XTL BIOPHARMACEUTICALS LTD
Form 20-F
March 31, 2016

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

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

For the fiscal year ended December 31, 2015

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 HaCharoshet St.

Raanana 43656, Israel

(Address of principal executive offices)

Josh Levine

Chief Executive Officer

5 HaCharoshet St.

Raanana 4365603, Israel

Tel: +972-9-955-7080

Fax: +972-9-951-9708

(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 twenty Ordinary Shares, par value NIS 0.1	The Nasdaq Capital Market
(Title of Class)	**(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.

4,440,150 American Depositary Shares	273,525,799 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 x

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 x

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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.)

Yes ¨ No ¨

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

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

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

¨ US GAAP x International Financial Reporting Standards as issued ¨ Other

by the International Accounting Standards Board

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 x

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 Lupus, rHuEPO for the treatment of Multiple Myeloma 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.

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 subsidiaries. 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 as of December 31, 2015, 2014, 2013, 2012 and 2011. We have derived the selected financial data for the fiscal years ended December 31, 2015, 2014 and 2013, and as of December 31, 2015 and 2014, 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"). 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. Financial Statements."

Consolidated Statements of Comprehensive income:

	Year ended December 31,				
	2015	2014	2013	2012	2011
	U.S Dollars in thousands				
Research and development expenses	(578)	(278)	(82)	(92)	(158)
General and administrative expenses	(1,419)	(1,744)	(1,329)	(2,448)	(1,078)
Impairment of intangible assets	(1,604)	-	-	-	-
Other gains, net	(10)	-	1,059	802	12
Operating loss	(3,611)	(2,022)	(352)	(1,738)	(1,224)
Finance income	4	10	65	57	24
Finance expenses	(15)	(107)	(6)	(7)	(7)
Financial income (expenses), net	(11)	(97)	59	50	17
Earnings (losses) from investment in associate	-	-	(845)	569	-
Total loss from continuing operations	(3,622)	(2,119)	(1,138)	(1,119)	(1,207)
Other comprehensive income (loss):					
Items that might be classified to profit or loss:					
Foreign currency translation adjustments	-	-	108	114	-
	-	-	(221)	-	-

Reclassification of foreign currency translation adjustments to Other gains, net					
Total other comprehensive income	-	-	(113)	114	-
Total comprehensive loss from continuing operations	(3,622)	(2,119)	(1,251)	(1,005)	(1,207)
Total loss from discontinued operations	(689)	(746)	(2,575)	(623)	-
Total comprehensive loss for the year	(4,311)	(2,865)	(3,826)	(1,628)	(1,207)
Loss for the year attributable to:					
Equity holders of the Company	(4,313)	(2,527)	(2,476)	(1,390)	(1,207)
Non-controlling interests	2	(338)	(1,237)	(352)	-
	(4,311)	(2,865)	(3,713)	(1,742)	(1,207)
Total comprehensive loss for the year attributable to:					
Equity holders of the Company	(4,313)	(2,527)	(2,589)	(1,276)	(1,207)
Non-controlling interests	2	(338)	(1,237)	(352)	-
	(4,311)	(2,865)	(3,826)	(1,628)	(1,207)
Basic and diluted loss from continuing and discontinued operations (in US dollars)					
From continuing operations	(0.014)	(0.009)	(0.005)	(0.005)	(0.006)
From discontinued operations	(0.003)	(0.002)	(0.006)	(0.001)	-
Basic and diluted loss per share (in US dollars)	(0.017)	(0.011)	(0.011)	(0.006)	(0.006)
Weighted average number of issued ordinary shares	263,730,467	231,224,512	223,605,181	217,689,926	201,825,645

Consolidated Statements of Financial Position Data:

	As of December 31,				
	2015	2014	2013	2012	2011
	U.S Dollars in thousands				
Cash, cash equivalents and bank deposits	3,817	2,159	4,165	3,312	1,495
Working capital	3,829	2,081	3,870	2,143	955
Total assets	5,323	5,644	8,015	11,086	4,073
Long term liabilities	-	-	11	13	-
Total shareholders' equity	4,887	4,660	6,265	7,353	3,444
Non-controlling interests	-	19	520	2,071	-

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 financial statements and related notes included elsewhere in this report, before you decide to purchase our ordinary shares or 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.

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 of December 31, 2015, we had approximately $3,817 thousand in cash, cash equivalents and bank deposits, working capital of approximately $3,829 thousand and an accumulated deficit of approximately $152,487 thousand. As of December 31, 2015, we had sufficient cash and cash commitments to fund operations based on existing business plans, for at least the next twelve months. We have expended and believe that 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 ("CMOs") and research organizations ("CROs"), 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.

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;

- rHuEPO patent expiration in 2019 and failure to retain orphan drug designation in the U.S. or obtain orphan drug designation in 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.

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.

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 or rHuEPO. We currently do not have any drug candidates pending approval with the Food and Drug Administration (“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.

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 we receive regulatory approval for our products, they 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.

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 candidates, hCDR1 and rHuEPO, are each 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 would materially impact our corporate strategy and adversely impact our financial results.

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;
- 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, each of hCDR1 or rHuEPO, if successfully developed and commercially launched for the treatment of systemic lupus erythematosus ("SLE") or multiple myeloma, respectively, 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 ("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.

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.

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.

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;
- 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.

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.

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.

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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

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

The trading volume of our ADSs has historically been low. Even if the trading volume of our 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 you can sell your ADSs in desirable volume and you may be unable to sell your ADSs at an established market price, at a price that is favorable to you, or at all. A low volume market also limits your ability to sell large blocks of our ADSs at a desirable or stable price at any one time. You should be prepared to own our 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 our 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;
- 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 our 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 our ADSs could depress the market for our ADSs.

Future issuances of a substantial number of our 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.

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

There are three shareholders (Mr. Alexander Rabinovitch, Sabby Management LLC and Mr. David Bassa), who each beneficially hold more than 5% of our outstanding ordinary shares (approximately 34% cumulative, as of the date hereof). 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.

Notwithstanding the aforesaid, in connection with Section 239 of the Israeli Companies Law that focuses on the number of votes required to appoint external directors, and in connection with Section 121(c) of the Israeli Companies Law that focuses on the number of votes required to authorize the Chairman of the Board in a company to act also as the Chief Executive Officer of such company, we will deem these three shareholders as controlling shareholders, for as long as such individuals are interested parties. In addition, any contractual arrangement as detailed in Section 270 (4) of the Israeli Companies Law with any of these three shareholders and/or their relatives will be presented for approval in accordance with the provisions of Section 275 of the Israeli Companies Law. In all of these situations, we will consider any of these three parties, who are not part of the transaction presented for approval, as individual interested parties in such transaction so that their vote will not be included in the quorum comprising a majority (50%) of the votes who are not interested parties in such transaction.

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 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 ("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 2015 and although we have not determined whether we will be a PFIC in 2016, 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.

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 are 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 our 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 our ADSs. Holders of our 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 our ADSs. Our shareholders have shareholder rights prescribed by Israeli law. Israeli law and our Articles of Association (“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 depositary to ask for their instructions, the ADS holders are not entitled to

receive our notices of general meeting or instruct the depositary 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 depositary will notify the ADS holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depositary 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 depositary 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 depositary to vote their shares. In addition, there may be other circumstances in which the ