marketing approval. The FDA recommended that the trial be a Phase 2 study and also provided additional guidance on other aspects of the trial design including doses and study duration. Based on the FDA's response, subject to receipt of adequate financing and/or entry into a collaboration agreement, XTL plans to file its IND, and in the coming quarters initiate a global clinical trial for hCDR1 in the treatment of SLE.

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**hCDR1 for the Treatment of Sjogren's Syndrome**

*Market Opportunity*

hCDR1 (Edratide) is a Phase 2-ready asset for the treatment of SS. SS is a chronic systemic autoimmune disease characterized by lymphocytic infiltration of exocrine glands. Sjogren's syndrome may be an isolated disease, termed primary Sjogren syndrome (pSS) or may accompany another autoimmune disease, thus termed secondary Sjogren's syndrome. Clinical presentation varies from mild symptoms such as classic sicca symptoms of dry eyes (xerophthalmia), dry mouth (xerostomia) and parotid gland enlargements to severe systemic symptoms involving multiple organ systems such as arthritis, arthralgia, myalgia, pulmonary disease, gastrointestinal disease, neuropathy and lymphoma.

Similar to SLE, SS is a heterogenous, chronic, inflammatory autoimmune disease. Some of the autoantibodies characteristic of pSS occur in SLE as well, including antinuclear antibody (ANA), anti-Ro (also termed anti SSA), anti-La (also termed anti SSB) as well as rheumatoid factor (RF). Hypergammaglobulinemia is common as well. pSS affects the salivary and lacrimal glands with chronic inflammation leading to the most common symptoms seen in SS including dry eyes and dry mouth. In addition, SS may affect multiple systems with clinical manifestations similar to those seen in SLE including fever, fatigue and malaise along with symptoms in one or only a few organs including arthralgia, arthritis, fatigue, vasculitic rashes, interstitial lung disease, kidney disease as well as neurologic manifestations.

Disease prevalence estimations vary from 2.5 million (Global Data Research 2016) to 4 million patients (Sjogren's Syndrome Fopundation) in the US alone, with a worldwide estimate of up to 7.7 million in the 7 Major Markets (US, France, Germany, Italy, Spain, the UK and Japan) by the year 2024 (Global Data Research). pSS affects mostly middle aged women (40-50 years of age) with a female to male prevalence ratio of 9:1 (some estimates even go as far as 20:1). pSS patients have an increased risk of developing non-Hodgkin's B cell lymphoma (relative risk of 13.76.)

pSS treatment is highly individualized and is based on a patient's disease severity, organ involvement and previous response. Mild forms of pSS may be treated symptomatically with artificial tears and salivary flow stimulation. Fatigue and arthralgia may respond to antimalarial medications. More severe, systemic manifestations may be treated with high-dose glucocorticoids and immunosuppressive or cytotoxic drugs to suppress the immune system.

Global Data estimates the drug sales for SS in 2014 were approximately \$990 million in the US and \$1.1 billion across the markets covered in its forecast. By the end of the forecast period of 2024, sales are estimated to grow to \$1.9 billion in the US and \$2.2 billion across the markets covered in its forecast with a Compound Annual Growth

Rate of 7.2%. The market size estimate in 2014 includes Salagen (pilocarpine) and Evoxac (cevimeline), the only two agents to ever be approved for SS, and the use of off-label agents, such as biologics approved for other autoimmune diseases, and systemic and topical immunosuppressants and corticosteroids. This growth is expected to be driven by the anticipated approval of Orencia for use in patients with SS in the US and EU in 2021 and Japan in 2022.

#### *hCDR1: General & Mechanism of Action*

See above discussion regarding the Mechanism of Action of hCDR1 for SLE.

Since SS is an autoimmune disease similar to SLE with some autoantibodies and clinical manifestations identical with those detected in SLE, and since there is no specific treatment for Sjogren's syndrome, the experiments were undertaken on the Company's behalf by Professor Edna Mozes of the Weizmann Institute in Israel to determine the ability of hCDR1 to beneficially affect autoimmune responses related to this disease. To this end, PBMCs obtained from blood samples of pSS patients were incubated in vitro in the presence of hCDR1 and a control peptide. Following 48 hours of incubation, cells were collected and mRNA was prepared from all samples. The expression of various genes was determined using real-time PCR. The results obtained to date indicate that in vitro incubation of PBMCs of pSS patients with hCDR1 resulted in a significant reduction of gene expression of four pathogenic cytokines known to be involved in SS and lupus (including B-lymphocyte stimulator or BLyS), as well as upregulation of two immunosuppressive genes, one of which is a marker for activity of regulatory T cells. The vast majority of such effects were previously seen in similar studies involving lupus patients.

#### *Clinical Trial History*

No clinical trials with hCDR1 in SS have been performed to date.

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### *Planned Clinical Trial*

As noted above, hCDR1 has been tested in greater than 400 SLE patients to date. Given its clean safety profile, shown in three different clinical studies, subject to receipt of adequate financing and/or entry into a collaboration agreement, we will consider whether to test hCDR1 in a small Phase 2 clinical trial in pSS. The objectives of the study will be to test the safety & efficacy of different doses of hCDR1 in pSS patients in addition to a control arm. Such study is not being actively considered due to financial constraints and, therefore, we do not have accurate forecasts regarding the size and duration of such study.

### **rHuEPO for the Treatment of Multiple Myeloma**

As our focus is currently on the development of our lead drug candidate, we do not anticipate conducting material research and development activities for rHuEPO.

### **Intellectual Property**

#### **Patents**

#### *General*

Patents and other proprietary rights are very important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. We intend to seek and maintain patent and trade secret protection for our drug candidates and our proprietary technologies. As part of our business strategy, our policy is to file patent applications in the U.S. and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and compositions and improvements in each of these. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any commercial advantage or financial value attributable to the patent.



Generally, patent applications in the U.S. are maintained in secrecy for a period of at least 18 months. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. Granted patents can be challenged and ruled invalid at any time, therefore the grant of a patent is not of itself sufficient to demonstrate our entitlement to a proprietary right. The disallowance of a claim or invalidation of a patent in any one territory can have adverse commercial consequences in other territories.

If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may choose to challenge competing patent rights, which could result in substantial cost, even if the eventual outcome is favorable to us. While we have the right to defend patent rights related to our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of a litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope, validity and/or enforceability of third-party proprietary rights. Litigation would involve substantial costs.

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*hCDR1 for the Treatment of SLE and SS*

We have exclusively licensed from Yeda, two families of patents relating to hCDR1.

A basic patent family entitled “Synthetic Human Peptides and Pharmaceutical Compositions Comprising Them” for the Treatment of Systemic Lupus Erythematosus” that covers the active pharmaceutical agent, the Edratide peptide. The patent has been granted in a large number of jurisdictions: U.S., Europe (Austria, Denmark, Finland, France, Germany, Ireland, Italy, Liechtenstein, Spain, Sweden, Switzerland, The Netherlands and the UK), Australia, Canada, Hong Kong, India, Israel, Japan, Korea, Mexico, Norway, Hungary and Russia. The patent expires on February 26, 2022 except in the case of the U.S., which expires on September 22, 2022.

A patent family for the formulation entitled “Parenteral Formulations of Peptides for the Treatment of Systemic Lupus Erythematosus” that covers a very specific pharmaceutical composition comprising Edratide. It has been granted in the U.S., Europe (Switzerland, Germany, Denmark, Spain, Finland, France, Great Britain, Ireland, Italy, Netherlands and Sweden), China, India, Israel, Japan, and Mexico, and is allowed in Canada. The patent expires on January 14, 2024.

Two patent applications for specific treatment regimens were filed in the U.S. on August 10, 2017 and three provisional patent applications for treatment of Sjögren’s syndrome were filed on January 5, 2017, April 5, 2017 and September 12, 2017.

*rHuEPO for the Treatment of Multiple Myeloma*

We have exclusively licensed from Yeda and Mor a family of patents relating to rHuEPO.

A main use patent entitled “Use of Erythropoietin in the Treatment of Multiple Myeloma that covers the active pharmaceutical agent, EPO. The main claims of this patent is directed to a method for the treatment of a multiple myeloma patient, comprising the administration of Erythropoietin or Recombinant Human Erythropoietin, for the inhibition of tumor growth, triggering of tumor regression or inhibition of multiple myeloma cell metastasis in the said patient. The patent was granted in the United States, Europe (Austria, Belgium, France, Germany, Great Britain, Ireland, Italy, Netherlands, Spain, Sweden and Switzerland), Israel, Japan, Hong Kong and Canada. The issued patent will expire on March 30, 2019.

**Other Intellectual Property Rights**

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

### *Licensing Agreements and Collaborations*

#### **hCDR1**

On January 7, 2014, we entered into a license agreement with Yeda, as amended on September 6, 2015, which grants us the exclusive worldwide right to research, develop, and commercialize hCDR1 for all indications. Yeda is the commercial arm of the Weizmann Institute of Science.

In consideration, we are responsible for a patent expense reimbursement to Yeda in six installments totaling \$382,989. On May 14, 2014, we issued 222,605 of our ordinary shares to Yeda, as the first of six installments, representing a value of approximately \$38,000. On January 21, 2015, we issued a further 802,912 of our ordinary shares to Yeda as the second of six installments, representing a value of approximately \$84,000. The remaining installments of approximately \$64,000 each, payable in cash, are due every six months commencing on July 1, 2015, with the final payment due on January 1, 2017. In July 2016, the Company and Yeda signed a second amendment to the license agreement whereby, the final two payments due under the Agreement were made on April 7, 2017, provided that if we receive funding of at least \$5,000,000 then we shall be required to promptly pay Yeda any unpaid patent expense reimbursement in one lump-sum cash payment. To this date the patent expenses were incurred but not yet paid and the Company and Yeda are currently negotiating further amendment to the payment scheme under the license agreement.

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Under the license agreement, we are required to make milestone payments of up to \$2.2 million: \$200,000 upon starting a Phase 3 clinical trial, \$1 million upon FDA approval to market in the U.S., and \$250,000 for marketing approval in each of China and three of the European Union's Group of Five. In addition, we are required to pay 2-3% royalties of annual net sales and sublicense fees of 15-20% of whatever we receive from any sub-licensee. Under the license agreement, we are also required to meet certain development milestones including the delivery of a trial protocol to Yeda by January 1, 2016 (which we delivered), receipt of investment of at least \$5 million by August 1, 2016 (of which \$4 million was received in April 2015) and commencement of a Phase II clinical trial by January 1, 2017. In subsequent amendments signed between the Company and Yeda, the parties agreed to postpone the last two installments of the patent expense reimbursement until April 7, 2017, receipt of the remainder of the required \$5 million investment by May 1, 2017 and commencement of a Phase 2 clinical trial in respect of hCDR1 by October 1, 2017. To this date the Company and Yeda are currently negotiating further amendment to the payment scheme under the license agreement.

The term of the license agreement is the later of the date of expiry of the last of the licensed patents or the expiry of a continuous period of 11 years after first commercial sale in any country during which there shall not have been a first commercial sale in the U.S., EU, Japan, China or any OECD member. The license agreement may be terminated by us without cause upon 60 days prior written notice. The license agreement may also be terminated by Yeda if either we fail to meet certain development milestones or commercial sale shall have commenced and there shall be a period of 6 months of no sales, subject to certain exceptions. Yeda shall also be entitled to terminate the license agreement if we were to commence legal action against Yeda challenging the validity of any of the licensed patents, and we were unsuccessful in such challenge, in which event we would be required to pay to Yeda liquidated damages of \$8 million. Either party may also terminate the license agreement in the case of a material breach that remains uncured or certain bankruptcy events.

## rHuEPO

In August 2010 we acquired from Bio-Gal, the rights to develop rHuEPO for the treatment of multiple myeloma under a research and license agreement with Yeda and Mor. Bio-Gal had previously performed certain research and development studies under the research and license agreement. Mor is the Israeli corporation and licensing arm of Kupat Holim Clalit, one of the largest HMOs in Israel.

We are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 upon the successful completion of Phase 2. Such payment of \$350,000 is payable to Yeda upon the earlier of (i) six months from the successful completion of Phase 2 or (ii) the completion of a successful fundraising by XTL at any time after the completion of the Phase 2 of at least \$2 million.

## *Competition*

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier.

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***Competing Products for Treatment of SLE***

There is only one drug that has been approved for SLE in the last 50 years, GlaxoSmithKline's Benlysta (belimumab) which was approved in 2011. Other current therapies include non-steroidal anti-inflammatory drugs, corticosteroids, anti-malarials and immunosuppressants. Corticosteroids and immunosuppressants lead to broad, non-selective immunosuppression often associated with significant adverse events. In addition these therapies are not effective in all SLE patients.

Despite initial enthusiasm following approval of Benlysta as the first drug approved for SLE with a selective target, it has been approved to date only in patients with mild to moderate disease, without active renal or CNS disease, its onset of action is slow and sales have been lower than expected. Additional drugs are being evaluated or developed to treat SLE including, among others, anifrolumab developed by MedImmune, blisibimod developed by Anthera Pharmaceuticals, forigerimod acetate (lupuzor) developed by Immupharma, abatacept developed by Bristol-Myers Squibb, ACT-334441 developed by Actelion, ataccept developed by Merck Serono, CC-220 developed by Celgene, and INV-103 being developed by Invion. In the past eighteen months, there have been two late stage drugs, tabalumab developed by Eli Lilly and epratuzumab developed by UCB/Immunomedics, for the treatment of SLE which have both failed to meet the primary endpoint in Phase 3 trials.

***Competing Products for Treatment of pSS***

No specific drug has been approved for pSS so far apart from the symptomatic relief of signs and symptoms with the use of cholinergic agonists e.g. Salagen (pilocarpine) and Evoxac (cevimeline). Immunomodulatory treatments, usually for extra-glandular disease, which may be used include cyclosporine (ocular inflammation), hydroxychloroquine (mild inflammatory symptoms of joints, muscles & skin), corticosteroids (rare but serious symptoms: vasculitic rash, interstitial lung disease, interstitial nephritis, glomerulonephritis), immunosuppressive agents e.g. methotrexate, azathioprine, cyclophosphamide (used to treat serious internal organ manifestations) and biologic agents e.g. rituximab. Corticosteroids and immunosuppressants lead to broad, non-selective immunosuppression often associated with significant adverse events.

The pipeline of drugs in development for the indication of SS is relatively small with only one product in Phase 3, Orencia (abatacept), being developed by Bristol-Myers Squibb, and a number of drugs in Phase 1 or 2 stages of development including AMG/MEDI5872 developed by Amgen, BIIB063 developed by Biogen, CFZ533 and VAY736 developed by Novartis, GSK618960 developed by GSK, LY3090106 developed by Eli Lilly, MEDI4920 developed by MedImmune, RG7625 developed by Roche, RSLV developed by Resolve Therapeutics and Actemra (tocilizumab) developed by the University Hospital of Strasbourg. In addition, there is an ongoing Phase 2 combination study combining Benlysta (belimumab) and Rituxan (rituximab).

### **Seasonality**

Our business and operations are generally not affected by seasonal fluctuations or factors.

### **Raw Materials and Suppliers**

We believe that the raw materials that we require to manufacture hCDR1 and rHuEPO are widely available from numerous suppliers and are generally considered to be generic industrial chemical supplies. We do not rely on a single or unique supplier for the current production of any therapeutic small molecule in our pipeline.

### **Manufacturing**

We currently have no manufacturing capabilities and do not intend to establish any such capabilities.

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With respect to our drug candidate, hCDR1, we believe that we will be able to outsource production to a contract manufacturer in order to obtain sufficient inventory to satisfy the clinical supply needs for our future development for the treatment of SLE and SS. With respect to our drug candidate rHuEPO, we believe that we will either be able to purchase rHuEPO from existing pharmaceutical companies or to enter into collaborative agreements with contract manufacturers or other third-parties.

At the time of commercial sale, to the extent that it is possible and commercially practicable, we plan to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under cGMP regulations. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for conducting clinical trials or for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect our contractor's ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control. We anticipate that we will similarly rely on contract manufacturers for our future proprietary product candidates.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic inspections by the FDA, the U.S. Drug Enforcement Agency and corresponding state and local agencies to ensure strict compliance with cGMP and other state and federal regulations. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations.

If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

## **Environmental Matters**

We may from time to time be subject to various environmental, health and safety laws and regulations, including those governing air emissions, water and wastewater discharges, noise emissions, the use, management and disposal



of hazardous, radioactive and biological materials and wastes and the cleanup of contaminated sites. We believe that our business, operations and facilities are being operated in compliance in all material respects with applicable environmental and health and safety laws and regulations. Based on information currently available to us, we do not expect environmental costs and contingencies to have a material adverse effect on us. The operation of our testing facilities, however, entails risks in these areas. Significant expenditures could be required in the future if these facilities are required to comply with new or more stringent environmental or health and safety laws, regulations or requirements.

### **Government and Industry Regulation**

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our drug candidates and technologies, as well as our ongoing research and development activities. None of our drug candidates have been approved for sale in any market in which we have marketing rights. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA, under the Federal Food, Drug and Cosmetic Act of 1938, as amended. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

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The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. According to the FDA, before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

We were granted an Orphan-drug designation from the FDA in May 2011, for rHuEPO. In the U.S., Orphan-drug designation is granted by the FDA Office of Orphan Drug Products to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S.. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity if the drug is the first of its type approved for the specified indication or if it demonstrates superior safety, efficacy, or a major contribution to patient care versus another drug of its type previously granted the designation for the same indication, as well as with tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act filing fees.

We may apply to the European Medicines Agency in order to obtain Orphan-drug designation for its Recombinant Erythropoietin in Europe. Orphan designation is granted by the European Medicines Agency, following a positive opinion from the Committee for Orphan Medicinal Products, to a medicinal product that is intended for the diagnosis, prevention or treatment of a life-threatening or a chronically debilitating condition affecting not more than five in 10,000 persons in the European Community when the application for designation is submitted. Orphan drug designation provides the sponsor with access to the Centralized Procedure for the application for marketing authorization, protocol assistance, up to a 100% reduction in fees related to a marketing authorization application, pre-authorization inspection and post-authorization activities, and could provide ten years of market exclusivity in the EU, once approved for the treatment of Multiple Myeloma.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the NDA. To receive fast track designation, an applicant must demonstrate that the drug:

is intended to treat a serious or life-threatening condition;

is intended to treat a serious aspect of the condition; and

has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

Phase 1: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.

Phase 2: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.

Phase 3: Studies establish safety and efficacy in an expanded patient population.

Phase 4: The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations, such as children.

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The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors, and the number of sites participating in the trial;

inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;

longer treatment time required to demonstrate efficacy or determine the appropriate product dose;

insufficient supply of the drug candidates;

adverse medical events or side effects in treated patients; and

ineffectiveness of the drug candidates.

In addition, the FDA may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk. Any drug is likely to produce some toxicity or undesirable side effects when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could bring us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend time, money and effort to ensure compliance with cGMP, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP and other FDA regulatory requirements. If we or our contract manufacturers fail to comply, then the FDA will not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will be limited to those specified in an FDA approval, and the advertising of our products will be subject to comprehensive regulation by the FDA. Claims exceeding those that are approved will constitute a violation of the Federal Food, Drug, and Cosmetic Act. Violations of the Federal Food, Drug, and Cosmetic Act or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Should we wish to market our products in countries other than the U.S., we must receive marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the EU, registration procedures are available to companies wishing to market a product in more than one EU member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country. Our current development strategy calls for us to seek marketing authorization for our drug candidates in countries other than the United States.

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Failure to comply with applicable laws and regulations would likely have a material adverse effect on our business. In addition, laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action.

**Employees**

As of March 10, 2019, we have one part-time employee, our Chief Executive Officer, and five part-time service providers. We and our Israeli employees are subject, by an extension order of the Israeli Ministry of Welfare, to certain provisions of collective bargaining agreements between the Histadrut, the General Federation of Labor Unions in Israel and the Coordination Bureau of Economic Organizations, including the Industrialists Associations. Our part-time service providers are not subject to these collective bargaining agreements. These provisions principally address cost of living increases, recreation pay, travel expenses, vacation pay and other conditions of employment. We provide our employees with benefits and working conditions equal to or above the required minimum. Other than those provisions, our employees are not represented by a labor union.

*Organizational structure*

Our legal and commercial name is XTL Biopharmaceuticals Ltd. We were established as a private company limited by shares under the laws of the State of Israel on March 9, 1993, under the name Xenograft Technologies Ltd. We re-registered as a public company on June 7, 1993, in Israel, and changed our name to XTL Biopharmaceuticals Ltd. on July 3, 1995.

We commenced operations to use and commercialize technology developed at the Weizmann Institute, in Rehovot, Israel. Since 1993 we pursued therapeutic and pharmaceutical development programs for the treatment of a variety of indications including hepatitis B, hepatitis C, diabetic neuropathic pain, schizophrenia, SLE and multiple myeloma, most of which have terminated. Our current drug development program is currently focused on the treatment of SLE and multiple myeloma.

We currently have one subsidiary, Xtepo Ltd., a private company limited by shares under the laws of the State of Israel which holds a license for the exclusive use of rHuEPO for the treatment of multiple myeloma. As of March 2018, we hold approximately 3.78% of the issued and outstanding share capital of InterCure Ltd., a now former subsidiary of ours.

The ADSs are listed for trading on the Nasdaq Capital Market under the symbol “XTLB.” Our ordinary shares are traded on the TASE under the symbol “XTLB.” We operate under the laws of the State of Israel under the Israeli Companies Law, and in the U.S., the Securities Act and the Exchange Act.

Our principal offices are located at 5 Badner St., Ramat Gan 5218102, Israel, and our telephone number is (972) 3-6116600. Our primary internet address is [www.xtlbio.com](http://www.xtlbio.com). None of the information on our website is incorporated by reference herein.

#### **ITEM 4A. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

You should read the following discussion and analysis in conjunction with our audited consolidated financial statements, including the related notes, prepared in accordance with International Financial Reporting Standards (“IFRS”) for the years ended December 31, 2018, 2017 and 2016, and as of December 31, 2018 and 2017, contained in “Item 18. Consolidated Financial Statements” and with any other selected financial data included elsewhere in this annual report.

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The tables below present selected financial data for the fiscal years ended as of December 31, 2018, 2017 and 2016 and as of December 31, 2018 and 2017. We have derived this selected financial data from our audited consolidated financial statements, included elsewhere in this report and prepared in accordance with IFRS issued by the IASB. You should read the selected financial data in conjunction with “Item 3. Key Information” and “Item 8. Financial Information” and “Item 18. Consolidated Financial Statements.”

**Consolidated Statements of Comprehensive Income (Loss):**

	Year ended December 31, 2018    2017    2016		
	U.S. dollars in thousands		
	<b>(except per share data)</b>		
<u>Continuing operations:</u>			
Research and development expenses	(38 )	(43 )	(443 )
General and administrative expenses	(755 )	(1,203 )	(1,270 )
Impairment of intangible assets	-	-	(848 )
Other gains, net	-	-	-
Operating loss	(793 )	(1,246 )	(2,561 )
Issuance cost related to warrants to investors	-	(329 )	-
Revaluation of warrants to purchase ADS's	974	765	-
Revaluation of marketable securities	2,753	-	-
Other finance income	87	37	23
Other finance expenses	(35 )	(8 )	(7 )
Finance income (expenses), net	3,779	465	16
Total income (loss) for the year	2,986	(781 )	(2,545 )
Other comprehensive income:			
Items that might be classified to profit or loss:			
Changes in the fair value of available-for-sale financial assets	-	(116 )	163
Total comprehensive income (loss)	2,986	(897 )	(2,382 )



Total income (loss) attributable to:			
Equity holders of the Company	2,986	(781 )	(2,545)
Total comprehensive loss attributable to:			
Equity holders of the Company	2,986	(897 )	(2,382)
Basic and diluted earnings (loss) per share (in U.S. dollars)	0.006	(0.002)	(0.009)

Table of Contents**Consolidated Statements of Financial Position Data:**

	As of December 31,		
	2018	2017	2016
	U.S Dollars in thousands		
Cash, cash equivalents and bank deposits	5,275	5,796	2,019
Working capital	7,942	5,906	2,424
Total assets	8,575	6,586	3,017
Long term liabilities	-	2,667	-
Total shareholders' equity	8,322	3,619	2,687
Non-controlling interests	-	-	-

**Overview**

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical drugs for the treatment of autoimmune diseases. Our current lead drug compound, hCDR1, is for the treatment of SLE and SS.

We were established as a corporation under the laws of Israel in 1993, and commenced operations to use and commercialize technology developed at the Weizmann Institute, in Rehovot, Israel. Since commencing operations, our activities have been primarily devoted to developing our technologies and drug candidates, acquiring pre-clinical and clinical-stage compounds, raising capital, purchasing assets for our facilities, and recruiting personnel. We have had no drug product sales to date. Our major sources of working capital have been proceeds from various private and public offerings of our securities and option and warrant exercises.

We have incurred negative cash flow from operations each year since our inception and we anticipate incurring negative cash flows from operating activities for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and potential in-licensing and acquisition opportunities.

Our research and development expenses primarily consisted of expenses related to the hCDR1 development plan. As part of the preparations for future clinical trials of hCDR1, we engaged regulatory and clinical consultants and commenced work on Chemistry, Manufacturing and Control, or CMC, including production and testing of the drug substance. The Company is expanding its IP portfolio surrounding hCDR1 and has decided to reduce its research and development expenditures in connection with execution of its clinical trials until full funding for the trials or

cooperation with a strategic partner is secured. In parallel, the Company will look to identify additional assets to add to XTL's portfolio.

Subject to receiving adequate financing and/or entering into a collaboration agreement, we plan to:

initiate an international, prospective advanced clinical study intended to assess the safety and efficacy of hCDR1 when given to patients with SLE;

initiate a prospective Phase 2 study intended to assess the safety and efficacy of hCDR1 when given to patients with pSS; and

continually build our pipeline of therapeutic candidates.

Our general and administrative expenses consist primarily of salaries, consultant fees, and related expenses for executive, finance and other administrative personnel, professional fees, director fees and other corporate expenses, including investor relations, business development costs and facilities related expenses. We expense our general and administrative costs as incurred.

Our results of operations include non-cash compensation expense as a result of the grants of XTL stock options. Compensation expense for awards of options granted to employees and directors represents the fair value of the award (measured using the Black-Scholes valuation model) recorded over the respective vesting periods of the individual stock options (see details below.)

For awards of options and warrants to consultants and other third-parties, according to IFRS 2, the treatment of such options and warrants is the same as employee options compensation expense (see note 16 to the consolidated financial statements for the year ended December 31, 2018). We record compensation expense based on the fair value of the award at the grant date according to the Black-Scholes valuation model. According to IFRS 2, in non-performance-based options, we recognize options expenses using the graded vesting method (accelerated amortization). Graded vesting means that portions of a single option grant will vest on several dates, equal to the number of tranches. We treat each tranche as a separate share option grant; because each tranche has a different vesting period, and hence the fair value of each tranche is different. Therefore, under this method the compensation cost amortization is accelerated to earlier periods in the overall vesting period.

Our planned clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our product candidates in the near future or generate licensing revenues from upfront payments associated with out-licensing transactions. In addition, we expect losses in our drug development activity to continue as we continue to fund development of our drug candidates. As we continue our development efforts, we may enter into additional

third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. As a result, our periodical results may fluctuate and a period-by-period comparison of our operating results may not be a meaningful indication of our future performance.

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**A. Results of Operations**

***Year ended December 31, 2018 compared to the year ended December 31, 2017***

*Research and Development Expenses.* Research and development expenses in the years ended December 31, 2018 and 2017 totaled approximately \$38 thousand and \$43 thousand, respectively. Research and development expenses are comprised mainly of expenses related to maintenance of our intangible assets.

*General and Administrative Expenses.* General and administrative expenses for the years ended December 31, 2018 and 2017 totaled approximately \$755 thousand and \$1,203 thousand, respectively. The decrease in 2018 compared to 2017 is mainly due to F-1 filing in 2017 (\$206 thousands), decrease in salaries expenses, decrease in public and investor relations.

*Impairment of intangible assets.* The Company is required to determine, at least on an annual basis and as of year-end, whether the fair value of its unamortized intangible assets exceeds their book value. As of December 31, 2018 and 2017, the Company recognized no impairments. For further information, see also Note 9 of the consolidated financial statements for the year ended December 31, 2018.

*Finance income, net.* Finance income, net for the years ended December 31, 2018 and 2017 totaled approximately \$3,779 thousand and \$465 thousand, respectively. The increase in finance income in 2018 compared to 2017 derives mainly due to financial income from the revaluation of the Company's derivative securities (warrants to purchase ADSs) and the revaluation of marketable securities.

***Year ended December 31, 2017 compared to the year ended December 31, 2016***

*Research and Development Expenses.* Research and development expenses in the years ended December 31, 2017 and 2016 totaled approximately \$43 thousand and \$443 thousand, respectively. Research and development expenses are comprised mainly of expenses related to preparations for initiating the phase 2 clinical trials of the hCDR1 drug designed to treat SLE and pSS patients. The decrease in expenses in 2017 compared to 2016 is mainly due to our focus in 2016 on preparing hCDR1 for upcoming clinical trials including regulatory and consulting services and the completion of production and testing of the drug product. In 2017, the Company decided to reduce its research and development expenditures in connection with execution of its clinical trials until full funding for the trials or cooperation with a strategic partner is secured.

*General and Administrative Expenses.* General and administrative expenses for the years ended December 31, 2017 and 2016 totaled approximately \$1,203 thousand and \$1,270 thousand, respectively. The decrease in 2017 compared to 2016 is mainly due to the Company's efforts to reduce overhead costs offset by one time costs related to our F-1 registration.

*Impairment of intangible assets.* The Company is required to determine, at least on an annual basis and as of year-end, whether the fair value of its unamortized intangible assets exceeds their book value. As of December 31, 2017 and 2016, the Company recognized an impairment in the amount of \$0 and \$848, respectively, with regard to the rHuEPO intangible asset which is fully impaired as of December 31, 2016. For further information, see also Note 9 of the consolidated financial statements for the year ended December 31, 2017.

*Finance income, net.* Finance income, net for the years ended December 31, 2017 and 2016 totaled approximately \$465 thousand and \$16 thousand, respectively. The increase in finance income in 2017 compared to 2016 derives mainly due to financial income from the revaluation of the Company's derivative securities (warrants to purchase ADSs).

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*Significant Accounting Policies*

We describe our significant accounting policies more fully in Note 2 to our consolidated financial statements for the year ended December 31, 2018.

*Basis of presentation of the consolidated financial statements.* The consolidated financial statements of the Company and its subsidiary (the “Group”) as of December 31, 2018 and 2017, and for each of the three years in the period ended December 31, 2018 have been prepared in accordance with International Financial Reporting Standards which are standards and interpretations issued by the IASB (“IFRS”).

The significant accounting policies described below are consistent with those of all periods presented, unless indicated otherwise.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires the Company’s management to exercise its judgment in the process of applying the Group’s accounting policies. The areas that involve judgment which has significant effect or complexity or where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 3 to the annual consolidated financial statements. Actual results could significantly differ from the estimates and assumptions used by the Group’s management.

*Financial liabilities at fair value through profit or loss:*

In accordance with International Accounting Standard 32: “Financial Instruments: Presentation”, warrants allotted to investors with a cashless exercise mechanism are a “financial liability”. As the aforementioned liability was a non-equity derivative financial instrument, it was classified in accordance with International Accounting Standard 39 “Financial Instruments: Recognition and Measurement” (“IAS 39”) as a financial liability at fair value through profit or loss, which was measured at its fair value at each date of the balance sheet, with changes in the fair value carried to “revaluation of warrants to purchase ADS’s” in the statement of comprehensive loss. The aforementioned is not relevant since March 2018, when the Company registered its warrants. This act cancelled the cashless exercise mechanism and therefore the Company allocated the warrants from non-current liability to share premium.

The Company analyzes the expenses recognized in the statement of comprehensive loss by classification based on the function of expense.

*Subsidiaries consolidation and business combinations*

The consolidated financial statements include the accounts of the Company and entities controlled by the Company. Control exists when the Company has the power over the investee, has exposure, or rights, to variable returns from involvement in the investee, and has the ability to use its power over the investee to affect its returns.

The Company examines whether it controls another entity even when it does not hold more than 50% of the voting rights, but can control the entity's financial and operating policies by de-facto control. De-facto control can be created under circumstances in which the ratio of the Company's voting rights in the entity to the percentage and dispersion of the holdings of the other shareholders grants the Company the power to control the entity's financial and operating policies.

Subsidiaries are fully consolidated starting from the date on which control therein is attained by the Company. Their consolidation ceases when such control is discontinued.

Intra-group balances and transactions, including revenues, expenses and dividends in respect of transactions between the Group companies, are eliminated. Gains and losses arising from intra-group transactions that have been recognized as assets (such as inventories and property, plant and equipment) are also eliminated. Such intra-group losses may point to the impairment of assets which is tested and accounted for as specified below.

Transactions with non-controlling interests in subsidiaries which do not result in loss of control in the subsidiaries are accounted for as transactions with owners. In these transactions, the difference between the fair value of any consideration paid or received and the amount of adjustment of the non-controlling interests to reflect the changes in their relative rights in the subsidiaries is directly recognized in equity and attributed to the equity holders of the parent.

*Associate*

An associate is an entity over which the Group exercises significant influence, but not control, which is usually expressed in holding 20%-50% of the voting rights. The investment in an associate is presented using the equity method of accounting. According to the equity method of accounting, the investment is initially recognized at cost and its carrying amount varies to the extent that the Group recognizes its share of the associate's earnings or losses from the acquisition date.



The Group's share in the earnings or losses of associates after the acquisition date is carried to profit or loss and its share in the other comprehensive income movements after the acquisition date is carried to other comprehensive income against the carrying amount of the investment.

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*Intangible assets*

1. Unamortized intangible assets (licenses and patent rights)

The amortization of an asset on a straight-line basis over its useful life begins when the development procedure is completed and the asset is available for use. These assets are reviewed for impairment once a year or whenever there are indicators of a possible impairment, in accordance with the provisions of IAS 36, "Impairment of Assets".

2. Research and development

Research expenditures are recognized as expenses when incurred. Costs arising from development projects are recognized as intangible assets when the following criteria are met:

it is technically feasible to complete the intangible asset so that it will be available for use;

management intends to complete the intangible asset and use or sell it;

there is an ability to use or sell the intangible asset;

it can be demonstrated how the intangible asset will generate probable future economic benefits;

adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and

the expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as an expense when incurred. Development costs that were previously recognized as an expense are not recognized as an asset in a later period. During the three years ended December 31, 2016, the Group did not capitalize development costs to intangible assets.

*Impairment of intangible assets*

Intangible assets which are not yet available for use are not depreciated and impairment in their respect is tested every year. Depreciable assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets that sustained impairment are reviewed for possible reversal of the impairment at each date of the statement of financial position.

#### *Share capital*

The Company's ordinary shares are classified as share capital. Incremental costs directly attributable to the issuance of new shares or options are shown in equity as a deduction, net of tax, from the issuance proceeds.

When Group companies purchase Company shares (treasury shares), the consideration paid, including incremental costs directly attributable to the purchase (less the effect of taxes on income), is deducted from the equity attributable to equity holders of the parent until the shares are eliminated or reissued. When these shares are reissued in subsequent periods, the consideration received, less incremental costs directly attributable to the transaction and less the effect of taxes on income, is included in equity attributable to equity holders of the parent.

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*Share-based payment*

The Group operates a number of share-based payment plans to employees and to other service providers who render services that are similar to employees' services that are settled with the Group's equity instruments. In this framework, the Group grants employees, from time to time, and at its sole discretion, options to purchase shares of the Group companies. The fair value of services received from employees in consideration of the grant of options is recognized as an expense in the statement of comprehensive income (loss) and correspondingly carried to equity. The total amount recognized as an expense over the vesting term of the options (the term over which all pre-established vesting conditions are expected to be satisfied) is determined by reference to the fair value of the options granted at grant date, except the effect of any non-market vesting conditions.

Non-market vesting conditions are included in the assumptions used in estimating the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions of the share-based payment arrangement are to be satisfied.

In each reporting date, the Company revises its estimates of the number of options that are expected to vest based on the non-market vesting conditions and recognizes the impact of the revision to original estimates, if any, in the statement of comprehensive income (loss) with a corresponding adjustment in equity.

When the options are exercised, the Company issues new shares. The proceeds net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

Share-based payment transactions in which the Company acquired assets as consideration for the Company's equity instruments are measured at the value of the assets acquired.

*Provisions*

A provision in accordance to IAS 37 is recognized when the Group has a present obligation (legal or constructive) as a result of an event that occurred in the past, it is probable that the Group will be required to use economic resources to settle the obligation and it can be reliably estimated. The group recognizes a provision for warranty when the product is sold to the customer or when the service is provided to the customer. Initial recognition is based on past experience. The estimated provision is re-tested every year.



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***Critical Accounting Estimates***

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

1. Critical accounting estimates and assumptions

Accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

Intangible assets

In testing impairment of research and development assets, the Company's management is required to estimate, among other things, the probable endpoints of trials conducted by the Company, the commercial technical feasibility of the development and the resulting economic benefits. Actual results and estimates to be made in the future may significantly differ from current estimates.

The Group is required to determine at the end of each reporting period whether there is any indication that an asset (ii) may be impaired. If indicators for impairment are identified, the Group estimates the assets' recoverable amount, which is the higher of an asset's fair value less costs to sell and its value-in-use.

***Impact of Inflation and Currency Fluctuations***

We hold most of our cash, cash equivalents and bank deposits in US dollars. While a substantial amount of our operating expenses are in US dollars, we incur a portion of our expenses in New Israeli Shekels. In addition, we also pay for some of our services and supplies in the local currencies of our suppliers. As a result, we are exposed to the risk that the US dollar will be devalued against the New Israeli Shekel or other currencies, and as result our financial results could be harmed if we are unable to protect against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. The Company's treasury's risk management policy is to hold NIS-denominated cash and cash equivalents and short-term deposits in the amount of the anticipated NIS-denominated liabilities for six consecutive months from time to time in line with the directives of the Company's Board. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of

the New Israeli Shekel in relation to the US Dollar or that the timing of any devaluation may lag behind inflation in Israel. Future activities may lead us to perform a clinical trial in Israel, which may lead us to reassess our use of the US dollar as our functional currency.

As of December 31, 2018, had the Group's functional currency strengthened by 8% against the NIS with all other variables remaining constant, profit for the year would have been \$289 thousand higher (2017 loss approximately \$38 thousand lower; 2016 - loss approximately \$22 thousand lower), mainly as a result of exchange rate changes on translation of other accounts receivable, net and exchange rate changes on NIS-denominated cash and cash equivalents and short-term deposits. Profit was more sensitive to fluctuations in the exchange rate in relation to the NIS in 2017 than in 2016 mainly because of the increased amount of the NIS-denominated balances in the items of cash, receivables and payables of the Group.

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***Governmental Economic, Fiscal, Monetary or Political Policies that Materially Affected or Could Materially Affect Our Operations***

Tax rates applicable to the Company:

Taxable income of the Company is subject to a corporate tax rate as follow: 2018 - 23% and 2017 – 24%.

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%.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

As of December 31, 2018, XTL Biopharmaceuticals Ltd. did not have any taxable income. As of December 31, 2018, our net operating loss carry forwards for Israeli tax purposes registered on behalf of XTL Biopharmaceuticals Ltd. amounted to approximately \$35 million. Under Israeli law, these net-operating losses may be carried forward indefinitely and offset within XTL Biopharmaceuticals Ltd only, against future taxable income, including capital gains from the sale of assets used in the business, with no expiration date.

**B. Liquidity and Capital Resources**

We have financed our operations from inception primarily through various proceeds from various private and public offerings of our securities and option and warrant exercises. As of December 31, 2018, we received net proceeds of approximately \$85.5 million from various private placement transactions, public offerings and exercises of warrants, including most recently \$2.8 million from our private placement in March 2017.

As of December 31, 2018, we had approximately \$3.3 million in cash and cash equivalents (not including short-term bank deposits), similar to December 31, 2017.

Net cash used in operating activities for the year ended December 31, 2018 was \$0.8 million, compared to net cash used in operating activities of \$1.1 million for year ended December 31, 2017. The decrease in net cash used in



operating activities is mainly due to decrease in our research and development expenses.

Net cash provided by (used in) investing activities for the year ended December 31, 2018 was \$778 thousand compared to net cash used in investing activities of \$(2,495) for the year ended December 31, 2017. The increase in net cash provided by investing activities is primarily due to repayment of short term bank deposit during 2018 offset investment in short term bank deposit in 2017.

Net cash provided by financing activities for the year ended December 31, 2018 was \$0 million compared to net cash provided by investing activities of \$4.9 million for the year ended December 31, 2017.

We have incurred continuing losses and depend on outside financing resources to continue our activities. We have decided to reduce our research and development expenditures in connection with execution of our clinical trials until full funding for the trials or cooperation with a strategic partner is secured. In parallel, we will look to identify additional assets to add to our portfolio.

Subject to receiving adequate financing and/or entering into a collaboration agreement, we plan to:

initiate an international, prospective advanced clinical study intended to assess the safety and efficacy of hCDR1 when given to patients with SLE;

initiate a prospective Phase 2 study intended to assess the safety and efficacy of hCDR1 when given to patients with pSS; and

continually build our pipeline of therapeutic candidates.

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Based on existing business plans, our management estimates that our outstanding cash and cash equivalent balances will allow us to finance our activities for an additional period of at least 12 months from the date of this report. However, the amount of cash which we will need in practice to finance our activities depends on numerous factors which include, but are not limited to, the timing, planning and execution of clinical trials of existing drugs and future projects which we might acquire or other business development activities such as acquiring new technologies and/or changes in circumstances which are liable to cause significant expenses to us in excess of management's current and known expectations as of the date of these financial statements and which will require us to reallocate funds against plans, also due to circumstances beyond our control.

We expect to incur additional losses through the end of 2018 and beyond arising from research and development activities, testing additional technologies and operating activities, which will be reflected in negative cash flows from operating activities. In order to perform the clinical trials aimed at developing a product until obtaining its marketing approval, we may be required to raise additional funds in the future by issuing securities. Should we fail to raise additional capital in the future under standard terms, we will be required to minimize our activities or sell or grant a sublicense to third parties to use all or part of its technologies.

### **C. Research and Development, Patents and Licenses**

Research and development costs in 2018, 2017, 2016 substantially derived from costs related to the hCDR1 and, to a lesser degree, development plans. As part of the preparations for a planned clinical study of hCDR1, the Company engaged regulatory and clinical consultants and completed work on CMC, including production and testing of the drug substance and drug product.

#### ***hCDR1 for the Treatment of SLE***

The Company is expanding its IP portfolio surrounding hCDR1 and has decided to reduce its R&D expenditure in connection with execution of its clinical trials until full funding for the trials or cooperation with a strategic partner is secured.

Subject to receiving adequate financing and/or entering into a collaboration agreement, we plan to:

initiate an international, prospective advanced clinical study intended to assess the safety and efficacy of hCDR1 when given to patients with SLE;

initiate a prospective Phase 2 study intended to assess the safety and efficacy of hCDR1 when given to patients with pSS; and

continually build our pipeline of therapeutic candidates.

***rHuEPO for the Treatment of Multiple Myeloma***

We have decided to concentrate our efforts and resources on the development of hCDR1 and therefore do not expect to initiate any activities related to rHuEPO.

The following table sets forth the research and development costs for the years 2018, 2017 and 2016 including all costs related to the clinical-stage projects, our pre-clinical activities, and all other research and development. We in-licensed hCDR1 in January 2014 and started preparations for clinical development of this asset during the year. We started preparations for rHuEPO clinical development in the last quarter of 2010 (after the completion of the Bio-Gal transaction on August 2010). We in-licensed SAM-101 in November 2011 and in June 2015, the Company terminated the license agreement and all rights in and to the licensed technology reverted to MinoGuard. Whether or not and how quickly we commence and complete development of our clinical stage projects is dependent on a variety of factors, including the rate at which we are able to engage clinical trial sites and the rate of enrollment of patients. As such, the costs associated with the development of our drug candidates will probably increase significantly.

	Research and development Expenses in thousand US\$ Year ended December 31, 2018 2017 2016		
hCDR1	38	43	443
Total Research and Development	38	43	443

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**D. Trend Information**

We are a development stage company and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are identified in the preceding subsections.

**E. Off-Balance Sheet Arrangements**

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

**F. Tabular disclosure of contractual Obligations**

As of December 31, 2018 and 2017, we do not carry any contractual obligations, commitments or contingencies relates to research and development operations.

As of December 31, 2016, we had known contractual obligations, commitments and contingencies of approximately \$10 thousand which related to lease obligations for our previous offices in Ra'anana, all of which were due within the next year. In April 2015, we signed an operational lease agreement for our previous offices in Ra'anana. In addition, we entered into an agreement with subtenants to lease part of the office space in exchange for approximately \$1,200 per month. The agreement was in effect until April 2017. In November 2017 we signed a new lease agreement for our offices in Herzeliya, Israel. Under this agreement, we pay approximately \$1,200 per month for rent. The agreement was terminated during 2018.

Pursuant to our asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of Multiple Myeloma from Bio-Gal Ltd., we are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350 thousand upon the successful completion of Phase 2. The payment of

\$350 thousand is to be made to Yeda upon the earlier of (i) six months from the successful completion of Phase 2 or (ii) the completion of a successful fundraising by XTL at any time after the completion of the Phase 2 in an amount of at least \$2 million. No Phase 2 study has been initiated on this compound.

According to the licensing agreement signed with Yeda to develop hCDR1, a Phase II-ready asset for the treatment of SLE. The terms of the licensing agreement include, among other things, expense reimbursement for patent expenses payable in six installments (as of December 31, 2017 four out of the six installments have been paid in cash or through issuance of shares), certain milestone payments to Yeda, low single-digit royalties based on net sales, and additional customary royalties to the Office of the Chief Scientist.

## **ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES**

### **A. Directors and Senior Management**

B. The following sets forth information with respect to our directors and executive officers as of the date hereof.

Name	Age	Position
Doron Turgeman	50	Chairman of the Board of Directors
Osnat Hillel Fain	53	Non-Executive and External Director
Oded Nagar	50	Non-Executive and External Director
Alexander Rabinovich	48	Non-Executive Director
Shlomo Shalev	57	Non-Executive Director
Dr. Jonathan Schapiro	58	Non-Executive Director
Dr. Dobroslav Melamed	41	Non-Executive Director
Josh Levine	54	Chief Executive Officer
Itay Weinstein	47	Chief Financial Officer

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**Doron Turgeman** joined our Board of Directors in December 2014. He has significant public company experience with both NASDAQ and TASE listed companies. Mr. Turgeman is currently the Chief Executive Officer of Internet Gold (IGLD), which is listed on the NASDAQ. He has gained considerable experience in mergers and acquisitions involving both debt and equity, with, among other things, the purchase of the controlling interest of Bezeq by B Communications. He is knowledgeable in capital markets in Israel, the U.S. and Europe as well as SEC and TASE reporting standards. Throughout his career, he has proved to be a strong manager and has developed close relationships with key constituents throughout the industry. Mr. Turgeman holds a B.A. degree in Economics and Accounting from the Hebrew University of Jerusalem and is a certified public accountant in Israel. He has served as Chairman of our Board of Directors since July 2018.

**Osnat Hillel Fain** joined our Board of Directors in March 2015. She most recently served as Founder, Director and Managing Partner of Newton Propulsion Technologies LTD. In addition to serving as a board member on a number of TASE listed companies, including First ET View LTD, Priortech LTD, Aran R&D (1982) LTD, LeumiStart Fund and SDS LTD, Ms. Fain was the Business Development Manager at Giora Eiland Ltd., a representative of The Cheyne Capital Group in Israel, CEO of InterVision, Co-manager of the Aran Medical Ventures hedge fund, Marketing Manager at Datasphere Ltd. and an independent marketing consultant for TCB. She earned an Executive MBA and a BA in Humanities at Tel Aviv University and completed a one year course in Management at the Tel Aviv campus of the College of Management.

**Oded Nagar** joined our Board of Directors in March 2015. He currently serves as CEO and Owner of ABC - Advance Business Consulting Ltd. In addition to serving as a board member on a number of TASE listed companies, including Alon Blue Square Ltd, Blue Square Real Estate Ltd and Dor Alon Energy in Israel 1988 Ltd. Previously Mr. Nagar served as board member at IDB Development LTD, Gamatronic Electronic Industries LTD and Biri-Barashi Ltd. Mr. Nagar was the CEO and Founder of Pretium Group LTD/Pretium Renewable Energy LTD, VP Finance and Operations at Matrix IT (Formula Group) and the CFO of Bashan Systems (Formula Group). Previously, Oded worked in the Department of the General Controller at the Ministry of Finance in Israel, as an accountant at KPMG Israel and as an Economist at Bank Leumi. He earned an MBA in Finance and Banking and Information Systems and a BA in Accounting and Economics from the Hebrew University of Jerusalem. Mr. Nagar is also a Certified Public Accountant in Israel.

**Alexander Rabinovich** joined our Board of Directors in April 2017. He has significant public company experience with both NASDAQ and TASE listed companies. Mr. Rabinovich is currently the Chief Executive Officer and director of Green Forest Holdings Ltd., a fully owned company engaged in capital investments. He served as director in Pilat Media Global PLC, public company listed on TASE and on the Alternative Investment Market of the London Stock Exchange and several other private companies such as Visualety Systems Ltd. Mr. Rabinovich holds a B.A. degree in Economics and Accounting from the University of Haifa.

**Shlomo Shalev** joined our Board of Directors in December 2014 and in August 2015 was appointed to serve as interim Chairman, and served in such capacity through June 2018. He most recently served as Chairman of the Board

of Micronet, a TASE listed company. In addition to serving as a board member on a number of NASDAQ and TASE listed companies, such as OphirOptronics, Arel Communications and PowerDsine, Mr. Shalev was the Senior Vice President of Investments for Ampal. He has also worked on a number of transactions in mergers and acquisitions and initial public offerings. With an educational background in economics, Mr. Shalev was Israel's Consul for Economic Affairs and the Economic Advisor to the Director General, Ministry of Industry and Trade. Mr. Shalev holds an MBA from the University of San Francisco and a B.A. degree in Economics from the University of Ben Gurion, Beer Sheva, Israel.

**Dr. Jonathan Schapiro** joined our Board of Directors in December 2014. He is currently an Adjunct Clinical Assistant Professor in the Department of Medicine, Division of Infectious Diseases and Geographic Medicine at Stanford University School of Medicine and a Director of HIV/AIDS at the National Hemophilia Center at Sheba Medical Center in Tel-Aviv, Israel. He has served as a committee member on the United States Food and Drug Administration Antiviral Drugs Advisory Committee and is a member of the World Health Organization Global HIV Drug Resistance Network Steering Group. Dr. Schapiro is on the organizing and scientific committee of international conferences on antiviral drug development, clinical pharmacology and resistance, as well as contributing to guidelines publications. His research has appeared in major journals such as Lancet and Annals of Internal Medicine. He has served on the scientific advisory boards of major pharmaceutical and molecular diagnostic companies and has been involved in the development of multiple antiviral drugs over the last 20 years. Dr. Schapiro has devoted his career to HIV clinical care, research and education since completing his Fellowship in Infectious Diseases and Geographic Medicine at Stanford University School of Medicine, Stanford CA. He graduated from the Ben Gurion University School of Medicine and completed his Medical Residency at the Rabin Medical Center in Israel.

**Dr. Dobroslav Melamed** joined our Board of Directors in December 2014. He is a biotech entrepreneur with over 10 years of experience in the life science industry. He has demonstrated success in taking drugs from the lab to the shelf by identifying target markets, planning regulatory strategy, raising capital, executing successful clinical trials and scaling up to commercial production. He is currently establishing two companies involved in the development of a treatment for Ebola and novel drug delivery. Until September 2014, he was the President of SciVac (formerly SciGen IL), a high growth biopharmaceutical company that develops, manufactures and markets recombinant human health care biotechnology derived products, including vaccines. Dr. Melamed was responsible for SciVac's operations, clinical trials and new business. Dr. Melamed is the co-founder of Periness LTD, a developer of new drugs for male infertility and Oshadi LTD, a developer of oral carriers for proteins like insulin. He has also been a researcher at Bar-Ilan University's Male Fertility clinic, where he assisted in the development of new drugs for male infertility; and QBI, where he worked in the Pre-clinical and Research Pharmacology Department establishing In-Vivo models for drug discovery and delivery. Dr. Melamed earned a PhD in Biotechnology and a Bachelor of Arts degree in Biotechnology from the Bar-Ilan University, Israel.

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**Josh Levine** was appointed our Chief Executive Officer in October 2013. Mr. Levine was the Chief Executive Officer of Proteologics Ltd. (TASE: PRTL) from January 2011 until October 2013. Previously, from September 2008 until September 2010, he was Chairman of the Board of Proteologics Ltd. Concurrently, he was Senior Director at Teva Innovative Ventures responsible for, among other things, business development as well as alliance management for the unit. He had also held several executive positions within venture capital funds and boutique investment banks. Previously, he was a corporate attorney at a large New York City law firm. Mr. Levine holds a JD degree from Columbia University Law School and a BA degree in Chemistry from Yeshiva University.

**Itay Weinstein** was appointed our Chief Financial Officer in July, 2017. Mr. Itay Weinstein is a Partner at Shimony C.P.A. and has been employed there since 1999. Mr. Weinstein served as the Controller of Can-Fite BioPharma Ltd. since 2003 and as the Chief Financial Officer of Ophthalix Inc. from November 2011 through November 2017. Prior to joining Shimony C.P.A, Mr. Weinstein served as an auditor at Oren Horowitz. Mr. Weinstein holds a B.A. in economics and accounting from the Tel Aviv University, Israel, and has been a licensed CPA since 1999. Mr. Weinstein is also a board member of Uno Management and Consulting Ltd.

**B. Compensation**

The aggregate compensation paid by us to all persons who served as directors or officers for the year 2018 (9 persons) was approximately \$312,000. This amount includes payments of approximately \$20,000 made for social security, pension, disability insurance and health insurance premiums, severance accruals, payments made in lieu of statutory severance, payments for continuing education plans and payments made for the redemption of accrued vacation.

All members of our Board of Directors who are not our employees are reimbursed for their expenses for each meeting attended, save for Mr. David Bassa and Mr. Alex Rabinovich, who are a significant shareholders of our Company. Our directors are eligible to receive stock options under our stock option plans. With the exception of the Chairman of the Board of Directors who receives monthly compensation, non-executive directors do not receive any remuneration from us other than fees for their services as members of the board or committees of the board and expense reimbursement, save for one director who is eligible for fees for consulting services provided to the Company.

In 2017, we fixed the monetary compensation for non-executive directors as follows: annual consideration of NIS 29 thousand (to be paid in 4 equal quarterly payments), payments of NIS 1,460 for attendance at each board or committee meeting in person, NIS 876 for meetings held by teleconference, NIS 730 for unanimous written board resolutions and reimbursement of reasonable out-of-pocket expenses.



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On December 22, 2018, a general meeting of shareholders of the Company approved the remuneration terms of the Chairman of the Board of Directors of the Company, retroactive to as to July 2018. The terms include monthly remuneration in the amount of NIS 20 thousand.

For further details regarding share options granted to our employees, directors and service providers, see Note 15 to the consolidated financial statements for the year ended December 31, 2018.

## **Employment Agreements**

### *Joshua Levine*

On August 3, 2017, we entered into a new employment agreement with Mr. Levine, our Chief Executive Officer, or CEO, effective as of June 14, 2017 (“Effective Date”). This agreement replaced our prior agreement with Mr. Levine originally entered into in September 2013. Under the terms of the new agreement, Mr. Levine shall be employed at a 50% to 100% capacity and is entitled to a gross monthly salary of NIS 40,000, which shall be adjusted at a pro rata basis if he is engaged at below 100% capacity. As of June 11, 2017, and through the date of this report, Mr. Levine was engaged at 50% capacity. All ancillary benefits derived from the monthly salary shall be adjusted on a pro rata basis to his level of engagement. Under the employment agreement, Mr. Levine was issued options to purchase 1,000,000 ordinary shares at an exercise price of NIS 0.11. The options shall vest on a quarterly basis over 36 months, such that one-third of the options shall vest within 12 months of the effective date of the agreement and thereafter 1/12 of the options shall vest on the last day of each three month period, provided that on such date Mr. Levine is still employed by the Company. All vested options shall remain exercisable for a period of 12 months from the end or termination of the agreement. The employment agreement also provides that Mr. Levine will be entitled to benefits such as convalescence pay, managers’ insurance, a study fund and a company car. The agreement may be terminated by the Company or Mr. Levine without cause, subject to each party giving the other party four months advance written notice. Following delivery of the notice, Mr. Levine shall be entitled to four months of base salary and an additional adaptation fee to compensate him as if he were working on a full time basis through the notice period. Mr. Levine, or his estate, shall receive four months of salary, as was actually paid, following termination for disability or death. In the event of a transaction with a third party regarding the Company’s lupus property and/or HCDR1 product, alone or as part of a combination therapy for any indication (sale / cooperation / joint trial) provided that on such date Mr. Levine is employed by the Company, he shall be entitled to a onetime cash bonus of NIS 180,000 and the options issued to him in connection with this agreement June 2017 shall vest immediately, subject to its approval by the Company’s shareholders obtained on August 3, 2017, the agreement became effective on the Effective Date and shall remain in effect until terminated by either party subject to a 4 months prior written notice.

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*Itay Weinstein*

In July 2017, we entered into a service agreement with Mr. Itay Weinstein pursuant to which he serves as our Chief Financial Officer on a part time basis. Mr. Weinstein is entitled to a monthly gross payment of NIS 11,000 (NIS 131,000 annually).

In addition, we pay Shimony C.P.A, the accounting firm of which Mr. Weinstein is a Partner, monthly fees of NIS 14,000 for controller and bookkeeping services.

*Shlomo Shalev*

On December 28, 2015, our Board of Directors approved the terms upon which Shlomo Shalev shall serve as Chairman, subject to shareholder approval. Commencing September 1, 2015, Mr. Shalev shall be entitled to a monthly fee of NIS 20,000 (which decreased in 2017 to NIS 16,000) for at least 65 hours per month. In addition, Mr. Shalev shall be entitled to options to purchase 1,500,000 ordinary shares at an exercise price of NIS 0.60 per share. One third of the options vest on the twelve month anniversary of the grant date, and the remaining two thirds vest on a quarterly basis over the following two years provided Mr. Shalev provides services to us. The options have a term of ten years. On March 31, 2016, Mr. Shalev's remuneration as Chairman was approved by an annual general meeting of the Company's shareholders. Mr. Shalev resigned as our Chairman in July 2018.

*Doron Turgemen*

On December 22, 2018, our Board of Directors approved the terms upon which Shlomo Shalev shall serve as Chairman, subject to shareholder approval. Commencing July 2018, Mr. Shalev shall be entitled to a monthly fee of NIS 20,000.

*Jonathan Schapiro*

We entered into a consulting agreement dated January 1, 2015 with Dr. Jonathan Schapiro, a director. Commencing on such date, Dr. Schapiro shall serve as a consultant to us for a monthly fee of \$1,500 increasing to \$3,000 upon the successful completion of a cash fund raising of at least \$3 million in a public offering or private placement of equity

securities, including securities convertible or exercisable into equity by us or any entity in our control. In addition under the consulting agreement, on December 30, 2014, Dr. Schapiro was granted options to purchase 150,000 ordinary shares at an exercise price of NIS 0.4915 per share (in addition to the options granted to him as a director on the same day as described above). One third of the options vest on the twelve month anniversary of the grant date, and the remaining two thirds vest on a quarterly basis over the following two years provided Dr. Schapiro provides services to us. The options have a term of ten years. The consulting agreement continues in force unless terminated without cause upon 30 days' advance written notice.

In accordance with the requirements of Israeli Law, we determine our directors' compensation in the following manner:

first, our compensation committee reviews the proposal for compensation.

second, provided that the compensation committee approves the proposed compensation, the proposal is then submitted to our Board of Directors for review, except that a director who is the beneficiary of the proposed compensation does not participate in any discussion or voting with respect to such proposal; and

finally, if our Board of Directors approves the proposal, it must then submit its recommendation to our shareholders, which is usually done in connection with our shareholders' general meeting.

The approval of a majority of the shareholders voting at a duly convened shareholders meeting is required to implement any such compensation proposal.

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**C. Board Practices**

*Election of Directors and Terms of Office*

Our Board of Directors currently consists of seven members, including our non-executive Chairman. Other than our two external directors, our directors are elected by an ordinary resolution at the annual general meeting of our shareholders. The nomination of our directors is proposed by our Board of Directors or a designated nomination committee composed of three members of our Board of Directors, whose proposal is then approved by the board. Our board, following receipt of a proposal of the nomination committee, has the authority to add additional directors up to the maximum number of 12 directors allowed under our Articles. Such directors appointed by the board serve until the next annual general meeting of the shareholders. Unless they resign before the end of their term or are removed in accordance with our Articles, all of our directors, other than our external directors, will serve as directors until our next annual general meeting of shareholders.

None of our directors or officers has any family relationship with any other director or officer.

Our Articles permit us to maintain directors' and officers' liability insurance and to indemnify our directors and officers for actions performed on behalf of us, subject to specified limitations. We maintain a directors and officers insurance policy which covers the liability of our directors and officers as allowed under Israeli Companies Law.

There are no service contracts or similar arrangements with any director that provide for benefits upon termination of a directorship.

*External and Independent Directors*

The Israeli Companies Law requires Israeli companies with shares that have been offered to the public either in or outside of Israel to appoint two external directors. No person may be appointed as an external director if that person or that person's relative, partner, employer or any entity under the person's control, has or had, on or within the two years preceding the date of that person's appointment to serve as an external director, any affiliation with the company or any entity controlling, controlled by or under common control with the company. The term affiliation includes:

an employment relationship;

a business or professional relationship maintained on a regular basis;

control; and

service as an office holder, other than service as an officer for a period of not more than three months, during which the company first offered shares to the public.

No person may serve as an external director if that person's position or business activities create, or may create, a conflict of interest with that person's responsibilities as an external director or may otherwise interfere with his/her ability to serve as an external director. If, at the time external directors are to be appointed, all current members of the Board of Directors are of the same gender, then at least one external director must be of the other gender. A director in one company shall not be appointed as an external director in another company if at that time a director of the other company serves as an external director in the first company. In addition, no person may be appointed as an external director if he/she is a member or employee of the Israeli Security Authority, and also not if he/she is a member of the Board of Directors or an employee of a stock exchange in Israel.

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External directors are to be elected by a majority vote at a shareholders' meeting, provided that either:

the majority of shares voted at the meeting, including at least one-half of the shares held by non-controlling shareholders or other shareholders who have a personal interest in such election voted at the meeting, vote in favor of election of the director, with abstaining votes not being counted in this vote; or

the total number of shares held by non-controlling shareholders voted against the election of the director does not exceed two percent of the aggregate voting rights in the company.

The initial term of an external director is three years and may be extended for two additional three-year terms. An external director may be removed only by the same percentage of shareholders as is required for their election, or by a court, and then only if such external director ceases to meet the statutory qualifications for their appointment or violates his or her duty of loyalty to the company. Both external directors must serve on every committee that is empowered to exercise one of the functions of the Board of Directors.

An external director is entitled to compensation as provided in regulations adopted under the Israeli Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with service provided as an external director.

Osnat Hillel Fain and Oded Nagar serve as external directors pursuant to the provisions of the Israeli Companies Law. They both serve on our audit committee, our committee for the approval of financial statements, our nomination committee and our compensation committee.

***Audit Committee***

The Israeli Companies Law requires public companies to appoint an audit committee. The responsibilities of the audit committee include identifying irregularities in the management of the company's business and approving related party transactions as required by law. An audit committee must consist of at least three directors, including all of its external directors. The chairman of the Board of Directors, any director employed by or otherwise providing services to the company, and a controlling shareholder or any relative of a controlling shareholder, may not serve as members of the audit committee. An audit committee may not approve an action or a transaction with a controlling shareholder, or with an office holder, unless at the time of approval two external directors are serving as members of the audit committee and at least one of the external directors was present at the meeting in which an approval was granted.

Our audit committee is currently comprised of three independent non-executive directors. The audit committee is chaired by Osnat Hillel Fain, with Dobroslav Melamed, who serves as the audit committee financial expert, and Oded Nagar as members. The audit committee meets at least four times a year and monitors the adequacy of our internal controls, accounting policies and financial reporting. It regularly reviews the results of the ongoing risk self-assessment process, which we undertake, and our interim and annual reports prior to their submission for approval by the full Board of Directors. The audit committee oversees the activities of the internal auditor, sets its annual tasks and goals and reviews its reports. The audit committee reviews the objectivity and independence of the external auditors and also considers the scope of their work and fees.

We have adopted a written charter for our audit committee, setting forth its responsibilities as outlined by the regulations of the SEC. In addition, our audit committee has adopted procedures for the receipt, retention and treatment of complaints we may receive regarding accounting, internal accounting controls, or auditing matters and the submission by our employees of concerns regarding questionable accounting or auditing matters. In addition, SEC rules mandate that the audit committee of a listed issuer consist of at least three members, all of whom must be independent, as such term is defined by rules and regulations promulgated by the SEC. We are in compliance with the independence requirements of the SEC rules.

#### ***Financial Statement Examination Committee***

According to regulations promulgated under the Companies law and since we are considered as a “Small Corporation” under the Israeli Securities law Regulation, we are not required to appoint a financial statement examination committee, therefore our financial statements are examined and approved by our board of directors.

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*Compensation Committee*

Under the Companies Law, the board of directors of any public company must establish a compensation committee and to adopt a compensation policy with respect to its officers, or the Compensation Policy. In addition, the Companies Law sets forth the approval process required for a public company's engagement with its officers (with specific reference to a director, a non-director officer, a chief executive officer and controlling shareholders and their relatives who are employed by the company).

The compensation committee shall be nominated by the board of directors and be comprised of its members. The compensation committee must consist of at least three members. All of the external directors must serve on the compensation committee and constitute a majority of its members. The remaining members of the compensation committee must be directors who qualify to serve as members of the audit committee (including the fact that they are independent) and their compensation should be identical to the compensation paid to the external directors of the company. The approval of the compensation committee is required in order to approve terms of office and/or employment of office holders. The Company's Compensation Policy was duly approved on August 3, 2017.

Similar to the rules that apply to the audit committee, the compensation committee may not include the chairman of the board, or any director employed by the company, by a controlling shareholder or by any entity controlled by a controlling shareholder, or any director providing services to the company, to a controlling shareholder or to any entity controlled by a controlling shareholder on a regular basis, or any director whose primary income is dependent on a controlling shareholder, and may not include a controlling shareholder or any of its relatives. Individuals who are not permitted to be compensation committee members may not participate in the committee's meetings other than to present a particular issue; provided, however, that an employee that is not a controlling shareholder or relative may participate in the committee's discussions, but not in any vote, and the company's legal counsel and corporate secretary may participate in the committee's discussions and votes if requested by the committee.

The roles of the compensation committee are, among other things, to: (i) recommend to the board of directors the Compensation Policy for office holders and recommend to the board once every three years the extension of a Compensation Policy that had been approved for a period of more than three years; (ii) recommend to the directors any update of the Compensation Policy, from time to time, and examine its implementation; (iii) decide whether to approve the terms of office and of employment of office holders that require approval of the compensation committee; and (iv) decide, in certain circumstances, whether to exempt the approval of terms of office of a chief executive officer from the requirement of shareholder approval.

The Compensation Policy requires the approval of the general meeting of shareholders with a "Special Majority", which requires a majority of the shareholders of the company who are not either a controlling shareholder or an "interested party" in the proposed resolution, or the shareholders holding less than 2% of the voting power in the company voted



against the proposed resolution at such meeting. However, under special circumstances, the board of directors may approve the Compensation Policy without shareholder approval, if the compensation committee and thereafter the board of directors decided, based on substantiated reasons after they have reviewed the compensation policy again, that the Compensation Policy is in the best interest of the company.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of executive officers and directors, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The Compensation Policy must relate to certain factors, including advancement of the company's objectives, the company's business and its long-term strategy, and creation of appropriate incentives for executives. It must also consider, among other things, the company's risk management, size and the nature of its operations. The Compensation Policy must furthermore consider the following additional factors:

the knowledge, skills, expertise and accomplishments of the relevant director or executive;

the director's or executive's roles and responsibilities and prior compensation agreements with him or her;

the relationship between the terms offered and the average and median compensation of the other employees of the company;

the impact of disparities in salary upon work relationships in the company;

the possibility of reducing variable compensation at the discretion of the board of directors; and the possibility of setting a limit on the exercise value of non-cash variable compensation; and

as to severance compensation, the period of service of the director or executive, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

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The compensation policy must also include the following principles:

the link between variable compensation and long-term performance and measurable criteria;

the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;

the conditions under which a director or executive would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;

the minimum holding or vesting period for variable, equity-based compensation; and

maximum limits for severance compensation.

The compensation policy must also consider appropriate incentives from a long-term perspective and maximum limits for severance compensation.

Osnat Hillel Fain is the chairman of our compensation committee. Dobroslav Melamed and Oded Nagar serve as the other members of our compensation committee.

***Approval of Compensation to Our Officers***

The Israeli Companies Law prescribes that compensation to officers must be approved by a company's board of directors.

As detailed above, our compensation committee consists of three independent directors: Dobroslav Melamed, Osnat Hillel Fain and Oded Nagar. The responsibilities of the compensation committee are to set our overall policy on executive remuneration and to decide the specific remuneration, benefits and terms of employment for directors, officers and the Chief Executive Officer.

The objectives of the compensation committee's policies are that such individuals should receive compensation which is appropriate given their performance, level of responsibility and experience. Compensation packages should also allow us to attract and retain executives of the necessary caliber while, at the same time, motivating them to achieve the highest level of corporate performance in line with the best interests of shareholders. In order to determine the elements and level of remuneration appropriate to each executive director, the compensation committee reviews surveys on executive pay, obtains external professional advice and considers individual performance.

***Internal Auditor***

Under the Israeli Companies Law, the board of directors must appoint an internal auditor, nominated by the audit committee. Our internal auditor is Daniel Spira. The role of the internal auditor is to examine, among other matters, whether the company's actions comply with the law and orderly business procedure. Under the Israeli Companies Law, an internal auditor may not be:

a person (or a relative of a person) who holds more than 5% of the company's shares;

a person (or a relative of a person) who has the power to appoint a director or the general manager of the company;

an executive officer or director of the company; or

a member of the company's independent accounting firm.

We comply with the requirement of the Israeli Companies Law relating to internal auditors. Our internal auditors examine whether our various activities comply with the law and orderly business procedure. Our internal auditor is not our employee, but the managing partner of a firm which specializes in internal auditing.

Table of Contents**D. Employees**

As of March 10, 2019, we have one part-time employee, our Chief Executive Officer, and five part-time service providers. We and our Israeli employees are subject, by an extension order of the Israeli Ministry of Welfare, to certain provisions of collective bargaining agreements between the Histadrut, the General Federation of Labor Unions in Israel and the Coordination Bureau of Economic Organizations, including the Industrialists Associations. Our part-time service providers are not subject to these collective bargaining agreements. These provisions principally address cost of living increases, recreation pay, travel expenses, vacation pay and other conditions of employment. We provide our employees with benefits and working conditions equal to or above the required minimum. Other than those provisions, our employees are not represented by a labor union.

**E. Share Ownership**

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of March 10, 2019 by the members of our senior management, board of directors, individually and as a group, and each person who we know beneficially owns 5% or more of our outstanding ordinary shares. The beneficial ownership of ordinary shares is based on 514,205,799 ordinary shares outstanding as of March 10, 2019 and is determined in accordance with the rules of the SEC and generally includes any ordinary shares over which a person exercises sole or shared voting or investment power. For purposes of the table below, we deem shares subject to options or warrants that are currently exercisable or exercisable within 60 days of March 10, 2019, to be outstanding and to be beneficially owned by the person holding the options or warrants for the purposes of computing the percentage ownership of that person but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person.

Name of Beneficial Owner	Number of Ordinary Shares	Percentage of Class*
Senior Management and Directors		
Shlomo Shalev <i>Director</i>	1,650,000 (1)	*
Josh Levine <i>Chief Executive Officer</i>	3,183,329 (2)	*
Osnat Hillel Fain <i>Director</i>	150,000 (3)	-
Oded Nagar <i>Director</i>	150,000 (3)	-
	154,177,783(4)	28.55 %

Alexander Rabinovich <i>Director</i>				
Jonathan Schapiro <i>Director</i>	300,000	(5)	*	
Dobroslav Melamed <i>Director</i>	150,000	(6)	*	
Doron Turgeman <i>Chairman of the Board</i>	640,000	(7)	*	
Itay Weinstein <i>Chief Finance Officer</i>				
Directors and Senior Management as a group (9 persons)	160,653,566		29.80	%
Beneficial owners of 5% or more				
Alexander Rabinovitch	154,177,783		28.55	%
David Bassa	48,339,347	(8)	9.17	%

\*Denotes less than 1%

Includes (i) 150,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.4325 per (1) share exercisable until December 29, 2024 (ii) 1,500,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.6 per share exercisable until March 30, 2026.

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(2) Includes (i) 600,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.60 per share exercisable until October 13, 2023, (ii) 900,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.90 per share exercisable until October 13, 2023, (iii) 100,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.40 per share exercisable until March 24, 2025 and (iv) 863,329 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.60 per share exercisable until March 30, 2026. Excludes 1,136,671 ordinary shares issuable upon the exercise of options that vest in more than 60 days from the date hereof.

(3) Includes 150,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.4 per share exercisable until March 24, 2025.

(4) Includes (i) 62,149,487 ordinary shares, (ii) 661,394 ADSs representing 66,139,400 ordinary shares, (iii) warrants to purchase 8,889 ADSs representing 888,896 ordinary shares at \$11.25 per ADS until March 31, 2020 and (iv) warrants to purchase 250,000 ADSs representing 25,000,000 ordinary shares at \$2.30 per ADS until September 21, 2022. Pursuant to the terms of the foregoing warrants the holder cannot exercise such warrants if it would beneficially own, after any such exercise, more than 4.99% of the outstanding ordinary shares. The percentage in the table above does not give effect to the blocker.

(5) Includes (i) 150,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.4325 per share exercisable until December 29, 2024, and (ii) 150,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.4915 per share exercisable until December 29, 2024.

(6) Includes (i) 150,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.4325 per share exercisable until December 29, 2024.

(7) Includes (i) 340,000 ordinary shares represented by 3,400 ADSs, (ii) 150,000 ordinary shares, and (iii) 150,000 ordinary shares issuable upon the exercise of options at an exercise price of NIS 0.4325 per share exercisable until December 29, 2024.

(8) Includes (i) 35,378,227 ordinary shares represented by 353,782 ADSs; (ii) 12,250,000 ordinary shares represented by 1,250,000 ADSs issuable upon the exercise of warrant at a price of \$2.30 per share; and (iii) 7,111 ADSs representing 711,120 ordinary shares. This shareholder is a former director of our company.

***Share Option Plans***

We maintain the following share option plans for our and our subsidiary's employees, directors and consultants. In addition to the discussion below, see note 15 of our consolidated financial statements for the year ended December 31, 2018.

Our Board of Directors administers our share option plans and has the authority to designate all terms of the options granted under our plans including the grantees, exercise prices, grant dates, vesting schedules and expiration dates, which may be no more than ten years after the grant date. Options may not be granted with an exercise price of less than the fair market value of our ordinary shares on the date of grant, unless otherwise determined by our Board of Directors.

As of December 31, 2018, we have granted to employees, directors and consultants options that are outstanding to purchase up to 6,200,000 ordinary shares under two share option plans.

### *2001 Share Option Plan*

Under a share option plan established in 2001, referred to as the 2001 Plan, we granted options between 2001 and 2011, at exercise prices between \$0.03 and \$1.58 per ordinary share. Up to 2,200,000 ordinary shares were available to be granted under the 2001 Plan. On July 29, 2009, the option pool was increased by 5,000,000 unissued additional ordinary shares, as well as forfeited and expired options that reverted to the pool due to departure of employees. Options granted to Israeli employees were made in accordance with section 102 of the Tax Ordinance, under the capital gains option set out in section 102(b)(2) of the ordinance. The options were non-transferable.

As of December 31, 2018, there are no outstanding options to purchase ordinary shares. The options that were outstanding at December 31, 2017 to purchase 60,000 ordinary shares expired in January 2018. On May 2, 2011, the 2001 Plan expired and no further options may be granted under this plan.

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*2011 Share Option Plan*

On August 29, 2011, our Board of Directors approved the adoption of an employee stock option scheme for the grant of options exercisable into shares of the Company according to section 102 to the Israeli Tax Ordinance, or the 2011 Plan, and to reserve up to 10 million ordinary shares in the framework of the 2011 Plan, for options allocation to employees, directors and consultants.

The 2011 Plan shall be subject to section 102 of the Israeli Tax Ordinance. According to the Capital Gain Track, which was adopted by us and the abovementioned section 102, we are not entitled to receive a tax deduction that relates to remuneration paid to our employees, including amounts recorded as salary benefit in our accounts for options granted to employees in the framework of the 2011 Plan, except the yield benefit component, if available, that was determined on the grant date. The terms of the options which will be granted according to the 2011 Plan, including option period, exercise price, vesting period and exercise period, shall be determined by our Board of Directors on the date of the actual allocation.

As of December 31, 2018, we have granted options to purchase 6,200,000 ordinary shares under the 2011 Plan at exercise prices between \$0.03 and \$0.25 per ordinary share.

For further details regarding share options granted to our employees, directors and service providers, see note 15 to the consolidated financial statements for the year ended December 31, 2018.

**ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS**

**A. Major shareholders**

As of the date hereof, there were 2,118,400 ADSs outstanding, held by 50 DTC participants and 2 registered shareholder, whose holdings represented approximately 25% of the total outstanding ordinary shares.

The following table sets forth the number of our ordinary shares owned by any person known to us to be the beneficial owner of 5% or more of our ordinary shares as of the date hereof. The information in this table is based on 784,678,019 outstanding ordinary shares as of such date. The number of Ordinary Shares beneficially owned by a



person includes Ordinary Shares subject to options held by that person that were currently exercisable. None of the holders of the Ordinary Shares listed in this table have voting rights different from other holders of the Ordinary Shares.

Name	Number of shares owned	Percent of ordinary shares	
Alexander Rabinovitch	154,430,237	19.68	%
David Bassa	48,339,347	6.16	%

## **B. Related Party Transactions**

The following is a description of some of the transactions with related parties to which we, or our subsidiaries, are party, and which were in effect within the past three fiscal years. The descriptions provided below are summaries of the terms of such agreements, do not purport to be complete and are qualified in their entirety by the complete agreements.

We believe that we have executed all of our transactions with related parties on terms no less favorable to us than those we could have obtained from unaffiliated third parties. We are required by Israeli law to ensure that all future transactions between us and our officers, directors and principal shareholders and their affiliates are approved by a majority of our board of directors, including a majority of the independent and disinterested members of our board of directors, and that they are on terms no less favorable to us than those that we could obtain from unaffiliated third parties.

### ***Employment and Consulting Agreements***

We have or have had employment, consulting or related agreements with each member of our senior management. See “Management-Compensation-Employment Agreements”.

### ***Employment and Consulting Agreements***

We have or have had employment, consulting or related agreements with each member of our senior management. See “Management—Compensation—Employment Agreements”.

*Alexander Rabinovitch*

In March 2017, Alexander Rabinovitch entered into a security purchase agreement resulting in the issuance of an aggregate of 250,000 unregistered ADSs representing 25,000,000 ordinary shares at \$2.00 per ADS for a purchase price of \$500,000 and unregistered warrants to purchase 250,000 ADSs representing 25,000,000 ordinary shares. The warrants may be exercised at any time for a period of five and one-half years from issuance and have an exercise price of \$2.30 per ADS, subject to adjustment as set forth therein.

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*David Bassa*

In March 2017, David Bassa entered into a security purchase agreement resulting in the issuance of an aggregate of 122,500 unregistered ADSs representing 12,250,000 ordinary shares at \$2.00 per ADS for a purchase price of \$245,000 and unregistered warrants to purchase 122,500 ADSs representing 12,250,000 ordinary shares. The warrants may be exercised at any time for a period of five and one-half years from issuance and have an exercise price of \$2.30 per ADS, subject to adjustment as set forth therein.

*Indemnification Agreements*

Israeli law permits a company to insure an office holder in respect of liabilities incurred by him or her as a result of an act or omission in the capacity of an office holder for:

a breach of the office holder's duty of care towards the company or towards another person;

a breach of the office holder's fiduciary duty to the company, provided that he or she acted in good faith and had reasonable cause to believe that the act would not prejudice the company; and

a financial liability imposed upon the office holder in favor of another person.

A financial liability imposed on the office holder's for all victims of the violation in an Administrative Proceeding.

Expenses incurred by the office holder's in connection with an Administrative Proceeding conducted in his or her case, including litigation expenses and reasonable legal fees.

Moreover, a company can indemnify an office holder for any of the following obligations or expenses incurred in connection with the acts or omissions of such person in his or her capacity as an office holder:

monetary liability imposed upon him or her in favor of a third party by a judgment, including a settlement or an arbitral award confirmed by the court; and

reasonable litigation expenses, including legal fees, actually incurred by the office holder or imposed upon him or her by a court, in a proceeding brought against him or her by or on behalf of the company or by a third party, or in a criminal action in which he or she was acquitted, or in a criminal action which does not require criminal intent in which he or she was convicted; furthermore, a company can, with a limited exception, exculpate an office holder in advance, in whole or in part, from liability for damages sustained by a breach of duty of care to the company.

financial liability imposed on the office holder for all victims of the violation in an Administrative Proceeding.

expenses incurred by the office holder in connection with an Administrative Proceeding conducted in his or her case, including litigation expenses and reasonable legal fees.

Our Articles of Association allow for insurance, exculpation and indemnification of office holders to the fullest extent permitted by law. We have entered into indemnification, insurance and exculpation agreements with our directors and executive officers, following shareholder approval of these agreements. We have directors' and officers' liability insurance covering our officers and directors for a claim imposed upon them as a result of an action carried out while serving as an officer or director, for (a) the breach of duty of care towards us or towards another person, (b) the breach of fiduciary duty towards us, provided that the officer or director acted in good faith and had reasonable grounds to assume that the action would not harm our interests, and (c) a monetary liability imposed upon him in favor of a third party.

## **ITEM 8. FINANCIAL INFORMATION**

### **A. Consolidated Statements and Other Financial Information**

Our audited consolidated financial statements appear in this annual report on Form 20-F. See "Item 18. Financial Statements."

#### **Significant Changes**

None.

## **ITEM 9. THE OFFER AND LISTING**

### **Markets and Share Price History**

Our ordinary shares have been trading on the Tel Aviv Stock Exchange, or TASE, since July 2005. Our ordinary shares currently trade on the TASE under the symbol “XTLB”.

On June 1, 2012, the Company filed an application for relisting its ADSs on the Nasdaq Capital Market, or Nasdaq. On July 10, 2013, the Company received a notice from Nasdaq stating that the admission committee had approved the Company’s application to relist its ADSs for trading on the Nasdaq Capital Market. Accordingly, on July 15, 2013, the Company’s ADSs began trading on Nasdaq under the ticker symbol “XTLB”.

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**ITEM 10. ADDITIONAL INFORMATION**

**Memorandum and Articles of Association**

*Objects and Purposes of the Company*

Pursuant to Part B, Section 3 of our Articles of Association, we may undertake any lawful activity.

*Powers and Obligations of the Directors*

Pursuant to the Israeli Companies Law and our Articles of Association, a director is not permitted to vote on a proposal, arrangement or contract in which he or she has a personal interest. Also, the directors may not vote on compensation to themselves or any members of their body, as that term is defined under Israeli law, without the approval of our audit committee and our shareholders at a general meeting. The power of our directors to enter into borrowing arrangements on our behalf is limited to the same extent as any other transaction by us.

The Israeli Companies Law codifies the fiduciary duties that office holders, including directors and executive officers, owe to a company. An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care generally requires an office holder to act with the same level of care as a reasonable office holder in the same position would employ under the same circumstances. The duty of loyalty includes avoiding any conflict of interest between the office holder's position in the company and such person's personal affairs, avoiding any competition with the company, avoiding exploiting any corporate opportunity of the company in order to receive personal advantage for such person or others, and revealing to the company any information or documents relating to the company's affairs which the office holder has received due to his or her position as an office holder.

*Indemnification of Directors and Officers; Limitations on Liability*

Israeli law permits a company to insure an office holder in respect of liabilities incurred by him or her as a result of an act or omission in the capacity of an office holder for:

a breach of the office holder's duty of care towards the company or towards another person;

a breach of the office holder's fiduciary duty to the company, provided that he or she acted in good faith and had reasonable cause to believe that the act would not prejudice the company; and

a financial liability imposed upon the office holder in favor of another person.

A financial liability imposed on the office holder's for all victims of the violation in an Administrative Proceeding.

Expenses incurred by the office holder's in connection with an Administrative Proceeding conducted in his or her case, including litigation expenses and reasonable legal fees.

Moreover, a company can indemnify an office holder for any of the following obligations or expenses incurred in connection with the acts or omissions of such person in his or her capacity as an office holder:

monetary liability imposed upon him or her in favor of a third party by a judgment, including a settlement or an arbitral award confirmed by the court; and

reasonable litigation expenses, including legal fees, actually incurred by the office holder or imposed upon him or her by a court, in a proceeding brought against him or her by or on behalf of the company or by a third party, or in a criminal action in which he or she was acquitted, or in a criminal action which does not require criminal intent in which he or she was convicted; furthermore, a company can, with a limited exception, exculpate an office holder in advance, in whole or in part, from liability for damages sustained by a breach of duty of care to the company.

financial liability imposed on the office holder for all victims of the violation in an Administrative Proceeding.

expenses incurred by the office holder in connection with an Administrative Proceeding conducted in his or her case, including litigation expenses and reasonable legal fees.

Our Articles of Association allow for insurance, exculpation and indemnification of office holders to the fullest extent permitted by law. We have entered into indemnification, insurance and exculpation agreements with our directors and executive officers, following shareholder approval of these agreements. We have directors' and officers' liability insurance covering our officers and directors for a claim imposed upon them as a result of an action carried out while serving as an officer or director, for (a) the breach of duty of care towards us or towards another person, (b) the breach of fiduciary duty towards us, provided that the officer or director acted in good faith and had reasonable grounds to assume that the action would not harm our interests, and (c) a monetary liability imposed upon him in favor of a third party.





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*Approval of Related Party Transactions under the Israeli Companies Law*

*Fiduciary duties of the office holders*

The Israeli Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company. The duty of care of an office holder is based on the duty of care set forth in connection with the tort of negligence under the Israeli Torts Ordinance (New Version) 5728-1968. This duty of care requires an office holder to act with the degree of proficiency with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of care includes a duty to use reasonable means, in light of the circumstances, to obtain:

information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and

All other important information pertaining to these actions.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes the duty to:

refrain from any act involving a conflict of interest between the performance of his or her duties in the company and his or her other duties or personal affairs;

refrain from any activity that is competitive with the business of the company;

refrain from exploiting any business opportunity of the company for the purpose of gaining a personal advantage for himself or herself or others; and

disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

We may approve an act performed in breach of the duty of loyalty of an office holder provided that the office holder acted in good faith, the act or its approval does not harm the company, and the office holder discloses his or her personal interest, as described below.

*Disclosure of personal interests of an office holder and approval of acts and transactions*

The Israeli Companies Law requires that an office holder promptly disclose to the company any personal interest that he or she may have and all related material information or documents relating to any existing or proposed transaction by the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. An office holder is not obligated to disclose such information if the personal interest of the office holder derives solely from the personal interest of his or her relative in a transaction that is not considered as an extraordinary transaction.

The term personal interest is defined under the Israeli Companies Law to include the personal interest of a person in an action or in the business of a company, including the personal interest of such person's relative or the interest of any corporation in which the person is an interested party, but excluding a personal interest stemming solely from the fact of holding shares in the company. A personal interest furthermore includes the personal interest of a person for whom the office holder holds a voting proxy or the interest of the office holder with respect to his or her vote on behalf of the shareholder for whom he or she holds a proxy even if such shareholder itself has no personal interest in the approval of the matter. An office holder is not, however, obligated to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an extraordinary transaction.

Under the Israeli Companies Law, an extraordinary transaction which requires approval is defined any of the following:

a transaction other than in the ordinary course of business;

a transaction that is not on market terms; or

a transaction that may have a material impact on the company's profitability, assets or liabilities.

Under the Israeli Companies Law, once an office holder has complied with the disclosure requirement described above, a company may approve a transaction between the company and the office holder or a third party in which the office holder has a personal interest, or approve an action by the office holder that would otherwise be deemed a breach of duty of loyalty. However, a company may not approve a transaction or action that is adverse to the company's interest or that is not performed by the office holder in good faith.

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Under the Companies Law, unless the articles of association of a company provide otherwise, a transaction with an office holder, a transaction with a third party in which the office holder has a personal interest, and an action of an office holder that would otherwise be deemed a breach of duty of loyalty requires approval by the board of directors. Our Articles of Association do not provide otherwise. If the transaction or action considered is (i) an extraordinary transaction, (ii) an action of an office holder that would otherwise be deemed a breach of duty of loyalty and may have a material impact on a company's profitability, assets or liabilities, (iii) an undertaking to indemnify or insure an office holder who is not a director, or (iv) for matters considered an undertaking concerning the terms of compensation of an office holder who is not a director, including, an undertaking to indemnify or insure such office holder, then approval by the audit committee is required prior to approval by the board of directors. Arrangements regarding the compensation, indemnification or insurance of a director require the approval of the audit committee, board of directors and shareholders, in that order.

A director who has a personal interest in a matter that is considered at a meeting of the board of directors or the audit committee may generally not be present at the meeting or vote on the matter, unless a majority of the directors or members of the audit committee have a personal interest in the matter or the chairman of the audit committee or board of directors, as applicable, determines that he or she should be present to present the transaction that is subject to approval. If a majority of the directors have a personal interest in the matter, such matter would also require approval of the shareholders of the company.

*Disclosure of personal interests of a controlling shareholder and approval of transactions*

Under the Israeli Companies Law, the disclosure requirements that apply to an office holder also apply to a controlling shareholder of a public company. See "Audit Committee" for a definition of controlling shareholder. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest, as well as transactions for the provision of services whether directly or indirectly by a controlling shareholder or his or her relative, or a company such controlling shareholder controls, and transactions concerning the terms of engagement of a controlling shareholder or a controlling shareholder's relative, whether as an office holder or an employee, require the approval of the audit committee, the board of directors and a majority of the shares voted by the shareholders of the company participating and voting on the matter in a shareholders' meeting. In addition, such shareholder approval must fulfill one of the following requirements:

at least a majority of the shares held by shareholders who have no personal interest in the transaction and are voting at the meeting must be voted in favor of approving the transaction, excluding abstentions; or

the shares voted by shareholders who have no personal interest in the transaction who vote against the transaction represent no more than 2% of the voting rights in the company.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless the audit committee determines that the duration of the transaction is reasonable given the circumstances related thereto.

*Duties of shareholders*

Under the Israeli Companies Law, a shareholder has a duty to refrain from abusing its power in the company and to act in good faith and in an acceptable manner in exercising its rights and performing its obligations to the company and other shareholders, including, among other things, voting at general meetings of shareholders on the following matters:

an amendment to the articles of association;

an increase in the company's authorized share capital;

a merger;

an increase in the company's authorized share capital; and

the approval of related party transactions and acts of office holders that require shareholder approval.

A shareholder also has a general duty to refrain from discriminating against other shareholders.

The remedies generally available upon a breach of contract will also apply to a breach of the above mentioned duties, and in the event of discrimination against other shareholders, additional remedies are available to the injured shareholder.

In addition, any controlling shareholder, any shareholder that knows that its vote can determine the outcome of a shareholder vote and any shareholder that, under a company's articles of association, has the power to appoint or prevent the appointment of an office holder, or has another power with respect to a company, is under a duty to act with fairness towards the company. The Israeli Companies Law does not describe the substance of this duty except to state that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness, taking the shareholder's position in the company into account.



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**ORDINARY SHARES**

*Rights Attached to Ordinary Shares*

Through March 18, 2009, our authorized share capital was NIS 10,000,000 consisting of 500,000,000 ordinary shares, par value NIS 0.02 per share. On March 18, 2009, pursuant to a shareholder's meeting, the share capital of our company was consolidated and re-divided so that each five (5) shares of NIS 0.02 nominal value was consolidated into one (1) share of NIS 0.1 nominal value so that following such consolidation and re-division, our authorized share capital consisted of 100,000,000 ordinary shares, par value NIS 0.10 per share. In addition, the authorized share capital of our company was increased from NIS 10,000,000 to NIS 70,000,000 divided into 700,000,000 ordinary shares, NIS 0.10 nominal value. The share consolidation was effected in June 22, 2009. Effective August 3, 2017, the authorized share capital of the company increased from NIS 70,000,000 divided into 700,000,000 ordinary shares to NIS 145,000,000 divided into 1,450,000,000 ordinary shares.

Holders of ordinary shares have one vote per share, and are entitled to participate equally in the payment of dividends and share distributions and, in the event of our liquidation, in the distribution of assets after satisfaction of liabilities to creditors. No preferred shares are currently authorized. All outstanding ordinary shares are validly issued and fully paid.

*Transfer of Shares*

Fully paid ordinary shares are issued in registered form and may be freely transferred under our Articles of Association unless the transfer is restricted or prohibited by another instrument or applicable securities laws.

*Dividend and Liquidation Rights*

We may declare a dividend to be paid to the holders of ordinary shares according to their rights and interests in our profits. In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of ordinary shares in proportion to the nominal value of their holdings.

This right may be affected by the grant of preferential dividend or distribution rights, to the holders of a class of shares with preferential rights that may be authorized in the future. Under the Israeli Companies Law, the declaration of a dividend does not require the approval of the shareholders of the company, unless the company's articles of association require otherwise. Our Articles provide that the Board of Directors may declare and distribute dividends without the approval of the shareholders.

### ***Annual and Extraordinary General Meetings***

We must hold our annual general meeting of shareholders each year and no later than 15 months from the last annual meeting, at a time and place determined by the Board of Directors, upon at least 21 days' prior notice to our shareholders, to which we need to add an additional three days for notices sent outside of Israel. A special meeting may be convened by request of two directors, 25% of the directors then in office, one or more shareholders holding at least 5% of our issued share capital and at least 1% of our issued voting rights, or one or more shareholders holding at least 5% of our issued voting rights. Notice of a general meeting must set forth the date, time and place of the meeting. Such notice must be given at least 21 days but not more than 45 days prior to the general meeting. The quorum required for a meeting of shareholders consists of at least two shareholders present in person or by proxy who hold or represent between them at least one-third of the voting rights in the company. A meeting adjourned for lack of a quorum generally is adjourned to the same day in the following week at the same time and place (with no need for any notice to the shareholders) or until such other later time if such time is specified in the original notice convening the general meeting, or if we serve notice to the shareholders no less than seven days before the date fixed for the adjourned meeting. If at an adjourned meeting there is no quorum present half an hour after the time set for the meeting, any number participating in the meeting shall represent a quorum and shall be entitled to discuss the matters set down on the agenda for the original meeting. All shareholders who are registered in our registrar on the record date, or who will provide us with proof of ownership on that date as applicable to the relevant registered shareholder, are entitled to participate in a general meeting and may vote as described in "Voting Rights" and "Voting by Proxy and in Other Manners," below.

### ***Voting Rights***

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of ordinary shares that represent more than 50% of the voting power represented at a shareholders meeting in which a quorum is present have the power to elect all of our directors, except the external directors whose election requires a special majority.

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Holders of ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders. Shareholders may vote in person or by proxy. These voting rights may be affected by the grant of any special voting rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Under the Israeli Companies Law, unless otherwise provided in the Articles of Association or by applicable law, all resolutions of the shareholders require a simple majority. Our Articles of Association provide that all decisions may be made by a simple majority. See “–Approval of Certain Transactions” above for certain duties of shareholders towards the company.

***Voting by Proxy and in Other Manners***

Our Articles of Association enable a shareholder to appoint a proxy, who need not be a shareholder, to vote at any shareholders meeting. We require that the appointment of a proxy be in writing signed by the person making the appointment or by an attorney authorized for this purpose, and if the person making the appointment is a corporation, by a person or persons authorized to bind the corporation. In the document appointing a proxy, each shareholder may specify how the proxy should vote on any matter presented at a shareholders meeting. The document appointing the proxy shall be deposited in our offices or at such other address as shall be specified in the notice of the meeting not less than 48 hours before the time of the meeting at which the person specified in the appointment is due to vote.

The Israeli Companies Law and our Articles of Association do not permit resolutions of the shareholders to be adopted by way of written consent, for as long as our ordinary shares are publicly traded.

***Limitations on the Rights to Own Securities***

The ownership or voting of ordinary shares by non-residents of Israel is not restricted in any way by our Articles of Association or the laws of the State of Israel, except that nationals of countries which are, or have been, in a state of war with Israel may not be recognized as owners of ordinary shares.

***Anti-Takeover Provisions under Israeli Law***



The Israeli Companies Law permits merger transactions with the approval of each party's board of directors and shareholders. In accordance with the Israeli Companies Law, a merger may be approved at a shareholders meeting by a majority of the voting power represented at the meeting, in person or by proxy, and voting on that resolution. In determining whether the required majority has approved the merger, shares held by the other party to the merger, any person holding at least 25% of the outstanding voting shares or means of appointing the board of directors of the other party to the merger, or the relatives or companies controlled by these persons, are excluded from the vote.

Under the Israeli Companies Law, a merging company must inform its creditors of the proposed merger. Any creditor of a party to the merger may seek a court order blocking the merger, if there is a reasonable concern that the surviving company will not be able to satisfy all of the obligations of the parties to the merger. Moreover, a merger may not be completed until at least 30 days have passed from the time the merger was approved in a general meeting of each of the merging companies, and at least 50 days have passed from the time that a merger proposal was filed with the Israeli Registrar of Companies.

Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of such acquisition, the purchaser would become a 25% or greater shareholder of the company. This rule does not apply if there is already another shareholder with 25% or greater shares in the company. Similarly, Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of the acquisition, the purchaser's shareholdings would entitle the purchaser to over 45% of the shares in the company, unless there is a shareholder with 45% or more of the shares in the company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received the approval of the company's shareholders; (2) was from a 25% or greater shareholder of the company which resulted in the purchaser becoming a 25% or greater shareholder of the company, or (3) was from a 45% or greater shareholder of the company which resulted in the acquirer becoming a 45% or greater shareholder of the company. These rules do not apply if the acquisition is made by way of a merger. Regulations promulgated under the Israeli Companies Law provide that these tender offer requirements do not apply to companies whose shares are listed for trading external of Israel if, according to the law in the country in which the shares are traded, including the rules and regulations of the stock exchange or which the shares are traded, either:

there is a limitation on acquisition of any level of control of the company; or

the acquisition of any level of control requires the purchaser to do so by means of a tender offer to the public.

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The Israeli Companies Law provides specific rules and procedures for the acquisition of shares held by minority shareholders, if the majority shareholder holds more than 90% of the outstanding shares. If, as a result of an acquisition of shares, the purchaser will hold more than 90% of a company's outstanding shares, the acquisition must be made by means of a tender offer for all of the outstanding shares. If less than 5% of the outstanding shares are not tendered in the tender offer, all the shares that the purchaser offered to purchase will be transferred to it. The Israeli Companies Law provides for appraisal rights if any shareholder files a request in court within three months following the consummation of a full tender offer. If more than 5% of the outstanding shares are not tendered in the tender offer, then the purchaser may not acquire shares in the tender offer that will cause his shareholding to exceed 90% of the outstanding shares of the company. Israeli tax law treats specified acquisitions, including a stock-for-stock swap between an Israeli company and a foreign company, less favorably than does U.S. tax law. These laws may have the effect of delaying or deterring a change in control of us, thereby limiting the opportunity for shareholders to receive a premium for their shares and possibly affecting the price that some investors are willing to pay for our securities.

### *Rights of Shareholders*

Under the Israeli Companies Law, our shareholders have the right to inspect certain documents and registers including the minutes of general meetings, the register of shareholders and the register of substantial shareholders, any document held by us that relates to an act or transaction requiring the consent of the general meeting as stated above under "Approval of Certain Transactions," our Articles of Association and our financial statements, and any other document which we are required to file under the Israeli Companies Law or under any law with the Registrar of Companies or the Israeli Securities Authority, and is available for public inspection at the Registrar of Companies or the Securities Authority, as the case may be.

If the document required for inspection by one of our shareholders relates to an act or transaction requiring the consent of the general meeting as stated above, we may refuse the request of the shareholder if in our opinion the request was not made in good faith, the documents requested contain a commercial secret or a patent, or disclosure of the documents could prejudice our good in some other way.

The Israeli Companies Law provides that with the approval of the court any of our shareholders or directors may file a derivative action on our behalf if the court finds the action is a priori, to our benefit, and the person demanding the action is acting in good faith. The demand to take action can be filed with the court only after it is serviced to us, and we decline or omit to act in accordance to this demand.

### *Enforceability of Civil Liabilities*

We are incorporated in Israel and most of our directors and officers named in this report reside outside the U.S. Service of process upon them may be difficult to effect within the U.S. Furthermore, because substantially all of our assets, and those of our non-U.S. directors and officers and the Israeli experts named herein, are located outside the U.S., any judgment obtained in the U.S. against us or any of these persons may not be collectible within the U.S.

We have been informed by our legal counsel in Israel, Doron Tikotsky Kantor Gutman & Amit Gross, that there is doubt as to the enforceability of civil liabilities under the Securities Act or the Exchange Act, pursuant to original actions instituted in Israel. However, subject to particular time limitations, executory judgments of a U.S. court for monetary damages in civil matters may be enforced by an Israeli court, provided that:

the judgment was obtained after due process before a court of competent jurisdiction, that recognizes and enforces similar judgments of Israeli courts, and the court had authority according to the rules of private international law currently prevailing in Israel;

adequate service of process was effected and the defendant had a reasonable opportunity to be heard;

the judgment is not contrary to the law, public policy, security or sovereignty of the State of Israel and its enforcement is not contrary to the laws governing enforcement of judgments;

the judgment was not obtained by fraud and does not conflict with any other valid judgment in the same matter between the same parties;

the judgment is no longer appealable; and

an action between the same parties in the same matter is not pending in any Israeli court at the time the lawsuit is instituted in the foreign court.

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Foreign judgments enforced by Israeli courts generally will be payable in Israeli currency. The usual practice in an action before an Israeli court to recover an amount in a non-Israeli currency is for the Israeli court to render judgment for the equivalent amount in Israeli currency at the rate of exchange in force on the date of the judgment. Under existing Israeli law, a foreign judgment payable in foreign currency may be paid in Israeli currency at the rate of exchange for the foreign currency published on the day before date of payment. Current Israeli exchange control regulations also permit a judgment debtor to make payment in foreign currency. Pending collection, the amount of the judgment of an Israeli court stated in Israeli currency ordinarily may be linked to Israel's consumer price index plus interest at the annual statutory rate set by Israeli regulations prevailing at that time. Judgment creditors must bear the risk of unfavorable exchange rates.

## **AMERICAN DEPOSITORY SHARES**

We have issued and deposited ordinary shares with Bank Hapoalim B.M., The Bank of New York's custodian in Tel Aviv, Israel. The Bank of New York in turn issued American Depositary Shares, or ADSs, representing American Depositary Shares, or ADSs. One ADS represents an ownership interest in one hundred of our ordinary shares. Each ADS also represents securities, cash or other property deposited with The Bank of New York but not distributed to ADS holders. The Bank of New York's Corporate Trust Office is located at 101 Barclay Street, New York, NY 10286, U.S.A. Their principal executive office is located at One Wall Street, New York, NY 10286, U.S.A.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, you are an ADS holder. This description assumes you hold your ADSs directly. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Because The Bank of New York will actually hold the ordinary shares, you must rely on it to exercise the rights of a shareholder. The obligations of The Bank of New York are set out in a deposit agreement among us, The Bank of New York and you, as an ADS holder. The agreement and the ADSs are generally governed by New York law.

The following is a summary of the agreement. Because it is a summary, it does not contain all the information that may be important to you. For more complete information, you should read the entire agreement and the ADS. Directions on how to obtain copies of these are provided in the section entitled "Where You Can Find More Information."

## ***Share Dividends and Other Distributions***

The Bank of New York has agreed to pay to you the cash dividends or other distributions it or the custodian receives on shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

*Cash.* The Bank of New York will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the U.S. If that is not possible or if any approval from any government or agency thereof is needed and cannot be obtained, the agreement allows The Bank of New York to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for the interest.

Before making a distribution, any withholding taxes that must be paid under U.S. law will be deducted. The Bank of New York will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when The Bank of New York cannot convert the foreign currency, you may lose some or all of the value of the distribution.

*Shares.* The Bank of New York may distribute new ADSs representing any shares we may distribute as a dividend or free distribution, if we furnish it promptly with satisfactory evidence that it is legal to do so. The Bank of New York will only distribute whole ADSs. It will sell shares which would require it to use a fractional ADS and distribute the net proceeds in the same way as it does with cash. If The Bank of New York does not distribute additional ADSs, each ADS will also represent the new shares.

*Rights to receive additional shares.* If we offer holders of our ordinary shares any rights to subscribe for additional shares or any other rights, The Bank of New York may make these rights available to you. We must first instruct The Bank of New York to do so and furnish it with satisfactory evidence that it is legal to do so. If we do not furnish this evidence and/or give these instructions, and The Bank of New York decides it is practical to sell the rights, The Bank of New York will sell the rights and distribute the proceeds, in the same way as it does with cash. The Bank of New York may allow rights that are not distributed or sold to lapse. In that case, you will receive no value for them. If The Bank of New York makes rights available to you, upon instruction from you, it will exercise the rights and purchase the shares on your behalf. The Bank of New York will then deposit the shares and issue ADSs to you. It will only exercise rights if you pay it the exercise price and any other charges the rights require you to pay.

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U.S. securities laws may restrict the sale, deposit, cancellation and transfer of the ADSs issued after exercise of rights. For example, you may not be able to trade the ADSs freely in the U.S. In this case, The Bank of New York may issue the ADSs under a separate restricted deposit agreement which will contain the same provisions as the agreement, except for the changes needed to put the restrictions in place.

*Other Distributions.* The Bank of New York will send to you anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, The Bank of New York has a choice. It may decide to sell what we distributed and distribute the net proceeds in the same way as it does with cash or it may decide to hold what we distributed, in which case the ADSs will also represent the newly distributed property.

The Bank of New York is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distribution we make on our shares or any value for them if it is illegal or impractical for us to make them available to you.

***Deposit, Withdrawal and Cancellation***

The Bank of New York will issue ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees. The Bank of New York will register the appropriate number of ADSs in the names you request and will deliver the ADSs at its office to the persons you request.

You may turn in your ADSs at The Bank of New York's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, The Bank of New York will deliver (1) the underlying shares to an account designated by you and (2) any other deposited securities underlying the ADS at the office of the custodian; or, at your request, risk and expense, The Bank of New York will deliver the deposited securities at its office.

***Voting Rights***

You may instruct The Bank of New York to vote the shares underlying your ADSs but only if we ask The Bank of New York to ask for your instructions. Otherwise, you will not be able to exercise your right to vote unless you withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares.

If we ask for your instructions, The Bank of New York will notify you of the upcoming vote and arrange to deliver our voting materials to you. The materials will (1) describe the matters to be voted on and (2) explain how you, on a certain date, may instruct The Bank of New York to vote the shares or other deposited securities underlying your ADSs as you direct. For instructions to be valid, The Bank of New York must receive them on or before the date specified. The Bank of New York will try, as far as practical, subject to Israeli law and the provisions of our Articles of Association, to vote or to have its agents vote the shares or other deposited securities as you instruct. The Bank of New York will only vote or attempt to vote as you instruct. However, if The Bank of New York does not receive your voting instructions, it will deem you to have instructed it to give a discretionary proxy to vote the shares underlying your ADSs to a person designated by us provided that no such instruction shall be deemed given and no such discretionary proxy shall be given with respect to any matter as to which we inform The Bank of New York that (x) we do not wish such proxy given, (y) substantial opposition exists, (z) such matter materially affects the rights of the holders of the shares underlying the ADSs.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct The Bank of New York to vote your shares. In addition, The Bank of New York and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that you may not be able to exercise your right to vote and there may be nothing you can do if your shares are not voted as you requested.

#### ***Rights of Non-Israeli Shareholders to Vote***

The ADSs may be freely held and traded pursuant to the General Permit and the Currency Control Law. The ownership or voting of ADSs by non-residents of Israel is not restricted in any way by our Articles of Association or by the laws of the State of Israel.

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***Fees and Expenses***

*ADS holders must pay:*

*For:*

\$5.00 (or less) per 100 ADSs

Each issuance of an ADS, including as a result of a distribution of shares or rights or other property.

(or portion thereof)

Each cancellation of an ADS, including if the agreement terminates.

\$0.05 (or less) per ADS

Any cash payment.

Registration or Transfer Fees

Transfer and registration of shares on the share register of the Foreign Registrar from your name to the name of The Bank of New York or its agent when you deposit or withdraw shares.

Conversion of foreign currency to U.S. dollars.

Expenses of The Bank of New York

Cable, telex and facsimile transmission expenses.

Servicing of shares or deposited securities.

\$0.02 (or less) per ADS per calendar year (if the depositary has not collected any cash distribution fee during that year)

Depositary services.

Taxes and other governmental charges

As necessary The Bank of New York or the Custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes.

A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs

Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to ADS holders.

***Payment of Taxes***



You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities underlying your ADSs. The Bank of New York may refuse to transfer your ADSs or allow you to withdraw the deposited securities underlying your ADSs until such taxes or other charges are paid. It may apply payments owed to you or sell deposited securities underlying your ADSs to pay any taxes owed and you will remain liable for any deficiency. If it sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to you any proceeds, or send to you any property, remaining after it has paid the taxes.

***Reclassifications, Recapitalizations and Mergers***

*If we:*

Change the nominal or par value of our shares;

Reclassify, split up or consolidate any of the deposited securities;

Distribute securities on the shares that are not distributed to you; or

Recapitalize, reorganize, merge, liquidate, sell all or substantially all of our assets, or takes any similar action.

*Then:*

The cash, shares or other securities received by The Bank of New York will become deposited securities. Each ADS will automatically represent its equal share of the new deposited securities. The Bank of New York may, and will if we ask it to, distribute some or all of the cash, shares or other securities it received. It may also issue new ADSs or ask you to surrender your outstanding ADSs in exchange for new ADSs, identifying the new deposited securities.

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***Amendment and Termination***

We may agree with The Bank of New York to amend the agreement and the ADSs without your consent for any reason. If the amendment adds or increases fees or charges, except for taxes and other governmental charges or registration fees, cable, telex or facsimile transmission costs, delivery costs or other such expenses, or prejudices an important right of ADS holders, it will only become effective thirty days after The Bank of New York notifies you of the amendment. At the time an amendment becomes effective, you are considered, by continuing to hold your ADS, to agree to the amendment and to be bound by the ADSs and the agreement is amended.

The Bank of New York will terminate the agreement if we ask it to do so. The Bank of New York may also terminate the agreement if The Bank of New York has told us that it would like to resign and we have not appointed a new depositary bank within ninety days. In both cases, The Bank of New York must notify you at least ninety days before termination.

After termination, The Bank of New York and its agents will be required to do only the following under the agreement: (1) advise you that the agreement is terminated, and (2) collect distributions on the deposited securities and deliver shares and other deposited securities upon cancellation of ADSs. After termination, The Bank of New York will, if practical, sell any remaining deposited securities by public or private sale. After that, The Bank of New York will hold the proceeds of the sale, as well as any other cash it is holding under the agreement for the pro rata benefit of the ADS holders that have not surrendered their ADSs. It will not invest the money and will have no liability for interest. The Bank of New York's only obligations will be to account for the proceeds of the sale and other cash. After termination our only obligations will be with respect to indemnification and to pay certain amounts to The Bank of New York.

***Limitations on Obligations and Liability to ADS Holders***

The agreement expressly limits our obligations and the obligations of The Bank of New York, and it limits our liability and the liability of The Bank of New York. We and The Bank of New York:

are only obligated to take the actions specifically set forth in the agreement without negligence or bad faith;

are not liable if either is prevented or delayed by law or circumstances beyond their control from performing their obligations under the agreement;

are not liable if either exercises discretion permitted under the agreement;

have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the agreement on your behalf or on behalf of any other party; and

may rely upon any documents they believe in good faith to be genuine and to have been signed or presented by the proper party.

In the agreement, we and The Bank of New York agree to indemnify each other under certain circumstances.

***Requirements for Depositary Actions***

Before The Bank of New York will issue or register transfer of an ADS, make a distribution on an ADS, or make a withdrawal of shares, The Bank of New York may require payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the:

transfer of any shares or other deposited securities;

production of satisfactory proof of the identity and genuineness of any signature or other information it deems necessary, and

compliance with regulations it may establish, from time to time, consistent with the agreement, including presentation of transfer documents.

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The Bank of New York may refuse to deliver, transfer, or register transfers of ADSs generally when the books of The Bank of New York or our books are closed, or at any time if The Bank of New York or we think it advisable to do so. You have the right to cancel your ADSs and withdraw the underlying shares at any time except:

when temporary delays arise because: (1) The Bank of New York or we have closed its transfer books; (2) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (3) we are paying a dividend on the shares; or

when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the agreement.

***Pre-Release of ADSs***

In certain circumstances, subject to the provisions of the agreement, The Bank of New York may issue ADSs before deposit of the underlying shares. This is called a pre-release of the ADS. The Bank of New York may also deliver shares upon cancellation of pre-released ADSs (even if the ADSs are cancelled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to The Bank of New York. The Bank of New York may receive ADSs instead of shares to close out a pre-release. The Bank of New York may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made must represent to The Bank of New York in writing that it or its customer owns the shares or ADSs to be deposited; (2) the pre-release must be fully collateralized with cash or other collateral that The Bank of New York considers appropriate; and (3) The Bank of New York must be able to close out the pre-release on not more than five business days' notice. In addition, The Bank of New York will limit the number of ADSs that may be outstanding at any time as a result of prerelease, although The Bank of New York may disregard the limit from time to time, if it thinks it is appropriate to do so.

***Inspection of Books of the Depositary***

Under the terms of the agreement, holders of ADSs may inspect the transfer books of the depositary at any reasonable time, provided that such inspection shall not be for the purpose of communicating with holders of ADSs in the interest of a business or object other than either our business or a matter related to the deposit agreement or ADSs.

***Book-Entry Only Issuance - The Depository Trust Company***

The Depository Trust Company, or DTC, New York, New York, will act as securities depository for the ADSs. The ADSs will be represented by one global security that will be deposited with and registered in the name of Cede & Co. (DTC's partnership nominee), or such other name as may be requested by an authorized representative of DTC. This means that we will not issue certificates to you for the ADSs. One global security will be issued to DTC, which will keep a computerized record of its participants (for example, your broker) whose clients have purchased the ADSs. Each participant will then keep a record of its clients. Unless it is exchanged in whole or in part for a certificated security, a global security may not be transferred. However, DTC, its nominees, and their successors may transfer a global security as a whole to one another. Beneficial interests in the global security will be shown on, and transfers of the global security will be made only through, records maintained by DTC and its participants.

DTC is a limited-purpose trust company organized under the New York Banking Law, a "banking organization" within the meaning of the New York Banking Law, a member of the United States Federal Reserve System, a "clearing corporation" within the meaning of the New York Uniform Commercial Code and a "clearing agency" registered under the provisions of Section 17A of the Exchange Act. DTC holds securities that its participants (direct participants) deposit with DTC. DTC also records the settlement among direct participants of securities transactions, such as transfers and pledges, in deposited securities through computerized records for direct participant's accounts. This eliminates the need to exchange certificates. Direct participants include securities brokers and dealers, banks, trust companies, clearing corporations and certain other organizations.

DTC's book-entry system is also used by other organizations such as securities brokers and dealers, banks and trust companies that work through a direct participant. The rules that apply to DTC and its participants are on file with the SEC.

DTC is a wholly-owned subsidiary of The Depository Trust & Clearing Corporation, or DTCC. DTCC is, in turn, owned by a number of DTC's direct participants and by the New York Stock Exchange, Inc., the American Stock Exchange, Inc. and the National Association of Securities Dealers, Inc.

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When you purchase ADSs through the DTC system, the purchases must be made by or through a direct participant, who will receive credit for the ADSs on DTC's records. Since you actually own the ADSs, you are the beneficial owner and your ownership interest will only be recorded on the direct (or indirect) participants' records. DTC has no knowledge of your individual ownership of the ADSs. DTC's records only show the identity of the direct participants and the amount of ADSs held by or through them. You will not receive a written confirmation of your purchase or sale or any periodic account statement directly from DTC. You will receive these from your direct (or indirect) participant. Thus the direct (or indirect) participants are responsible for keeping accurate account of the holdings of their customers like you.

We will wire dividend payments to DTC's nominee, and we will treat DTC's nominee as the owner of the global security for all purposes. Accordingly, we will have no direct responsibility or liability to pay amounts due on the global security to you or any other beneficial owners in the global security.

Any redemption notices will be sent by us directly to DTC, who will in turn inform the direct participants, who will then contact you as a beneficial holder.

It is DTC's current practice, upon receipt of any payment of dividends or liquidation amount, to credit direct participants' accounts on the payment date based on their holdings of beneficial interests in the global securities as shown on DTC's records. In addition, it is DTC's current practice to assign any consenting or voting rights to direct participants whose accounts are credited with preferred securities on a record date, by using an omnibus proxy. Payments by participants to owners of beneficial interests in the global securities, and voting by participants, will be based on the customary practices between the participants and owners of beneficial interests, as is the case with the ADSs held for the account of customers registered in "street name." However, payments will be the responsibility of the participants and not of DTC or us.

ADSs represented by a global security will be exchangeable for certificated securities with the same terms in authorized denominations only if:

DTC is unwilling or unable to continue as depository or if DTC ceases to be a clearing agency registered under applicable law and a successor depository is not appointed by us within 90 days; or

we determine not to require all of the ADSs to be represented by a global security.

If the book-entry only system is discontinued, the transfer agent will keep the registration books for the ADSs at its corporate office.

The information in this section concerning DTC and DTC's book-entry system has been obtained from sources we believe to be reliable, but we take no responsibility for the accuracy thereof.

## **Material Contracts**

### ***Bio-Gal Ltd.***

On March 18, 2009, we announced that we had entered into an asset purchase agreement with Bio-Gal Ltd. ("**Bio-Gal**"), a Gibraltar private company, for the rights to a use patent on rHuEPO for the prolongation of Multiple Myeloma patients' survival and improvement of their quality of life. On December 31, 2009, we amended the asset purchase agreement with Bio-Gal, so that XTL could acquire XTEPO Ltd., a special purpose company that was established by Bio-Gal's shareholders who received from Bio-Gal all of Bio-Gal's rights on rHuEPO and raised approximately \$1.5 million. We intend to develop rHuEPO for the prolongation of Multiple Myeloma patients' survival and improvement of their quality of life. Multiple Myeloma is a severe and incurable malignant hematological cancer of plasma cells. In accordance with the terms of the amended asset purchase agreement, we issued to XTEPO's shareholders ordinary shares representing approximately 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a \$10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350 thousand upon the successful completion of Phase 2. Such payment of \$350 thousand mentioned above shall be made to Yeda upon the earlier of (i) six months from the successful completion of the Phase 2 or (ii) the completion of a successful fundraising by XTL or XTEPO at any time after the completion of the Phase 2 of at least \$2 million. On August 3, 2010, the Bio-Gal transaction was completed according to the outline signed by the parties to the agreement on December 31, 2009, after all the prerequisites had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share swap transaction pursuant to article 104 and 103 to the Israeli tax ordinance (Revised), 1961. (See note 12 to the consolidated financial statements: Intangible Asset).

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*MinoGuard Ltd.*

On March 24, 2011, we entered into a Memorandum of Understanding with MinoGuard, pursuant to which we agreed to acquire the exclusive rights to SAM-101 by obtaining an exclusive license to use MinoGuard's entire technology. SAM-101 is based on a combination of anti-psychotic drugs with minocycline, a recognized medicinal compound. On November 30, 2011, we received a worldwide exclusive license from MinoGuard under which we agreed to develop and commercialize MinoGuard's technology for the treatment of psychotic disorders focusing on Schizophrenia. Under the agreement, we are to conduct clinical trials, develop, register, market, distribute and sell the drugs that will emerge from MinoGuard's technology, with no limitations for a specific disorder. In consideration, we shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately \$2.5 million. In addition, we agreed to pay MinoGuard royalty-based payments on products that are based on the technology, equal to 3.5% of the net sales and/or percentage from the Company third-party out-license receipts in the range of 7.5%-20% according to the clinical phase of the drug at the time of an out-license transaction. It should be noted that the Company had the sole discretion to pay any of the above amounts in cash or by way of issuing ordinary shares of the Company to MinoGuard. In addition to the above payments, and in accordance with the above agreement, since as of June 30, 2013, XTL had not commenced a phase 2 clinical trial, we have paid MinoGuard an annual license fee, by way of the issuance of 175,633 ordinary shares of the Company, representing a value of \$45 thousand, for the 12 month period between July 1, 2013 and June 30, 2014. On September 3, 2014, the Company issued an additional 889,822 ordinary shares, representing a value of \$135 thousand, for the 12 month period between July 1, 2014 and June 30, 2015.

On May 25, 2015, the Company provided MinoGuard with a notice of termination whereby, as of June 24, 2015, the rights and license granted according to the license agreement were terminated and all rights in and to the licensed technology reverted to MinoGuard.

*hCDR1*

On January 7, 2014, the Company entered into a licensing agreement with Yeda to research, develop, and commercialize hCDR1, a Phase II-ready asset for the treatment of SLE, among other indications. In consideration, the Company is responsible for a patent expense reimbursement in six installments totaling approximately \$400 thousand. The Company is required to make milestone payments of \$2.2 million: \$200 thousand upon starting Phase III, \$1 million upon U.S. Food and Drug Administration approval and \$250 thousand for regulatory approval in each of China and three of the European Union's Group of Six. In addition, the Company will pay 2-3% royalties of annual net sales and sublicense fees of 15-20% of whatever the Company receives from any sub-licensee.

Lupus is a debilitating disease affecting approximately five million people worldwide according to the Lupus Foundation of America. hCDR1, is a peptide and acts as a disease-specific treatment to modify the SLE-related



autoimmune process. It does so by specific upstream immunomodulation through the generation of regulatory T cells, reducing inflammation and resuming immune balance. Prior to being licensed to the Company by Yeda, hCDR1 was licensed to Teva Pharmaceutical Industries (“Teva”), which performed two placebo controlled Phase I trials and a placebo controlled Phase II trial called the PRELUDE trial. The studies consisted of over 400 patients, demonstrating that hCDR1 is well tolerated by patients and has a favorable safety profile. The PRELUDE trial did not achieve its primary efficacy endpoint based on the SLEDAI scale, resulting in Teva returning the asset to Yeda. However, the PRELUDE trial showed encouraging results in its secondary clinical endpoint, the BILAG index, and, in fact, the 0.5 mg weekly dose showed a substantial effect. Multiple post-hoc analyses also showed impressive results for this dose using the BILAG index. The Company plans that such dose be the focus of the clinical development plan moving forward. Subsequent to Teva’s return of the program to Yeda, the FDA directed that the primary endpoint in future trials for Lupus therapies, including those for hCDR1, should be based on either the BILAG index or the SRI. Given the FDA’s recommendation and the positive findings from the PRELUDE trial (which showed a substantial effect in the BILAG index), the Company intends to initiate a new Phase II clinical trial, which will include the 0.5 mg (and a 0.25 mg) weekly dose of hCDR1.

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### **Exchange Controls**

There are no Israeli government laws, decrees or regulations that restrict or that affect our export or import of capital or the remittance of dividends, interest or other payments to non-resident holders of our securities, including the availability of cash and cash equivalents for use by us and our wholly-owned subsidiaries, except or otherwise as set forth under Taxation.

### **Taxation**

The following discussion summarizes certain Israeli and U.S. federal income tax consequences that may be material to our shareholders, but is not intended, and should not be construed, as legal or professional tax advice and does not exhaust all possible tax considerations that may be relevant to holders of our ordinary shares. This discussion is based on existing law, judicial authorities and administrative interpretations, all of which are subject to change or differing interpretations, possibly with retroactive effect. This summary does not purport to be a complete analysis of all potential tax consequences of owning our ordinary shares. In particular, this discussion does not take into account the specific circumstances of any particular holder or holders who may be subject to special rules, such as tax-exempt entities, broker-dealers, shareholders subject to Alternative Minimum Tax, shareholders that actually or constructively own 10% or more of our voting securities, shareholders that hold ordinary shares or ADSs as part of straddle or hedging or conversion transaction, traders in securities that elect mark to market, banks and other financial institutions or partnerships or other pass-through entities. The following tax considerations are not relevant to employees of the company or any controlling shareholders. The tax aspects do not include reference to the Encouragement of Capital Investments Law and the Encouragement of Industry Taxes Law.

*We urge shareholders to consult their own tax advisors as to the potential U.S., Israeli, or other tax consequences of the purchase, ownership and disposition of ordinary shares and ADSs, including, in particular, the effect of any foreign, state or local taxes. For purposes of the entire Taxation discussion, we refer to ordinary shares and ADSs collectively as ordinary shares.*

### **Israeli Tax Considerations**

The following discussion refers to the current tax law applicable to companies in Israel, with special reference to its effect on us. This discussion also includes specified Israeli tax consequences to holders of our ordinary shares and Israeli Government programs benefiting us. This summary does not discuss all the aspects of Israeli income tax law that may be relevant to a particular investor in light of his or her personal investment circumstances or to some types of investors subject to special treatment under Israeli law. Examples of this kind of investor include residents of Israel

or traders in securities who are subject to special tax regimes not covered in this discussion. To the extent that the discussion is based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. This summary is based on laws and regulations in effect as of the date of this report and does not take into account possible future amendments which may be under consideration.”

### ***Corporate Tax Rate***

The corporate tax rate in Israel was 26.5%, 26.5% and 25% for the years ended December 31, 2015, 2014 and 2013, respectively.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018 and thereafter.

Capital gains derived by an Israeli resident company are generally subject to tax at the same rate as the corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an “Israeli Resident” if it meets one of the following: (a) it was incorporated in Israel; or (b) the control and management of its business are exercised in Israel.

### ***Tax Benefits for Research and Development***

Israeli tax law allows, under specific conditions, a tax deduction in the year incurred for expenditures, including capital expenditures, relating to scientific research and development projects, if the expenditures are approved by the relevant Israeli government ministry, determined by the field of research, and the research and development is for the promotion of the company and is carried out by or on behalf of the company seeking the deduction. Expenditures not so approved are deductible over a three-year period. In the past, expenditures that were made out of proceeds made available to us through government grants were automatically deducted during a one year period.

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***Israeli Estate and Gift Taxes***

Israel law presently does not impose estate or gift taxes.

***Capital Gains Tax on Sales of our Ordinary Shares by Both Residents and Non-Residents of Israel***

The Israeli Income Tax Ordinance of 1961 (New Version), or the Ordinance, generally imposes a capital gains tax on the sale of capital assets either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) the sold asset is abroad and it essentially represent, directly or indirectly, rights to assets located in Israel, , by both residents and non-residents of Israel, unless a specific exemption is available or unless a treaty between Israel and the country of the non-resident provides otherwise. The law distinguishes between the inflationary surplus and the real capital gain. The inflationary surplus is the portion of the total capital gain, which is equivalent to the increase of the relevant asset's purchase price attributable to the increase in the Israeli consumer price index from the date of purchase to the date of sale. The real capital gain is the excess of the total capital gain over the inflationary surplus. A non-resident that invests in taxable assets with foreign currency may elect to calculate the inflationary amount by using such foreign currency.

Non-Israeli residents are generally exempt from Israeli capital gains tax on any gains derived from the sale of shares publicly traded on a stock exchange recognized by the Israeli Ministry of Finance (including the Tel-Aviv Stock Exchange and Nasdaq), provided such shareholders did not acquire their shares prior to an initial public offering and that such capital gains are not derived by a permanent establishment of the foreign resident in Israel. Notwithstanding the foregoing, dealers in securities in Israel are taxed at the regular tax rates applicable to business income. However, Non-Israeli corporations will not be entitled to such exemption if an Israeli resident (1) has, directly, or indirectly, along or together with another, a controlling interest of 25% or more of the means of control in such non-Israeli corporation, or (2) is the beneficiary of, or is entitled to, 25% or more of the revenue or profits of such non-Israeli corporation, whether directly or indirectly. In such case the sale, exchange or disposition of ordinary shares would be subject to Israeli tax, to the extent applicable.

In addition, pursuant to the Convention Between the Government of the United States of America and the Government of Israel with Respect to Taxes on Income, as amended (the "United States- Israel Tax Treaty"), the sale, exchange or disposition of ordinary shares by a person who qualifies as a resident of the U.S. within the meaning of the United States-Israel Tax Treaty and who is entitled to claim the benefits afforded to such person by the United States- Israel Tax Treaty (a "Treaty United States Resident") generally will not be subject to the Israeli capital gains tax unless such Treaty United States Resident holds, directly or indirectly, shares representing 10% or more of our voting power during any part of the twelve- month period preceding such sale, exchange or disposition, subject to certain conditions or if the capital gains from such sale are considered as business income attributable to a permanent establishment of the U.S. resident in Israel. However, under the United States-Israel Tax Treaty, such "Treaty United

States Resident” would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations in U.S. laws applicable to foreign tax credits.

The income tax rate applicable to real capital gain (capital gain less inflationary surplus) derived by an Israeli individual from the sale of our ordinary shares, is 25%. However, if such shareholder is considered a “Substantial Shareholder” (as defined below) at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%.

Real capital gains derived by a shareholder who is a dealer or trader in securities, or to whom such income is otherwise taxable as ordinary business income instead of capital gain which , are taxed in Israel at the marginal tax rates applicable to business income (up to 50% for individuals, including Excess Tax). With respect to the above mentioned, VAT implication may be applicable. A “substantial shareholder” is defined as someone who alone, or together with another person, holds, directly or indirectly, at least 10% in one or all of any of the means of control in the corporation (including, among other things, the right to receive profits of the company, voting rights, the right to receive the company’s liquidation proceeds and the right to appoint a director). With respect to Israeli tax resident corporate investors, capital gains tax at the regular corporate rate will be imposed on such taxpayers on the sale of traded shares.

Either the purchaser, the Israeli stockbrokers or financial institution through which the shares are held is obliged, subject to the above mentioned exemptions, to withhold tax in the amount of consideration (applicable to individual) paid upon the sale of securities (or the Real Capital Gain realized on the sale applicable company, if known) at the Israeli corporate tax rate (23% in 2018 and thereafter) or 25% in case the seller is an individual.

At the sale of securities traded on a stock exchange a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and June 30 of every tax year in respect of sales of securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Ordinance and regulations promulgated thereunder the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

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*Excess Tax*

Individuals who are subject to tax in Israel, are also subject to an additional tax on annual income exceeding NIS 640,000 in 2018 at a rate of 3%, including, but not limited to, income derived from dividends, interest and capital gain.

*Taxation of Dividends*

Israeli tax resident individuals or non-Israeli resident individuals are generally subject to Israeli income tax on the receipt of dividends paid on our ordinary Shares at the rate of 25% or 30%, if such recipient is a “substantial shareholders” at the time receiving the dividend or on any date in the 12 months preceding such date, unless a lower tax rate is provided in a tax treaty between Israel and the shareholder’s country of residence and if a certificate for a reduced withholding tax rate would be provided in advance from the Israeli Tax Authority.

Payers of dividends on our common shares, including the Israeli stockbroker effectuating the transaction, or the financial institution through which the securities are held, are generally required, subject to any of the foregoing exemptions, reduced tax rates and the demonstration of a shareholder regarding his, her or its foreign residency, and subject to a certificate for a reduced withholding tax rate from the Israeli tax authority, to withhold tax upon the distribution of dividend at the rate of 25%, so long as the shares are registered with a Nominee Company (for corporations and individuals).

Under the U.S.-Israel Tax Treaty, the maximum Israeli tax and withholding tax on dividends paid to a holder of ordinary shares who is a resident of the U.S. is generally 25%, but is reduced to 12.5% if the dividends are paid to a U.S. corporation that holds in excess of 10% of the voting rights of a company during the company’s taxable year preceding the distribution of the dividend and the portion of the company’s taxable year in which the dividend was distributed as well as during the previous tax year, provided that not more than 25% of the gross income for such preceding year (if any) consists of certain types of interest or dividends and if a certificate for a reduced withholding tax rate is obtained in advance from the Israeli tax authority.

A non-resident of Israel who has dividend income derived from or accrued in Israel, from which full tax was withheld at the source, is generally exempt from the duty to file tax returns in Israel in respect of such income, provided such income was not derived from a business conducted in Israel by the taxpayer and the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

## U.S. Federal Income Tax Considerations

**TO ENSURE COMPLIANCE WITH U.S. TREASURY DEPARTMENT CIRCULAR 230, PROSPECTIVE HOLDERS OF ORDINARY SHARES ARE HEREBY NOTIFIED THAT: (A) ANY DISCUSSION OF U.S. FEDERAL TAX ISSUES IN THIS MEMORANDUM IS NOT INTENDED OR WRITTEN TO BE RELIED UPON, AND CANNOT BE RELIED UPON, BY HOLDERS OF ORDINARY SHARES FOR THE PURPOSE OF AVOIDING PENALTIES THAT MAY BE IMPOSED ON SUCH HOLDERS UNDER THE INTERNAL REVENUE CODE OF 1986, AS AMENDED (THE “CODE”); (B) SUCH DISCUSSION IS WRITTEN IN CONNECTION WITH THE PROMOTION OR MARKETING OF THE TRANSACTIONS OR MATTERS ADDRESSED HEREIN; AND (C) PROSPECTIVE HOLDERS OF ORDINARY SHARES SHOULD SEEK ADVICE BASED ON THEIR PARTICULAR CIRCUMSTANCES FROM AN INDEPENDENT TAX ADVISOR.**

The following discussion applies only to a holder of our ordinary shares who qualifies as a “U.S. holder”. For purposes of this discussion a “U.S. holder” is a beneficial owner of our ordinary shares that is for U.S. federal income tax purposes:

an individual who is a U.S. citizen or U.S. resident alien;

a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) that was created or organized under the laws of the U.S., any state thereof or the District of Columbia;

an estate whose income is subject to U.S. federal income taxation regardless of its source; or

a trust (i) if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more “United States persons” (as defined in the Code) have the authority to control all substantial decisions of the trust, or (ii) if the trust has a valid election in effect under applicable Treasury Regulations to be treated as a “United States person.”

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This discussion is based on current provisions of the Internal Revenue Code of 1986, as amended, which we refer to as the Code, current and proposed Treasury regulations promulgated under the Code, and administrative and judicial decisions as of the date of this *prospectus*, all of which are subject to change or differing interpretation, possibly on a retroactive basis. This discussion does not address any aspect of state, local or non-U.S. tax laws. Except where noted, this discussion addresses only those holders who hold our shares as capital assets. This discussion does not purport to be a comprehensive description of all of the tax considerations that may be relevant to U.S. holders entitled to special treatment under U.S. federal income tax laws, for example, financial institutions, insurance companies, tax-exempt organizations and broker/dealers, and it does not address all aspects of U.S. federal income taxation that may be relevant to any particular shareholder based on the shareholder's individual circumstances. In particular, this discussion does not address the potential application of the alternative minimum tax, or the special U.S. federal income tax rules applicable in special circumstances, including to U.S. holders who:

have elected mark-to-market accounting;

hold our ordinary shares as part of a straddle, hedge or conversion transaction with other investments;

own directly, indirectly or by attribution at least 10% of our voting power;

are tax exempt entities;

are persons who acquire shares in connection with employment or other performance of services; and

have a functional currency that is not the U.S. dollar.

Additionally, this discussion does not consider the tax treatment of partnerships or persons who hold ordinary shares through a partnership or other pass-through entity or the possible application of U.S. federal gift or estate taxes.

**EACH PROSPECTIVE SHAREHOLDER IS URGED TO CONSULT ITS TAX ADVISOR REGARDING THE PARTICULAR TAX CONSEQUENCES TO SUCH HOLDER OF OWNERSHIP AND DISPOSITION OF OUR SHARES, AS WELL AS ANY TAX CONSEQUENCES THAT MAY ARISE UNDER THE LAWS OF ANY OTHER RELEVANT FOREIGN, STATE, LOCAL, OR OTHER TAXING JURISDICTION.**

***Taxation of Distributions Paid on Ordinary Shares***



Subject to the description of the passive foreign investment company rules below, a U.S. holder will be required to include in gross income as ordinary income from sources outside of the U.S. the amount of any distribution paid on ordinary shares, including any Israeli taxes withheld from the amount paid, to the extent the distribution is paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Distributions in excess of these earnings and profits will be applied against and will reduce the U.S. holder's basis in the ordinary shares and, to the extent in excess of this basis, will be treated as gain from the sale or exchange of ordinary shares. We do not expect to maintain calculations of our earnings and profits under U.S. federal income tax principles and, therefore, U.S. holder should expect that the entire amount of any distribution generally will be reported as dividend income.

On December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the TCJA. The TCJA provides a 100% deduction for the foreign-source portion of dividends received from "specified 10-percent owned foreign corporations" by U.S. corporate holders, subject to a one-year holding period. No foreign tax credit, including Israeli withholding tax (or deduction for foreign taxes paid with respect to qualifying dividends) would be permitted for foreign taxes paid or accrued with respect to a qualifying dividend. Deduction would be unavailable for "hybrid dividends." The dividend received deduction enacted under the TCJA may not apply to dividends from a passive foreign investment company, as discussed below.

Certain dividend income may be eligible for a reduced rate of taxation. Dividend income will be taxed to a non-corporate holder at the applicable long-term capital gains rate if the dividend is received from a "qualified foreign corporation," and the shareholder of such foreign corporation holds such stock for more than 60 days during the 121 day period that begins on the date that is 60 days before the ex-dividend date for the stock. The holding period is tolled for any days on which the shareholder has reduced his risk of loss with respect to the stock. A "qualified foreign corporation" is either a corporation that is eligible for the benefits of a comprehensive income tax treaty with the U.S. or a corporation whose stock, the shares of which are with respect to any dividend paid by such corporation, is readily tradable on an established securities market in the United States (including, for this purpose, ADSs traded on a securities market in the United States with respect to the foreign corporation's shares). However, a foreign corporation will not be treated as a "qualified foreign corporation" if it is a passive foreign investment company (as discussed below) for the year in which the dividend was paid or the preceding year. Distributions of current or accumulated earnings and profits paid in foreign currency to a U.S. holder will be includible in the income of a U.S. holder in a U.S. dollar amount calculated by reference to the exchange rate in effect on the day the distribution is received by the U.S. holder (or, in the case of ADSs, on the day the distribution is received by the depository). A U.S. holder that receives a foreign currency distribution and converts the foreign currency into U.S. dollars subsequent to receipt will have foreign exchange gain or loss based on any appreciation or depreciation in the value of the foreign currency against the U.S. dollar, which will generally be U.S. source ordinary income or loss.

As described above, we will generally be required to withhold Israeli income tax from any dividends paid to holders who are not residents of Israel. See "- Israeli Tax Considerations—Taxation of Dividends" above.

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With respect to certain non-corporate U.S. Holders, including individual U.S. Holders, dividends may be taxed at the lower capital gain rates applicable to “qualified dividend income,” provided (1) our ordinary shares are readily tradable on an established securities market in the United States (such as Nasdaq), (2) we are neither a PFIC nor treated as such with respect to you (as discussed above) for either the taxable year in which the dividend was paid or the preceding taxable year, (3) certain holding period requirements are met and (4) you are not under an obligation to make related payments with respect to positions in substantially similar or related property. As discussed above under “Passive foreign investment company,” there is a significant risk that we will be a PFIC for U.S. federal income tax purposes, and, as a result, the qualified dividend rate may be unavailable with respect to dividends we pay.

The amount of any distribution paid in a currency other than U.S. dollars will be equal to the U.S. dollar value of such currency on the date such distribution is includible in your income, regardless of whether the payment is in fact converted into U.S. dollars at that time. The amount of any distribution of property other than cash will be the fair market value of such property on the date of distribution.

Any dividends will constitute foreign source income for foreign tax credit limitation purposes. If the dividends are taxed as qualified dividend income (as discussed above), the amount of the dividend taken into account for purposes of calculating the foreign tax credit limitation will in general be limited to the gross amount of the dividend, multiplied by the reduced tax rate applicable to qualified dividend income and divided by the highest tax rate normally applicable to dividends. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. For this purpose, dividends distributed by us with respect to our ordinary shares will generally constitute “passive category income” but could, in the case of certain U.S. Holders, constitute “general category income.”

If Israeli withholding taxes apply to any dividends paid to you with respect to our ordinary shares, subject to certain conditions and limitations, such withholding taxes may be treated as foreign taxes eligible for credit against your U.S. federal income tax liability. Instead of claiming a credit, you may elect to deduct such taxes in computing taxable income, subject to applicable limitations. If a refund of the tax withheld is available under the applicable laws of Israel or under the Israel-U.S. income tax treaty (the “Treaty”), the amount of tax withheld that is refundable will not be eligible for such credit against your U.S. federal income tax liability (and will not be eligible for the deduction against your U.S. federal taxable income). The rules relating to the determination of the foreign tax credit are complex, and you should consult your tax advisor regarding the availability of a foreign tax credit in your particular circumstances, including the effects of the Treaty.

Special rules, described below, apply if we are a passive foreign investment company.

***Taxation of the Disposition of Ordinary Shares***

Subject to the description of the passive foreign investment company rules below, upon the sale, exchange or other disposition of our ordinary shares, a U.S. holder will recognize capital gain or loss in an amount equal to the difference between the U.S. holder's basis in the ordinary shares, which is usually the cost of those shares, and the amount realized on the disposition. Capital gain from the sale, exchange or other disposition of ordinary shares held more than one year is long-term capital gain and is eligible for a reduced rate of taxation for non-corporate holders. In general, gain realized by a U.S. holder on a sale, exchange or other disposition of ordinary shares generally will be treated as U.S. source income for U.S. foreign tax credit purposes. A loss realized by a U.S. holder on the sale, exchange or other disposition of ordinary shares is generally allocated to U.S. source income. However, regulations require the loss to be allocated to foreign source income to the extent certain dividends were received by the taxpayer within the 24-month period preceding the date on which the taxpayer recognized the loss. The deductibility of a loss realized on the sale, exchange or other disposition of ordinary shares is subject to limitations for both corporate and individual shareholders.

A U.S. holder that uses the cash method of accounting calculates the U.S. dollar value of the proceeds received from a sale of ordinary shares as of the date that the sale settles, and will generally have no additional foreign currency gain or loss on the sale, while a U.S. holder that uses the accrual method of accounting is required to calculate the value of the proceeds of the sale as of the trade date and may therefore realize foreign currency gain or loss, unless the U.S. holder has elected to use the settlement date to determine its proceeds of sale for purposes of calculating this foreign currency gain or loss. In addition, a U.S. holder that receives foreign currency upon disposition of our ordinary shares and converts the foreign currency into U.S. dollars subsequent to receipt will have foreign exchange gain or loss based on any appreciation or depreciation in the value of the foreign currency against the U.S. dollar, which will generally be U.S. source ordinary income or loss.

#### ***Tax Consequences if we are a Passive Foreign Investment Company***

Special federal income tax rules apply to the timing and character of income received by a U.S. holder of a PFIC. We will be a PFIC if either 75% or more of our gross income in a tax year is passive income or the average percentage of our assets (by value) that produce or are held for the production of passive income in a tax year is at least 50%. The IRS has indicated that cash balances, even if held as working capital, are considered to be assets that produce passive income. Therefore, any determination of PFIC status will depend upon the sources of our income, and the relative values of passive and non-passive assets, including goodwill. Furthermore, because the goodwill of a publicly-traded corporation is largely a function of the trading price of its shares, the valuation of that goodwill is subject to significant change throughout each year. A determination as to a corporation's status as a PFIC must be made annually. We believe we may be a PFIC during 2018 and although we have not determined whether we will be a PFIC in 2019, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. Although we may not be a PFIC in any one year, the PFIC taint remains with respect to those years in which we were or are a PFIC and the special PFIC taxation regime will continue to apply.

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If we are classified as a PFIC, a special tax regime would apply to both (a) any “excess distribution” by us (generally, the U.S. holder’s ratable share of distributions in any year that are greater than 125% of the average annual distributions received by such U.S. holder in the three preceding years or its holding period, if shorter) and (b) any gain recognized on the sale or other disposition of your ordinary shares. Under this special regime, any excess distribution and recognized gain would be treated as ordinary income and the federal income tax on such ordinary income would be determined as follows: (i) the amount of the excess distribution or gain would be allocated ratably over the U.S. holder’s holding period for our ordinary shares; (ii) U.S. federal income tax would be determined for the amounts allocated to the first year in the holding period in which we were classified as a PFIC and for all subsequent years (except the year in which the excess distribution was received or the sale occurred) by applying the highest applicable tax rate in effect in the year to which the income was allocated; (iii) an interest charge would be added to this tax, calculated by applying the underpayment interest rate to the tax for each year determined under the preceding sentence from the due date of the income tax return for such year to the due date of the return for the year in which the excess distribution or sale occurs; and (iv) amounts allocated to a year prior to the first year in the U.S. holder’s holding period in which we were classified as a PFIC or to the year in which the excess distribution or the disposition occurred would be taxed as ordinary income but without the imposition of an interest charge.

A U.S. holder may generally avoid the PFIC “excess distribution” regime by electing to treat his PFIC shares as a “qualified electing fund.” If a U.S. holder elects to treat PFIC shares as a qualified electing fund, also known as a “QEF Election,” the U.S. holder must include annually in gross income (for each year in which PFIC status is met) his *pro rata* share of the PFIC’s ordinary earnings and net capital gains, whether or not such amounts are actually distributed to the U.S. holder. A U.S. holder may make a QEF Election with respect to a PFIC for any taxable year in which he was a shareholder. A QEF Election is effective for the year in which the election is made and all subsequent taxable years of the U.S. holder. Procedures exist for both retroactive elections and the filing of protective statements. A U.S. holder making the QEF Election must make the election on or before the due date, as extended, for the filing of the U.S. holder’s income tax return for the first taxable year to which the election will apply.

A QEF Election is made on a shareholder-by-shareholder basis. A U.S. holder must make a QEF Election by completing Form 8621, Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, and attaching it to the holder’s timely filed U.S. federal income tax return.

Alternatively, a U.S. holder may also generally avoid the PFIC regime by making a so-called “mark-to-market” election. Such an election may be made by a U.S. holder with respect to ordinary shares owned at the close of such holder’s taxable year, provided that we are a PFIC and the ordinary shares are considered “marketable stock.” The ordinary shares will be marketable stock if they are regularly traded on a national securities exchange that is registered with the Securities and Exchange Commission, or the national market system established pursuant to section 11A of the Securities Exchange Act of 1934, or an equivalent regulated and supervised foreign securities exchange.

If a U.S. holder were to make a mark-to-market election with respect to ordinary shares, such holder generally will be required to include in its annual gross income the excess of the fair market value of the PFIC shares at year-end over

such shareholder's adjusted tax basis in the ordinary shares. Such amounts will be taxable to the U.S. holder as ordinary income, and will increase the holder's tax basis in the ordinary shares. Alternatively, if in any year, a United States holder's tax basis exceeds the fair market value of the ordinary shares at year-end, then the U.S. holder generally may take an ordinary loss deduction to the extent of the aggregate amount of ordinary income inclusions for prior years not previously recovered through loss deductions and any loss deductions taken will reduce the shareholder's tax basis in the ordinary shares. Gains from an actual sale or other disposition of the ordinary shares with a "mark-to-market" election will be treated as ordinary income, and any losses incurred on an actual sale or other disposition of the ordinary shares will be treated as an ordinary loss to the extent of any prior "unreversed inclusions" as defined in Section 1296(d) of the Code.

The mark-to-market election is made on a shareholder-by-shareholder basis. The mark-to-market election is made by completing Form 8621, Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, and attaching it to the holder's timely filed U.S. federal income tax return for the year of election. Such election is effective for the taxable year for which made and all subsequent years until either (a) the ordinary shares cease to be marketable stock or (b) the election is revoked with the consent of the IRS.

***In view of the complexity of the issues regarding our treatment as a PFIC, U.S. shareholders are urged to consult their own tax advisors for guidance as to our status as a PFIC.***

#### ***Information Reporting and Back-Up Withholding***

U.S. holders generally are subject to information reporting requirements with respect to dividends paid in the U.S. on ordinary shares. Existing regulations impose information reporting and back-up withholding on dividends paid in the U.S. on ordinary shares and on proceeds from the disposition of ordinary shares unless the U.S. holder provides IRS Form W-9 or otherwise establishes an exemption.

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Prospective investors should consult their tax advisors concerning the effect, if any, of these Treasury regulations on an investment in ordinary shares. Back-up withholding is not an additional tax. The amount of any back-up withholding will be allowed as a credit against a holder's U.S. federal income tax liability and may entitle the holder to a refund, provided that specified required information is furnished to the IRS on a timely basis.

**Documents on Display**

We file reports and other information with the SEC under the Exchange Act and the regulations thereunder applicable to foreign private issuers. You may inspect and copy reports and other information filed by us with the SEC at the SEC's public reference facilities described below. Although as a foreign private issuer we are not required to file periodic information as frequently or as promptly as US companies, we generally announce publicly our interim and year-end results promptly on a voluntary basis and will file that periodic information with the SEC under cover of Form 6-K. As a foreign private issuer, we are also exempt from the rules under the Exchange Act prescribing the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and other provisions in Section 16 of the Exchange Act.

You may read and copy any document we file or furnish with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You can review our SEC filings and the registration statement by accessing the SEC's internet site at <http://www.sec.gov>.

We also maintain a website at <http://www.xtlbio.com>, but information contained on our website does not constitute a part of this report and is not incorporated by reference into this report.

**ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

*Interest Rate Risk.* The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in bank deposits and marketable securities in accordance with our investment policy. As of December 31, 2017, our portfolio of financial instruments consists of cash and cash equivalents, short-term bank deposits with multiple institutions and marketable securities. The average duration of all of our investments held as of December 31, 2017, was less than one year. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

*Foreign Currency and Inflation Risk.* We hold most of our cash, cash equivalents and bank deposits in U.S. dollars. While a substantial amount of our operating expenses are in U.S. dollars, we incur a portion of our expenses in New Israeli Shekels. In addition, we also pay for some of our services and supplies in the local currencies of our suppliers, as our head office is located in Israel. As a result, we are exposed to the risk that the U.S. dollar will be devalued against the New Israeli Shekel or other currencies, and as a result our financial results could be harmed if we are unable to guard against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. The Company's treasury risk management policy is to hold NIS-denominated cash and cash equivalents and short-term deposits in the amount of the anticipated NIS-denominated liabilities for six consecutive months from time to time and this in line with the directives of the Company's Board. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the dollar or that the timing of any devaluation may lag behind inflation in Israel.

As of December 31, 2017, had the Group's functional currency weakened by 10% against the NIS with all other variables remaining constant, post-tax loss for the year would have been \$38 thousand lower (2016 - post-tax loss approximately \$22 thousand lower; 2015 - post-tax loss approximately \$20 thousand lower), mainly as a result of exchange rate changes on translation of other accounts receivable and exchange rate changes on NIS-denominated cash and cash equivalents.

*Credit Risk.* Credit risks are managed at the Group level. The Group has no significant concentrations of credit risk. The Group has a policy to ensure collection through sales of its products to wholesalers with an appropriate credit history and through retail sales in cash or by credit card.

*Liquidity Risk.* Cash flow forecasting is performed by the Group's management both in the entities of the Group and aggregated by the Group. The Group's management monitors rolling forecasts of the Group's liquidity requirements to ensure it has sufficient cash to meet operations. The Group currently does not use credit facilities. Forecasting takes into consideration several factors such as raising capital to finance operations and certain liquidity ratios that the Group strives to achieve.

Surplus cash held to finance operating activities is invested in interest bearing current accounts, time deposits and other similar channels. These channels were chosen by reference to their appropriate maturities or liquidity to provide sufficient cash balances to the Group as determined by the abovementioned forecasts.

## **ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES**

Not applicable.





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**PART II**

**ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES**

Not applicable.

**ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS**

Not applicable.

**ITEM 15. CONTROLS AND PROCEDURES**

(a) *Disclosure controls and procedures.* Our management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rules 13a-15 and 15d-15 of the Securities Exchange Act of 1934. As of December 31, 2018, an evaluation was performed under the supervision and with the participation of our management of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, management, including the Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures as of December 31, 2017 were effective.

(b) *Internal controls over financial reporting.* Our management is responsible for establishing and maintaining adequate control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria established in *Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) (2013)*. Based on that evaluation, our management believes our internal control over financial reporting was effective as of December 31, 2018.

All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective may not prevent or detect misstatements and can provide only reasonable assurances with

respect to the preparation and presentation of financial statements.

(c) *Internal controls.* There have been no significant changes in our internal control over financial reporting that occurred during the year ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **ITEM 16. RESERVED**

### **ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT**

Our Board of Directors has determined that Osnat Hillel Fain, chairperson of our audit committee, is an audit committee financial expert, as defined by applicable SEC regulations, and is independent in accordance with applicable SEC regulations.

### **ITEM 16B. CODE OF ETHICS**

We have adopted a Code of Conduct applicable to all employees, directors and officers of our company, including our principal executive officer, principal financial officer, principal accounting officer or controller and other individuals performing similar functions. A copy of our Code of Conduct can be found on our website (<http://www.xtlbio.com>) and may also be obtained, without charge, upon a written request addressed to our investor relations department, XTL Biopharmaceuticals Ltd., 5 Badner St., Ramat Gan 5218102, Israel.

Table of Contents**ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES****Policy on Pre-Approval of Audit and Non-Audit Services of Independent Registered Public Accounting Firm**

Our audit committee is responsible for the oversight of the independent registered public accounting firm's work. The audit committee's policy is to pre-approve all audit and non-audit services provided by our independent registered public accounting firm, Kesselman & Kesselman, a member firm of PricewaterhouseCoopers International Ltd. ("PwC"). These services may include audit services, audit-related services and tax services, as further described below.

**Principal Accountant Fees and Services**

We were billed the following fees for professional services rendered by PwC, for the years ended December 31, 2018 and 2017.

	2018	2017
	U.S.	
	dollars in	
	thousands	
Audit fees	40	49
Tax services	5	6
Audit-related fees	-	25
Total	45	80

The audit fees for the years ended December 31, 2018 and 2017 were for professional services rendered for the audit of our annual consolidated financial statements, review of interim consolidated financial information and statutory audits, including Israeli tax reports.

The audit-related fees for the years ended December 31, 2018 and 2017 were for the Company's filing of registration statements.

For the fiscal years ended December 31, 2018 and 2017, all of our audit and audit-related fees were pre-approved by our audit committee.

**ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES**

Not applicable.

**ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS**

None.

**ITEM 16F. CHANGE IN REGISTRANT'S REGISTERED ACCOUNTANT**

None.

**ITEM 16G. CORPORATE GOVERNANCE**

Under the Nasdaq corporate governance rules, foreign private issuers are exempt from many of the requirements if they instead elect to comply with home country practices and disclose where they have elected to do so. As noted above, we are currently in compliance with Nasdaq rules relating to the independence of our board of directors and our audit committee. Our board of directors and our audit committee has adopted a written charter for the audit committee setting forth the responsibilities of the audit committee as required by the SEC and Nasdaq. Also as noted above, we currently have a nomination committee to identify, review and recommend to the Board of Directors individuals believed to be qualified to become directors. We have adopted a written charter for the nomination committee, as required by Nasdaq. We currently have in place a compensation committee, as discussed in more detail above. We have adopted a written charter for the compensation committee.

In August 2005, our board of directors adopted a Code of Conduct that applies to all employees, directors and officers of our company, including our principal executive officer, principal financial officer, principal accounting officer or controller and other individuals performing similar functions. A copy of our Code of Conduct may be obtained, without charge, upon a written request addressed to our investor relations department, XTL Biopharmaceuticals Ltd., 5 Badner St., Ramat Gan 5218102, Israel.

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**PART III**

**ITEM 17. FINANCIAL STATEMENTS**

We have elected to furnish financial statements and related information specified in Item 18.

**ITEM 18. FINANCIAL STATEMENTS**

**XTL BIOPHARMACEUTICALS LTD.**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2018**

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Report of Independent Registered Public Accounting Firm

**To the board of directors and the shareholders of XTL Biopharmaceuticals Ltd**

***Opinion on the Financial Statements***

We have audited the accompanying consolidated balance sheets of XTL Biopharmaceuticals Ltd and its subsidiary (the “Company”) as of December 31, 2018 and 2017, and the related consolidated statements of comprehensive income (loss), changes in equity and cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

***Basis for Opinion***

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures

included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Tel-Aviv, Israel /s/ Kesselman & Kesselman  
March 11, 2019 Certified Public Accountants (Isr.)  
A member firm of PricewaterhouseCoopers International Limited

We have served as the Company's auditor since 2001.

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,

P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, [www.pwc.com/il](http://www.pwc.com/il)

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## CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

	Note	December 31, 2018	2017 U.S. dollars in thousands
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents	5	3,255	3,289
Short term bank deposit	6	2,020	2,507
Marketable securities – InterCure Ltd	7	2,847	298
Prepaid expenses	8	73	112
		8,195	6,206
<b>NON-CURRENT ASSETS:</b>			
Intangible assets, net	9	380	380
Total assets		8,575	6,586
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Accounts payable	10	253	300
<b>NON-CURRENT LIABILITIES:</b>			
Warrants at fair value	12	-	2,667
<b>EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:</b>			
Share capital - ordinary shares of NIS 0.1 par value: Authorized - December 31, 2018 and 2017 – 1,450,000,000; Issued and outstanding - December 31, 2018 and 2017 - 514,205,799	14, 15	13,182	13,182
Premium on shares, options and warrants		147,708	146,015
Reserve from transactions with non-controlling interests		20	20
Other comprehensive income		-	47
Accumulated deficit		(152,588)	(155,645)
Total equity		8,322	3,619

Total liabilities and equity	8,575	6,586
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The accompanying notes are an integral part of the consolidated financial statements.

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Table of Contents**XTL BIOPHARMACEUTICALS LTD.**

## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Note	Year ended December 31,		
		2018	2017	2016
		U.S. dollars in thousands (except per share data)		
Research and development expenses	16	(38	) (43	) (443
General and administrative expenses	17	(755	) (1,203	) (1,270
Impairment of intangible assets	9	-	-	(848
Operating loss from continuing operations		(793	) (1,246	) (2,561
Issuance cost related to warrants to investors		-	(329	) -
Revaluation of warrants to purchase ADS's		974	765	-
Revaluation of marketable securities		2,753	-	-
Other finance income		87	37	23
Other finance expenses		(35	) (8	) (7
Finance income, net	18	3,779	465	16
Total income (loss)		2,986	(781	) (2,545
Other comprehensive income (loss)				
Items that may be reclassified to profit or loss:				
Changes in the fair value of available-for-sale financial assets		-	(116	) 163
Total comprehensive income (loss)		2,986	(897	) (2,382
Total income (loss) attributable to:				
Equity holders of the Company		2,986	(781	) (2,545
Total comprehensive income (loss) attributable to:				
Equity holders of the Company		2,986	(897	) (2,382
Basic and diluted earnings (loss) per share:		0.006	(0.002	) (0.009
Weighted average number of issued ordinary shares		514,205,799	470,188,629	274,035,533

\*)Representing amount less than \$1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

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XTL BIOPHARMACEUTICALS LTD.

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to equity holders of the Company					<b>Total equity</b>
	<b>Share capital</b>	Premium on shares, options and warrants	Accumulated deficit	Other comprehensive income	Reserve from transactions with non-controlling interests	
	U.S. dollars in thousands					
Balance as of January 1, 2018	13,182	146,015	(155,645 )	47	20	3,619
Impact of the adoption of IFRS 9	-	-	47	(47 )	-	-
Updated balance as of January 1, 2018	13,182	146,015	(155,598 )	-	20	3,619
Income for the year	-	-	2,986	-	-	2,986
Share-based payment to employees and non-employees	-	-	24	-	-	24
Reclassification of warrants (see Note 12)	-	1,693	-	-	-	1,693
Balance as of December 31, 2018	13,182	147,708	(152,588 )	-	20	8,322

	Attributable to equity holders of the Company					<b>Total equity</b>
	<b>Share capital</b>	Premium on shares, options and warrants	Accumulated deficit	Other comprehensive income	Reserve from transactions with non-controlling interests	
	U.S. dollars in thousands					
Balance as of January 1, 2017	6,624	150,784	(154,904 )	163	20	2,687
Loss for the year	-	-	(781 )	-	-	(781 )
Other comprehensive loss	-	-	-	(116 )	-	(116 )
Total comprehensive loss	-	-	(781 )	(116 )	-	(897 )
Share-based payment to employees and non-employees	-	-	40	-	-	40

Issuance of Ordinary Shares, net of issuance costs (\$ 164 thousands)	6,558	(4,769 )	-	-	-	1,789
Balance as of December 31, 2017	13,182	146,015	(155,645 )	47	20	3,619

The accompanying notes are an integral part of the consolidated financial statements.

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XTL BIOPHARMACEUTICALS LTD.

## CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY

	Attributable to equity holders of the Company					<b>Total equity</b>
	<b>Share capital</b>	Premium on shares, options and warrants	Accumulated deficit	Other comprehensive income	Reserve from transactions with non-controlling interests	
	U.S. dollars in thousands					
Balance as of January 1, 2016	6,606	150,748	(152,487 )	-	20	4,887
Loss for the year	-	-	(2,545 )	-	-	(2,545)
Other comprehensive loss	-	-	-	163	-	163
Total comprehensive loss	-	-	(2,545 )	163	-	(2,382)
Share-based payment to employees and non-employees	-	-	128	-	-	128
Issuance of shares	18	36	-	-	-	54
Balance as of December 31, 2016	6,624	150,784	(154,904 )	163	20	2,687

The accompanying notes are an integral part of the consolidated financial statements.

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XTL BIOPHARMACEUTICALS LTD.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2018	2017	2016
	Note U.S. dollars in thousands		
<u>Cash flows from operating activities:</u>			
Income (loss) for the year	2,986	(781 )	(2,545)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities (a)	(3,802)	(344 )	813
Net cash used in operating activities	(816 )	(1,125)	(1,732)
Cash flows from investing activities:			
Proceeds from selling of marketable securities	204	-	-
Investment in short-term bank deposit	(6,300)	(2,500)	-
Repayment of short-term bank deposit	6,800	-	-
Interest from bank deposit	74	4	-
Purchase of property and equipment	-	-	(2 )
Proceeds from sale of property and equipment	-	1	-
Purchase of intangible assets	9	-	(64 )
Net cash from (used in) investing activities	778	(2,495)	(66 )
Cash flows from financing activities:			
Proceeds from issuance of units comprise from ordinary shares and warrants, net of issuance costs	14	4,892	-
Net cash provided by financing activities	-	4,892	-
Increase (decrease) in cash and cash equivalents	(38 )	1,272	(1,798)
Gains (losses) from exchange rate differences on cash and cash equivalents	4	(2 )	* )-
Cash and cash equivalents at beginning of year	3,289	2,019	3,817
Cash and cash equivalents at end of year	3,255	3,289	2,019

\*)Representing amount less than \$1 thousand



The accompanying notes are an integral part of the consolidated financial statements.

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XTL BIOPHARMACEUTICALS LTD.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

		Year ended December 31,		
		2018	2017	2016
	Note	U.S. dollars in thousands		
<u>(a) Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:</u>				
Income and expenses not involving operating cash flows:				
Loss from disposal of property and equipment		-	9	3
Revaluation of marketable securities	7	(2,753)	-	-
Issuance costs related to warrants granted to investors		-	329	-
Revaluation of warrants to purchase ADS's		(974 )	(765)	-
Share-based payment transactions to employees and non-employees	15	24	40	182
Losses (gains) from exchange rate differences on cash and cash equivalents		(4 )	2	* )-
Impairment of intangible assets	9	-	-	848
Interest income		(87 )	(11 )	-
		(3,794)	(396)	1,033
Changes in operating asset and liability items:				
Decrease (increase) in other accounts receivable		39	209	(114 )
Decrease in accounts payable		(47 )	(157)	(106 )
		(8 )	52	(220 )
		(3,802)	(344)	813
<u>(b) Non-cash transactions:</u>				
Purchase of intangible asset		-	127	-
Interest on bank deposit		-	13	-
Share-based payment to third party		-	-	54

\*)Representing amount less than \$1 thousand

The accompanying notes are an integral part of the consolidated financial statements.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

NOTE 1: GENERAL

- a. A general description of the Company and its activity:

XTL Biopharmaceuticals Ltd. (the “Company”) is engaged in the development of therapeutics for the treatment of unmet medical needs. The Company was incorporated under the Israeli Companies Law on March 9, 1993. The registered office of the Company is located at 5 Badner Street, Ramat Gan, Israel.

The Company’s American Depository Shares (“ADSs”) are listed for trading on the Nasdaq Capital Market (“Nasdaq”) and its ordinary shares are traded on the Tel-Aviv Stock Exchange (“TASE”).

As of December 31, 2018, the Company has a wholly-owned subsidiary, Xtepo Ltd. (“Xtepo”), which was incorporated in Israel.

The Company and Xtepo are heretofore referred to as the Group.

The Company has incurred continuing losses and depends on outside financing resources to continue its activities. Based on existing business plans, the Company’s management estimates that its outstanding cash and cash equivalent balances will allow the Company to finance its activities for an additional period of at least 12 months from the date of this report. However, the amount of cash which the Company will need in practice to finance its activities depends on numerous factors which include, but are not limited to, the timing, planning and execution of clinical trials of existing drugs and future projects which the Company might acquire or other business development activities such as acquiring new technologies and/or changes in circumstances which are liable to cause significant expenses to the Company in excess of management’s current and known expectations as of the date of these Financial Statements and which will require the Company to reallocate funds against plans, also due to circumstances beyond its control.

The Company expects to incur additional losses in 2019 arising from research and development activities, testing additional technologies and operating activities, which will be reflected in negative cash flows from operating activities. In order to perform the clinical trials aimed at developing a product until obtaining its marketing approval, the Company will need to raise additional funds by issuing securities. Should the Company fail to raise additional capital at terms acceptable to the Company, it will be required to further reduce its development activities or sell or grant a sublicense to third parties to use all or part of its technologies.

c. Approval of financial statements:

These financial statements were authorized by the board of directors for issue on March 11, 2019.

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of the consolidated financial statements:

The consolidated financial statements of the Company (the “Financial Statements”) have been prepared in accordance with International Financial Reporting Standards (IFRSs), as issued by the International Accounting Standards Board (IASB).

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

The accounting policies have been consistently applied to all the years presented, unless otherwise stated and have been prepared under the historical cost convention, as adjusted for financial assets and liabilities measured at fair value.

The preparation of Financial Statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires the Group's management to exercise its judgment in the process of applying the Group's accounting policies. The areas that involve judgment which have significant effect or complexity or where assumptions and estimates are significant to the Financial Statements are disclosed in note 3. Actual results could significantly differ from the estimates and assumptions used by the Group's management.

b. Consolidated financial statements:

Subsidiary consolidation and business combinations:

The consolidated financial statements include the accounts of the Company and entities controlled by the Company. Control exists when the Company has the power over the investee; has exposure, or rights, to variable returns from involvement in the investee; and has the ability to use its power over the investee to affect its returns.

Subsidiary is fully consolidated starting from the date on which control therein is attained by the Company. The consolidation ceases when such control discontinues.

Intra-group balances and transactions, including expenses in respect of transactions between the Group companies, are eliminated.

c. Translation of balances and transactions in foreign currency:

1. Functional currency and presentation currency:

Items included in the Financial Statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the "Functional Currency"). The consolidated financial statements are presented in U.S. dollars, which is the Functional Currency of each of the Group's entities and the Company's presentation currency.

Below are the exchange rate of the U.S. dollar in relation to the NIS:

As of	Exchange rate of U.S. \$ 1 NIS
December 31, 2018	3.748
December 31, 2017	3.467

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)

2. Transactions and balances:

Transactions in a currency other than the Functional Currency (“Foreign Currency”) are translated into the Functional Currency using the exchange rates at the dates of the transactions. After initial recognition, monetary assets and liabilities denominated in Foreign Currency are translated at the end of each reporting period into the Functional Currency at the exchange rate at that date. Exchange differences are recognized in the statement of comprehensive income (loss) in the line item finance income (expenses), net. Non-monetary assets and liabilities denominated in foreign currency and measured at cost are translated at the exchange rate at the date of the transaction.

d. Property and equipment:

Items of property and equipment are measured at cost with the addition of direct acquisition costs, less accumulated depreciation and accumulated impairment losses.

Depreciation of property and equipment is calculated on a straight-line basis to reduce their cost to their residual value over their useful life as follows:

	<b>% per-year</b>
Computers	33
Office furniture and equipment	6 - 15 (mainly 6)

An asset’s carrying amount is written down immediately to its recoverable amount if the asset’s carrying amount is greater than its estimated recoverable amount (see also Note 2f).



e. Intangible assets:

1. Unamortized intangible assets (licenses and patent rights):

These assets are reviewed for impairment once a year and whenever there are indicators of a possible impairment, in accordance with the provisions of IAS 36, *Impairment of Assets* (see also Note 9). The amortization of an asset on a straight-line basis over its useful life begins when the development procedure is completed and the asset is available for use.

2. Research and development:

Research expenditures are recognized as expenses when incurred. Costs arising from development projects are recognized as intangible assets when the following criteria are met:

- it is technically feasible to complete the intangible asset so that it will be available for use;
- management intends to complete the intangible asset and use or sell it;
- there is an ability to use or sell the intangible asset;

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

- it can be demonstrated how the intangible asset will generate probable future economic benefits;  
adequate technical, financial and other resources to complete the development and to use or sell the intangible asset  
are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as an expense when incurred. Development costs that were previously recognized as an expense are not recognized as an asset in a later period. As of December 31, 2018 and 2017, the Group did not capitalize development project costs as intangible assets.

f. Impairment of non-financial assets:

Intangible assets which are not yet available for use are not depreciated and impairment in their respect is tested at least every year. Depreciable assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets that sustained impairment are reviewed for possible reversal of the impairment at each date of the statement of financial position.

g. Investments and other financial assets:

1. Classification:

From 1 January 2018, the Company classifies its financial assets in the following measurement categories:

those to be measured subsequently at fair value (either through OCI or through profit or loss)

those to be measured at amortized cost.

The influence of the initially applying the new standard was as follows:

The Company's marketable securities, which were equity instruments classified as Available-For-Sale financial assets, are now measured at fair value through profit or loss. Therefore, the accumulated appreciation of such marketable securities, which was included in accumulated other comprehensive income (\$47 as of December 31, 2017), were reclassified to the opening balance of retained earnings as of January 1, 2018.

The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

For assets measured at fair value, gains and losses will either be recorded in profit or loss or OCI. For investments in equity instruments that are not held for trading, this will depend on whether the group has made an irrevocable election at the time of initial recognition to account for the equity investment at fair value through other comprehensive income (FVOCI).

The Company reclassifies debt investments when and only when its business model for managing those assets changes.

2. Recognition and de-recognition:

Regular way purchases and sales of financial assets are recognized on trade-date, the date on which the group commits to purchase or sell the asset. Financial assets are derecognized when the rights to receive cash flows from the financial assets have expired or have been transferred and the Company has transferred substantially all the risks and rewards of ownership.

3. Measurement:

At initial recognition, the group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss (FVPL), transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at FVPL are expensed in profit or loss.

4. Impairment:

From 1 January 2018, the Company assesses on a forward looking basis the expected credit losses associated with its debt instruments carried at amortized cost and FVOCI. The impairment methodology applied depends on whether there has been a significant increase in credit risk.

Accounting policies applied until 31 December 2017:

1. Classification:

The Group classifies its financial assets into the loans and receivables and available for sale categories. The classification depends on the purpose for which the financial assets were acquired. The Group's management determines the classification of its financial assets at initial recognition.

*Loans and receivables:*

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than 12 months after the date of the statement of financial position. The Group's loans and receivables are included in the line items:

“other accounts receivable”, “cash and cash equivalents”, and short term bank deposit in the statements of financial position.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

2. Recognition and measurement:

Regular purchases and sales of financial assets are recognized in the books of the Group companies on the transaction settlement date which is the date on which the asset is transferred to the Group or transferred by the Group. Investments are initially recognized at fair value plus transaction costs and are subsequently carried at fair value through other comprehensive income (loss). Loans and receivables are subsequently carried at amortized cost using the effective interest method.

3. Impairment of financial assets:

*Assets classified as available-for-sale*

If there is objective evidence of impairment for available-for-sale financial assets, the cumulative loss is measured as the difference between the acquisition cost and the current fair value, less any impairment loss on that financial asset previously recognized in profit or loss is removed from equity and recognized in profit or loss.

Impairment losses on equity instruments that were recognized in profit or loss are not reversed through profit or loss in a subsequent period.

*Financial assets carried at amortized cost:*

The Group assesses at the date of each statement of financial position whether there is objective evidence that a financial asset or group of financial assets is impaired. Impairment losses are incurred only if there is an objective

evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset (a “loss event”) and that loss event (or events) has an impact on the estimated future cash flows of the financial asset or group of financial assets that can be reliably estimated.

The amount of the loss is measured as the difference between the asset’s carrying amount and the present value of estimated future cash flows (excluding future credit losses that have not been incurred) discounted at the financial asset’s original effective interest rate. The carrying amount of the asset is reduced and the amount of the loss is recognized in profit or loss

h. Cash and cash equivalents:

Cash and cash equivalents include cash at hand and short-term bank deposits with original maturities of three months or less, that are not restricted as to withdrawal or use, and are therefore considered to be cash equivalents.

i. Share capital:

The Company’s ordinary shares are classified as share capital. Incremental costs directly attributable to the issuance of new shares, options and warrants are shown in equity as a deduction, from the issuance proceeds.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

j. Trade payables:

Trade payables are the Group's obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Trade payables are initially recognized at fair value and subsequently measured at amortized cost using the effective interest method.

k. Employee benefits:

1. Employment benefits for retirement compensation/pension:

The Group operates various pension plans. The plans are generally funded through payments to insurance companies or trustee-administered funds. Said pension plans qualify for the criteria of defined contribution plan based on their terms.

2. Vacation and recreation benefits:

According to the Law, an employee is entitled to paid annual leave and sick leave on an annual basis. The entitlement is based on the number of years of service. The Company recognizes an obligation and expense for paid annual leave and sick leave based on the benefit accumulated for each employee.

l. Share-based payment:

The Group operates a number of share-based payment plan to employees, directors, officers and to other service providers who render services that are settled with the Group's equity instruments. In this framework, the Company



grants employees, from time to time, and, at its discretion, options to purchase shares of the Company. The fair value of options granted to employees is measured according to the Black-Scholes model as of the date of grant (the date of the Company's Board of Directors' decision unless shareholders' approval is required) and recognized as an expense in the statement of comprehensive income (loss) and correspondingly carried to equity. The total amount recognized as an expense over the vesting term of the options (the term over which all pre-established vesting conditions are expected to be satisfied) is determined by reference to the fair value of the options granted at grant date.

The fair value of options granted to service providers is measured based on the fair value of goods or services at the date it was received and recognized as an expense in the statement of comprehensive income (loss) during the period of the service/goods received and correspondingly carried to equity.

At each reporting date, the Company revises its estimates of the number of options that are expected to vest based on the non-market vesting conditions and recognizes the impact of the revision to original estimates, if any, in the statement of comprehensive income (loss) with a corresponding adjustment in equity.

When options are exercised, the Company issues new shares. The proceeds net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 2: SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

m. Income per share:

Basic income per share is calculated by dividing the income attributable to equity holders of the Company by the weighted average number of ordinary shares outstanding during the period, less treasury shares.

For the diluted earnings per share calculation, the weighted average number of shares outstanding during the year is adjusted for the average number of shares and warrants that are potentially issuable in connection with employee/service-provider share-based payment and warrants, using the treasury stock method. If the inclusion of potentially issuable shares would decrease loss per share, the potentially issuable shares are excluded from the weighted average number of shares outstanding used to calculate diluted earnings per share. In 2018 there was earning per share and not loss per share, therefore the weighted average number of shares for the diluted calculation could have been different from the one used for the basic calculation, if the share-based payment and warrants were in the money.

n. Issuance of units comprised of warrants and ordinary shares:

The Company allocated the total proceeds to the issuance components as follows:

While the warrants classified as financial liabilities, the Company has initially recognized them at fair value as of the date of issuance (measured through third-party appraiser, using a Black and Scholes model); In March 2018 the Company registered its warrants. This act cancelled the cashless exercise mechanism and therefore the Company reclassified the warrants from non-current liability to share premium.

The amount recognized in shareholders equity, which represents the funds attributed to the ordinary shares issued, was calculated as the difference between the total issuance proceeds and the fair value of the warrants at that date.

Incremental and direct issuance costs were allocated by the Company based on the relative value of the warrants (as calculated on the date of issuance) and the Ordinary Shares (calculated as the difference between the proceeds and the fair value of the warrants). The portion of issuance costs that was allocated to the warrants was recognized immediately as finance expenses in the statement of comprehensive income (loss) and the portion of issuance costs related to the Ordinary Shares was deducted from additional-paid in capital.

o. Segment information:

The Company operates in one operating segment.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 3: CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

a. Critical accounting estimates and assumptions:

Accounting estimates will, by definition, seldom equal the related actual results. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are addressed below.

Share-based payments - in evaluating the fair value of share-based payment, the Company's management is required to estimate, among others, different parameters included in the computation of the fair value of the options and the number of options that will vest.

Warrants - In accordance with International Accounting Standard 32: "Financial Instruments: Presentation", warrants allotted to investors with a cashless exercise mechanism are a "financial liability". As the aforementioned liability is a non-equity derivative financial instrument, it is classified in accordance with International Accounting Standard 32 "Financial Instruments: Presentation" as a financial liability at fair value through profit or loss, which is measured at its fair value using Black-Scholes model at each date of the balance sheet, with changes in the fair value carried to "revaluation of warrants to purchase ADS's" in the statements of comprehensive income (loss).

The Company's management is required to estimate, among others, different parameters included in the computation of the fair value of the warrants such as risk-free interest rate, expected volatility and dividend yield.

The aforementioned is not relevant since March 2018, when the Company registered its warrants. This act cancelled the cashless exercise mechanism and therefore the Company allocated the warrants from non-current liability to share premium.

**NOTE 4: FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT**

a. Financial risk management:

1. Financial risk factors:

The Group's activities expose it to a variety of financial risks: market risks, currency risk and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance.

Risk management is carried out by the Group's management under policies approved by the Board. The Group's treasury identifies, evaluates and defines financial risks. The Board provides written principles for overall risk management, as well as written policies covering specific areas, such as foreign exchange risk, interest rate risk and investment of excess liquidity.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 4: FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (Cont.)**

a. Market risks:

*Foreign currency exchange rate risk:*

The Group operates internationally and is exposed to foreign exchange risk arising from various currency exposures with respect to the NIS. Foreign

exchange risk arises from assets and liabilities denominated in currency that is other than the functional currency.

The Company treasury's risk management policy is to hold NIS-denominated cash and cash equivalents in the amount of the anticipated NIS-denominated

liabilities for six to twelve consecutive months from time to time and this in line with the directives of the Company's Board.

As of December 31, 2018, had the Group's functional currency strengthened by 8% against the NIS with all other variables remaining constant, post-tax profit for the year would have been \$289 thousand higher (2017 - loss approximately \$38 thousand lower; 2016 - loss approximately \$22 thousand lower), mainly as a result of exchange rate changes on translation of other accounts receivable and exchange rate changes on NIS-denominated cash and cash equivalents.

b. Liquidity risk:

Cash flow forecasting is performed by the Group's management both in the entities of the Group and aggregated by the Group. The Group's management monitors rolling forecasts of the Group's liquidity requirements to ensure it has sufficient cash to meet operations. The Group does not use borrowing credit facilities.

Surplus cash held to finance operating activities is invested in interest bearing current accounts and time deposits. These channels were chosen by reference to their appropriate maturities or liquidity to provide sufficient cash balances to the Group as determined by the abovementioned forecasts.

As of December 31, 2018 and 2017, the maturity of the Group's financial liabilities are less than one year from each of the reporting dates.

2.

Capital management:

The Group's objectives when managing capital are to ensure the Group's ability to continue as a going concern in order to provide returns on investments for shareholders and benefits for other interested parties and to maintain an optimal capital structure to reduce the cost of capital.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 4: FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (Cont.)**

In order to maintain or adjust the capital structure, the Group may take a variety of measures such as issue new shares or sell assets to reduce liabilities.

b. Financial instruments by category:

From January 1, 2018 all financial assets are classified in one of two categories: (a) those to be measured subsequently at fair value (either through OCI or through profit or loss) and (b) those to be measured at amortized cost.

As of December 31, 2017 all financial assets were classified in one of two categories: (a) loans and receivables, measured at amortized cost, and (b) marketable securities measured at fair value.

As of December 31, 2018 all financial liabilities were classified as (a) Trade and other account payables, measured at amortized cost.

As of December 31, 2017 all financial liabilities were classified in one of two categories: (a) Trade and other account payables, measured at amortized cost, and (b) warrants measured at fair value.

c. Changes in financial liabilities classified as cash flow from finance activities:

	Warrants Total U.S. dollars in thousands	
Balance as of January 1, 2018	2,667	2,667



Revaluation during the year	(974 )	(974 )
Reclassification of warrants (see Note 12)	(1,693)	(1,693)
Balance as of December 31, 2018	-	-

	Warrants	Total
	U.S. dollars in thousands	
Balance as of January 1, 2017	-	-
Fair value as of issuance date	3,432	3,432
Revaluation during the year	(765 )	(765 )
Balance as of December 31, 2017	2,667	2,667

**NOTE 5: CASH AND CASH EQUIVALENTS**

	December 31,	
	2018	2017
	U.S. dollars in thousands	
Cash in banks and on hand	946	1,083
Bank deposits with original maturities of three months or less*	2,309	2,206
	3,255	3,289

\*Deposit with maturity of three months, which bear an interest of 2.27% per annum (in 2017: 1.22%-1.4%).

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 5: CASH AND CASH EQUIVALENTS (Cont.)**

The currencies in which the cash and cash equivalents are denominated or linked to are:

	December 31,	
	2018	2017
	U.S. dollars in thousands	
U.S. dollars	3,168	3,172
NIS (not linked to the Israeli CPI)	87	117
	3,255	3,289

**NOTE 6: SHORT-TERM BANK DEPOSIT**

The deposit bears an annual interest of 2.38% (in 2017: 1.4%) and was deposited for a six months period.

The deposit is invested with high quality financial corporation in Israel.

**NOTE 7: MARKETABLE SECURITIES – InterCure Ltd**

All marketable securities held by the Company constitute Level 1 financial instruments, as defined in IFRS 13 - “*Fair a. Value Measurement*”. Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date.

- b. The Company holds the following financial instruments:

December  
31,  
2018 2017  
U.S. dollars  
in thousands

Marketable securities 2,847 298

Marketable securities 2,847 298

The entire investment in marketable securities is classified as a financial asset at fair value through profit or loss.

- c. Changes in marketable securities for the years ended December 31, 2018 and 2017, were as follows:

December 31,  
2018 2017  
U.S. dollars  
in thousands

Fair value opening balance	298	414
Sales	(204 )	-
Changes in fair value during the year	2,753	(116)
	2,847	298

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 8: PREPAID EXPENSES**

Composition:

	December 31, 2018 2017 U.S. dollars in thousands	
Government authorities (*)	11	15
Prepaid expenses	51	85
Other	11	12
	73	112

(\*) The government authorities and others are monetary items which are denominated or linked is NIS.

The carrying amount of other accounts receivable is a reasonable approximation of the fair value because the effect of discounting is immaterial.

**NOTE 9: INTANGIBLE ASSETS**

In 2010 the Company acquired 100% of the shares of Xtepo, which for the Transaction purposes held an exclusive<sup>a</sup> license to use the patented recombinant EPO (rHuEPO) drug for treating Multiple Myeloma.

Following the acquisition, the Company recognized in its accounts an intangible asset representing the license for the exclusive use of the patent for the rHuEPO drug as well as every clinical study and accumulated know how underlying the patent.

According to the guidance of IAS 38, this asset is not ready for usage according to the Company's management intention and therefore has not amortized yet and the Company reviews the asset for impairment once a year or more frequently if indicators show that the asset may be impaired.

As of December 2015, The asset impairment test (in accordance with the guidance of IAS 36) showed that the book value of the rHuEPO intangible asset exceeded its recoverable amount by \$1,604 thousand. Therefore, a loss from impairment was recorded.

The Company's Board of Directors decided on the abandonment of the EPO development and therefore the carrying amount of the rHuEPO intangible asset of \$848 has been reduced to zero as of December 31, 2016 in a separate line in the statement of comprehensive income (loss).

On January 7, 2014, the Company signed a licensing agreement with Yeda to develop hCDR1, a Phase II-ready asset for the treatment of Systemic Lupus Erythematosus ("SLE"). The terms of the licensing agreement include, b. among other things, expense reimbursement for patent expenses payable in six installments, certain milestone payments to Yeda, low single-digit royalties based on net sales, and additional customary royalties to the Office of the Israel innovation authority.

This asset is not ready for usage (the development was abandoned before finishing) and therefore has not been amortized yet.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 9: INTANGIBLE ASSETS (Cont.)**

As of December 31, 2018 all royalties to Yeda were paid except for a remaining liability of \$127 thousand, disclosed under other accounts payable.

The Company reviews the hCDR1 asset for impairment once a year on December 31 or more frequently if events or changes in circumstances indicate that there is impairment.

If the carrying amount exceeds their recoverable amount, the assets are reduced to their recoverable amount.

In order to measure the recoverable amount of the hCDR1 asset, Company management deducted the fair value of its other assets and liabilities from the amount representing its market value as of December 31, 2018. The resulting fair value attributable to the hCDR1 asset was higher than the book value of the hCDR1 asset and therefore no impairment was recorded in the Company's financial statements as of December 31, 2018.

The Company exclusively licensed two families of patents relating to hCDR1:

One expires on September 22, 2022 and the other expires on January 14, 2024.

c. Composition and movement:

The composition of intangible assets, net, by major classes, and the movement therein in the three years ended December 31, 2018, 2017 and 2016, are:

	rHuEPO	hCDR1	Total
Cost:			
Balance at January 1, 2018	-	380	380
Amortized cost at December 31, 2018	-	380	380

	rHuEPO	hCDR1	Total
Cost:			
Balance at January 1, 2017	-	253	253
Additions during the year	-	127	127
Amortized cost at December 31, 2017	-	380	380

	rHuEPO	hCDR1	Total
Cost:			
Balance at January 1, 2016	848	189	1,037
Additions during the year	-	64	64
Impairment of intangible assets	(848 )	-	(848 )
Amortized cost at December 31, 2016	-	253	253

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Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018****NOTE 10: ACCOUNTS PAYABLE**

## a. Composition:

	December 31, 2018 2017 U.S. dollars in thousands	
Trade payables	8	4
Employees, consultants and payroll accruals	20	20
Accrued expenses	225	276
	253	300

The carrying amount of other accounts payable is a reasonable approximation of their fair value because the effect of discounting is immaterial.

## b. The carrying amount of other accounts payable is denominated in the following currencies:

	December 31, 2018 2017 U.S. dollars in thousands	
U.S. dollars	189	244
NIS (not linked to the Israeli CPI)	64	56



**NOTE 11: EMPLOYEE BENEFIT LIABILITIES**

According to the effective labor laws and employment agreements in Israel, the Company is obligated to pay compensation and/or pension to employees who are dismissed and, under certain circumstances, to employees who retire.

The Company's obligation for pension payment in Israel and the Company's obligation for compensation payments to employees in Israel for whom the applicable obligation is pursuant to section 14 to the Severance Pay Law, are covered by fixed contributions into defined contribution plans. The amounts contributed as above are not reflected in the statements of financial position. Section 14 to the Severance Pay Law applies to all of the Company's employees.

The amounts recognized as expenses for defined contribution plans for employees of the Company in 2018, 2017 and 2016 was \$6, \$11 and \$17 thousand, respectively.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 12: WARRANTS**

During the year ended December 31, 2017, the Company raised gross funds amounted to \$5,300 thousand by issuance of 2,400,000 ADS's and 2,400,000 warrants to purchase the same amount of ADS's. The warrants shall be exercisable six months following the issuance date and will expire five and one-half years from the issuance date. The number of warrants and their exercise price could be adjusted upon standard anti-dilution protection clauses and subject to a cashless exercise mechanism (see also Note 14e).

IFRS 13 "Fair Value Measurement", ("IFRS 13"), defines fair value as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

IFRS 13 also establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. A financial instrument's categorization within the fair value hierarchy is based on the lowest level of input that is significant to the fair value measurement. IFRS 13 establishes three levels of inputs that may be used to measure fair value.

Level 1 - quoted prices in active markets for identical assets or liabilities;

Level 2 - inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices in active markets for similar assets or liabilities, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; or

Level 3 - unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The Company accounted for the warrants issued to investors with a cashless exercise mechanism as a non-current liability according to provisions of IAS 32. The Company measured the warrants at fair value by using a Black and Scholes model. The warrants were measured in each reporting period. Changes in the fair value were recognized in the Company's statement of comprehensive income (loss) as financial income or expense, as appropriate. The warrants were classified as level 3.

In March 2018 the Company registered its warrants. This act cancelled the cashless exercise mechanism and therefore the Company reclassified the warrants from non-current liability to share premium.

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Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018****NOTE 12: WARRANTS (Cont.)**

The Company used the following assumptions to estimate the Investors' warrants:

	<b>As of March 8, 2018 (Reclassification to premium)</b>		<b>As of December 31, 2017</b>		<b>As of March 7, 2017 (Second Issuance date)</b>		<b>As of February 16, 2017 (First Issuance date)</b>	
Risk-free interest rate (1)	2.61	%	2.18	%	2.11	%	2.05	%
Expected volatility (2)	65.5	%	61.1	%	70.26	%	70.22	%
Contractual term life (in years) (3)	4.5		4.6		5.5		5.5	
Dividend yield (4)	0	%	0	%	0	%	0	%

(1) Risk-free interest rate - based on yield rates of non-index linked U.S. Federal Reserve treasury bonds.

(2) Expected volatility - was calculated based on actual historical share price movements of the Company over a term that is equivalent to the contractual term of the option. If the change in standard deviation for that warrants shifted +/- 5%, the impact on profit or loss would be \$162 thousands and \$159 thousands, respectively. The higher the standard deviation, the higher the fair value.

(3) Expected life - the expected life was based on the expiration date of the warrants.

(4) Dividend yield - was based on the fact that the Company has not paid dividends to its shareholders in the past and does not expect to pay dividends to its shareholders in the future.

**NOTE 13: COMMITMENTS**

a. Royalty and contingent milestone payments:

On August 3, 2010, the Company entered into Asset Purchase Agreement (“APA”) to acquire from Bio-Gal the rights to develop rHuEPO for the treatment of multiple myeloma under the research and license agreement with Yeda (see also Note 9b). According to the APA, the Company is obligated to pay 1% royalties on net sales of the developed product as well as a fixed royalty payment in the amount of \$350 thousand upon the successful completion of a phase 2 clinical trial. The payment conditions for the above amount are at the earlier of occurrence of the following events:

- (i) Raising capital of at least \$2 million by the Company or Xtepo after a successful completion of a phase 2 clinical trial;
- (ii) Six months after the successful completion of a phase 2 clinical trial.

As of December 31, 2018, the Company has not completed the phase 2 clinical trial and therefore no royalty expenses have been recorded.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 13: COMMITMENTS (Cont.)**

In August 2017, the annual General Meeting of Shareholders, approved the terms of the new Employment Agreement with the Company's Chief Executive Officer ("CEO") which includes among the others reduction in his capacity to 50% commencing June 11, 2017, one-time bonus upon achieving milestones, grant of 1,000,000 options to purchase 1,000,000 Ordinary Shares of the Company at an exercise price of NIS 0.11 and acceleration of vesting period of the aforementioned granted options upon specific milestone achievement regarding the lupus property and/or HCDR1 product.

**NOTE 14: SHARE CAPITAL, RESERVES AND RETAINED EARNINGS**

The Company's Ordinary shares of NIS 0.1 are traded on the TASE. The Company's ADSs are listed for trading on the Nasdaq Capital Market in the U.S. The share price was NIS 0.064 as of December 31, 2018.

Ordinary shares confer upon their holders voting rights and right to participate in the shareholders' meeting, right to receive dividends and the right to participate in the excess of assets upon liquidation of the Company.

On June 1, 2012, the Company applied for the relisting of its ADSs on the Nasdaq (delisted in July 2009). The Company changed the number of shares underlying the ADSs such that 20 ordinary shares will constitute a single ADS, this in order to support the Company's compliance with the listing conditions. The relisting application was approved and on July 15, 2013, the Company's ADSs began trading on Nasdaq.

In February 2016 and May 2016, the Company issued total of 680,000 ordinary shares, represented by 6,800 ADSs, to a service provider, as part of the terms of a investor relationship service agreement signed in January 2016. Consequently, the Company recorded expenses amounted to \$54 thousand, which representing the fair value of the ordinary shares in January 2016.

On August 3, 2017, the Company held its Annual General Meeting of Shareholders, pursuant to which, inter alia, it was decided to increase the Company's authorized share capital from 700,000,000 Ordinary Shares to 1,450,000,000

Ordinary Shares.

e. Investment rounds:

On February 17, 2017, the Company entered into a Securities Purchase Agreement (“SPA”) with Institutional Investors (“Investors”) for the sale of 1,000,000 registered ADS’s for gross proceeds of \$2,500 thousand, representing a purchase price of \$2.50 per ADS in a registered direct offering (“Offering”). Additionally, for each ADS purchased by Investors, the Investors received an unregistered warrant to purchase one ADS (“Warrant”). The Warrant has an exercise price of \$4.10 per ADS, shall be exercisable six months following the issuance date and will expire five and one-half years from the issuance date. The closing of the Offering took place on February 23, 2017.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

**NOTE 14: SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

In addition, the Company entered into engagement agreement (“Agreement”) with an exclusive Placement Agent (“Agent”) pursuant to which at the closing of each Offering, the Company will compensate the Agent for its service under the Agreement as follows:

Cash fee equal to 7% of the aggregate gross proceeds raised in each Offering, except that in relation to any proceeds raised from certain existing shareholders of the Company participating in an Offering and listed in the Agreement (“Existing Shareholders”), the Company shall pay to the Agent a cash fee equal to 3.5% of the aggregate gross proceeds raised from such Existing Shareholders in each such Offering. In addition, the Company shall pay the Agent a cash management fee equal to 1% of the aggregate gross proceeds raised in each Offering.

Warrants to purchase ADS’s equal to 5% of the aggregate number of warrants to purchase ADS’s placed in each Offering. The Warrant shall have the same terms as the warrants, if any, issued to investors in the applicable Offering. If no warrants are issued to investors in an Offering, the Warrant shall have a term of five years and an exercise price equal to 120% of the then market price of the ADS’s. The fair value of such warrants amounted to \$84 thousand at the issuance date.

Expense allowance equal to \$35 thousand for accountable fees and expenses of HCW (other than legal) as defined in the Agreement.

The direct and incremental costs related to the aforementioned Offering under SPA amounted to approximately \$429 thousand (\$84 thousand related to warrants granted to Agent’s).

On March 7, 2017, the Company entered into private placement transaction with existing investors pursuant to which 1,400,000 ADS’s have been issued at a purchase price of \$2.00 per ADS for total gross consideration of \$2,800 thousand. The direct and incremental costs related to the aforesaid transaction amounted to \$64 thousand.



In addition, for each ADS's purchased by investors, the investors will receive an unregistered warrant to purchase one ADS subject to authorized capital increase through the Company's shareholders meeting. The warrants have a term of five and a half years, an exercise price of \$2.30 per ADS and shall be exercisable on the later of the effectiveness of the authorized share increase or six months following the issuance date. The closing of the offering took place on March 22, 2017.

The exercise price of the aforementioned warrants is adjusted upon standard anti-dilution protections clauses but the number of warrants is subject to cashless exercise mechanism pursuant to which the fixed to fixed test is not met and therefore the warrants are accounted for as a non-current liability.

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Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018****NOTE 14: SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

The Company allocated the issuance costs based on the relative value of the warrants (as calculated on the date of issuance) and the Ordinary Shares (calculated as the difference between the proceeds and the fair value of the warrants). The portion of issuance costs that was related to the warrants was recognized immediately as finance expenses in the statement of comprehensive income (loss) and the portion of issuance costs related to the Ordinary Shares was deducted from additional-paid in capital.

Total amount of \$329 thousand (\$291 thousand related to the investment during February 2017 and \$38 thousands related to the investment during March 2017) was recognized as finance expenses which is reflecting the portion of issuance costs that were allocated the issued warrants (see Note 12).

Amount of \$165 thousand was deducted from additional-paid in capital as it was allocated to the Ordinary Shares.

## f. Outstanding warrants:

The table below summarizes the outstanding warrants as of December 31, 2018 -

Warrants outstanding to purchase ADSs	Number of shares exercisable	Issuance date	Exercise price in USD (per warrant)	Expiration date
177,778 (*)	17,777,780	April 1, 2015	2.25	March 30, 2020
14,444 (*)	1,444,440	April 1, 2015	2.81	March 30, 2020
1,050,000	105,000,000	February 17, 2017	4.1	August 16, 2022
1,400,000	140,000,000	March 7, 2017	2.3	September 6, 2022

2,642,222      264,222,220

On January 17, 2017, the Company's Board of Directors approved the change which was effective as of February 10, 2017 in the number of shares underlying the ADSs such that 100 ordinary shares of the Company will constitute a single ADS, this in order to support the Company's compliance with the Nasdaq's ADS listing conditions. All ADS data was adjusted to reflect the current ADS to ordinary share ratio, meaning 1:100.

NOTE 15: SHARE-BASED PAYMENT

On August 29, 2011, the Company's Board of Directors approved the adoption of an employee share option plan for the grant of options exercisable into shares of the Company in accordance with section 102 to the Israeli Tax Ordinance (the "2011 Plan") which ended after 10 years, and the holding of up to 10,000,000 shares in the framework of the 2011 Plan, for option allocation to Company employees, directors and consultants. The terms of the options which will be granted according to the 2011 Plan, including the option period, exercise price, vesting period and exercise period shall be determined by the Company's Board of Directors on the date of the actual allocation. As of December 31, 2018, the remaining number of options available for grant under the 2011 Plan is 3,800,000 options.

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Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018**

## NOTE 15: SHARE-BASED PAYMENT (Cont.)

Movements in the number of share options and their related weighted average exercise prices (in dollars) during the years ended December 31, 2018, 2017 and 2016 are as follows:

	Year ended December 31, 2018		2017		2016	
	Number of options	Weighted average exercise price (USD)	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding at beginning of year	7,355,833	0.16	6,750,000	0.17	4,870,000	0.15
Granted	-	-	1,000,000	0.03	2,950,000	0.16
Exercised	-	-	-	-	-	-
Expired	(1,155,833)	0.16	(40,000 )	0.21	(1,070,000)	0.08
Forfeited	-	-	(354,167 )	0.14	-	-
Outstanding at end of year	6,200,000	0.15	7,355,833	0.16	6,750,000	0.17
Exercisable at end of year	5,529,166	0.16	5,514,166	0.19	3,833,333	0.18

Below is information about the exercise price (in dollars) and the remaining contractual life (in years) for options outstanding at end of year:

December 31, 2018	Options	Range of exercise prices (USD)	Weighted average remaining contractual	2017	Options	Range of exercise prices (USD)	Weighted average remaining contractual
Options outstanding at end of year				Options outstanding at end of year			

	life		life
2,150,000 0 - 0.14	7.24	2,362,500 0 - 0.14	7.55
4,050,000 0.15 - 1.6	6.12	4,993,333 0.15 -1.6	5.86
6,200,000		7,355,833	

Net expenses recognized in the Company's statements of comprehensive income (loss) for the years ended December 31, 2018, 2017 and 2016 for grant of options to employees were \$24, \$40 and \$182 thousand, respectively.

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Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018****NOTE 15: SHARE-BASED PAYMENT (Cont.)**

The table below summarizes the outstanding options as of December 31, 2018 that have been granted to the Company's executives, directors and consultants -

Options outstanding	Position	Grant date (*)	Exercise price in NIS	Fair value USD	Vesting schedule
900,000	Chief Executive Officer	October 15, 2013	0.9	143	12 equal portions each quarter over a period of 3 years from the grant date
600,000	Chief Executive Officer	October 15, 2013	0.6	97	12 equal portions each quarter over a period of 3 years from the grant date
600,000	Four Directors	December 30, 2014	0.4325	46	33.33% of the stock options vest following the lapse of 12 months from the grant date, and the remaining 66.67% vest in 8 equal portions each quarter over a period of 2 years from the first
150,000	Consultant	December 30, 2014	0.4915	12	33.33% of the stock options vest following the lapse of 12 months from the grant date, and the remaining 66.67% vest in 8 equal portions each quarter over a period of 2 years from the first
300,000	Two Directors	March 25, 2015	0.40	24	33.33% of the stock options vest following the lapse of 12 months from the grant date, and the remaining 66.67% vest in 8 equal portions each quarter over a period of 2 years from the first
100,000	Chief Executive Officer	March 25, 2015	0.4	7	33.33% of the stock options vest following the lapse of 12 months from the grant date, and the remaining 66.67% vest in 8 equal portions each quarter over a period of 2 years from the first
50,000	Medical Director	March 4, 2016	0.6	2	12 equal portions each quarter over a period of 3 years from the date of grant
1,500,000			0.6	63	

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	Chairman of Board	March 31, 2016			12 equal portions each quarter over a period of 3 years from the date of grant
1,000,000	Chief Executive Officer	March 31, 2016	0.6	42	33.33% of the stock options vest following the lapse of 12 months from the grant date, and the remaining 66.67% vest in 8 equal portions each quarter over a period of 2 years from the first anniversary
1,000,000	Chief Executive Officer	August 3, 2017	0.11	28	33.33% of the stock options vest following the lapse of 12 months from the grant date, and the remaining 66.67% vest in 8 equal portions each quarter over a period of 2 years from the first anniversary
6,200,000					

(\* )Date of the Company's Board of Directors' decision (or shareholders, if required).

The fair value for options granted in 2018 and 2017 is estimated at the date of grant using a Black-Scholes-Merton Options pricing model with the following weighted average assumptions:

	2018(*)	2017
Dividend yield	-	0 %
Expected volatility	-	76.8 %
Risk-free interest	-	1.87 %
Expected life (years)	-	10

(\* )There were no new grants in 2018.

We have calculated the volatility based on the company's historical volatility and comparable companies' historical volatility. The share price was set according to the Company's share market value.

Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018****NOTE 16: RESEARCH AND DEVELOPMENT EXPENSES**

	Year ended December 31, 2018 2017 2016 U.S. dollars in thousands		
Fees related to service providers	38	51	145
Expenses relating to options to employees and non-employees	-	2	7
Professional consulting	-	-	109
Lab materials	-	2	134
Other	-	(12 )	48
	38	43	443

**NOTE 17: GENERAL AND ADMINISTRATIVE EXPENSES**

	Year ended December 31, 2018 2017 2016 U.S. dollars in thousands		
Salaries and expenses relating to employees and service providers	109	247	297
Expenses relating to options and shares to employees and non-employees	22	37	175
Patents and fees	121	158	162
Directors' fees	140	119	124
Investor relations and travel	24	98	168
Rent and office maintenance	18	29	39
Insurance	48	34	48
Professional services	255	*440	213
Other	18	41	44



\*)An amount of \$206 thousands related to F-1 registration and amendments.

**NOTE 18: FINANCE INCOME (EXPENSES), NET**

	Year ended December 31, 2018 2017 2016		
	U.S. dollars in thousands		
Finance expenses:			
Issuance cost related to warrants to investors	-	329	-
Bank account management fees and commissions	7	8	7
Exchange differences	28	-	-
Total finance expenses	35	337	7
Finance income:			
Revaluation of warrants to purchase ADS's	974	765	-
Revaluation of marketable securities	2,753	-	-
Interest income on bank deposits	87	16	-
Exchange differences	-	21	23
Total finance income	3,814	802	23
Finance income, net	3,779	465	16

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Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018****NOTE 19: TAXES ON INCOME**

a. Tax rates applicable to the Company:

1. Taxable income of the Company is subject to a corporate tax rate as follow: 2016 - 25%, 2017 - 24% and 2018 - 23%.

In December 2016, the Israeli Parliament approved the Economic Efficiency Law (Legislative Amendments for 2. Applying the Economic Policy for the 2017 and 2018 Budget Years), 2016 which reduces the corporate income tax rate to 24% (instead of 25%) effective from January 1, 2017 and to 23% effective from January 1, 2018.

b. The Group's carryforward tax losses as of December 31, 2018, totaled approximately \$35 million which may be carried forward and offset against taxable income in the future for an indefinite period. The Company did not recognize deferred taxes for carryforward losses and temporary differences, as well as capital losses and real losses, because their utilization in the foreseeable future is not probable.

Below is the reconciliation between the "theoretical" tax expense, assuming that all the income were taxed at the regular tax rate applicable to companies in Israel and the taxes recorded in the statements of comprehensive income (loss) in the reporting year:

	Year ended December 31,		
	2018	2017	2016
	U.S. dollars in thousands		
Income (loss) before taxes on income, as reported in the statements of comprehensive income (loss)	2,986	(781)	(2,545)
Theoretical tax expense (benefit)	687	(187)	(636)
Expenses (income) not recognized for tax purposes	(201)	(95)	32
Temporary differences in the reported year for which no deferred taxes were recognized	(633)	-	-

Increase in taxes resulting mainly from taxable losses in the reported year for which no deferred taxes were recognized	147	282	604
Tax benefit	-	-	-

d. Tax assessments:

The Company filed self-assessments that are deemed final through the 2013 tax year. Xtepo has not received tax assessments since its incorporation in November 2009.

**NOTE 20: TRANSACTIONS AND BALANCES WITH RELATED PARTIES**

“Related party” - as the term is defined in IAS 24, “*Related Party Disclosures*” (“IAS 24”).

The Company’s key management personnel who are included, along with other factors, in the definition of related party, as above in IAS 24, includes directors, members of the executive committee and InterCure Ltd.

Table of Contents**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2018****NOTE 20: TRANSACTIONS AND BALANCES WITH RELATED PARTIES (Cont.)**

Compensation to key management personnel:

The compensation to key management personnel for employee services provided to the Company is shown below:

	Year ended December 31,		
	2018	2017	2016
	U.S. dollars in thousands		
Salaries, management and consulting fees and other short-term benefits	283	373	407
Pension, post retirement and other benefits	7	12	17
Share-based payments, net	22	39	127
	312	424	551
Number of persons	9	9	10

As of December 31, 2018 and 2017, the Company's balances with related parties total approximately \$71 thousand (\$20 thousand out of which were linked to the NIS) and \$24 thousand (of which \$24 thousand were linked to the NIS), respectively.

For further information regarding share-based payment to related parties, see also Note 15 above.

InterCure Ltd:

The Company's investment in the shares of InterCure Ltd (is presented as Marketable securities.

As of December 31, 2018 and 2017, the Company's balances of InterCure Ltd's shares total approximately \$2,847 thousand and \$298 thousand, respectively.

As of December 31, 2018 and 2017, the Company's share in the shares of InterCure Ltd was 2.56% and 3.58%, respectively.

#### **NOTE 21: EARNINGS (LOSS) PER SHARE**

In 2018 there was earning per share and not loss per share, therefore the weighted average number of shares for the diluted calculation could have been different from the one used for the basic calculation, if the share-based payment and warrants were in the money.

All outstanding options and warrants could be exercised to 6,200,000 and 264,222,220 ordinary shares, respectively.

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**ITEM 19. EXHIBITS**

The following exhibits are filed as part of this annual report:

**Exhibit No. Description**

- 1.1 Articles of Association (9)
- 1.2 Form of Share Certificate (including both Hebrew and English translations) (2)
- 1.3 Form of American Depositary Receipt (included in Exhibit 10.1)
- 4.1 Deposit Agreement, dated as of August 31, 2005, by and between XTL Biopharmaceuticals Ltd., The Bank of New York, as Depository, and each holder and beneficial owner of American Depositary Shares issued thereunder (1)
- 4.2 2011 Share Option Plan dated August 29, 2011 (6)
- 4.3 Research and License Agreement Between Yeda Research and Development Company Ltd., Mor Research Applications Ltd., Biogal Ltd. (under its previous name Haverfield Ltd.) and Biogal Advanced Biotechnology Ltd. dated January 7, 2002 (3) †
- 4.4 Amendment to Research and License Agreement Between Yeda Research and Development Company Ltd., Mor Research Applications Ltd., Haverfield Ltd. and Biogal Advanced Biotechnology Ltd. effective as of April 1, 2008 (3) †
- 4.5 Option to License Agreement, dated as of September 1, 2010, between XTL Biopharmaceuticals Ltd. and Yeda Research and Development Company Limited (4)
- 4.6 License Agreement dated January 7, 2014, by and between Yeda Research and Development Company Limited and XTL Biopharmaceuticals Ltd (5)
- 4.7 Form of First Amendment to License Agreement by and by and between Yeda Research and Development Company Limited and XTL Biopharmaceuticals Ltd (6)
- 4.8 Form of Employment Agreement dated September 11, 2013 between XTL Biopharmaceuticals Ltd. and Joshua Levine (6)
- 4.9 Form of Employment Agreement dated January 9, 2014 between XTL Biopharmaceuticals Ltd. and David Kestenbaum (6)
- 4.10 Form of Consulting Agreement dated January 1, 2015 between XTL Biopharmaceuticals Ltd. and Schapiro Education Ltd. (6)

- 4.11 Letter Agreement between Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC, and XTL Biopharmaceuticals Ltd. dated November 7, 2016 (7)
- 4.12 Amendment to Letter Agreement between Rodman & Renshaw, a unit of H.C. Wainwright & Co., LLC, and XTL Biopharmaceuticals Ltd. dated February 16, 2017 (7)
- 4.13 Form of Securities Purchase Agreement dated February 17, 2017 (7)
- 4.14 Form of Warrant issued February 17, 2017 (7)
- 4.15 Form of Employment Agreement dated June 11, 2017 between XTL Biopharmaceuticals Ltd. and Joshua Levine (10)
- 4.16 Form of Securities Purchase Agreement dated March 7, 2017 (8)
- 4.17 Form of Warrant issued March 10, 2017 (8)

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**Exhibit No. Description**

8.1	<u>List of Subsidiaries (6)</u>
12. 1	<u>Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 11, 2019.*</u>
12.2	<u>Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 11, 2019.*</u>
13.1	<u>Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 USC. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 11, 2019*</u>

\*Filed herewith.

€ Certain confidential information contained in this exhibit was omitted.

- (1) Incorporated by reference from the registration statement on F-6 filed with the Securities and Exchange Commission on November 28, 2007, as it may be amended or restated.
- (2) Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007.
- (3) Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on April 6, 2009.
- (4) Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on May 31, 2011.
- (5) Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on April 2, 2014.
- (6) Incorporated by reference from the registration statement on Form F-1 filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on December 31, 2015.
- (7) Incorporated by reference from the current report on Form 6-K filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on February 22, 2017.



- (8) Incorporated by reference from the current report on Form 6-K filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 9, 2017.
- (9) Incorporated by reference from the registration statement on Form 20-F filed with the Securities and Exchange Commission on August 10, 2005.
- (10) Incorporated by reference from the registration statement on Form F-1/A filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on February 1, 2018.

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**SIGNATURES**

The registrant hereby certifies that it meets all the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this registration statement on its behalf.

**XTL  
BIOPHARMACEUTICALS  
LTD.**  
*(Registrant)*

Date: March 11, 2019 Signature: /s/ Josh Levine  
Josh Levine  
Chief Executive Officer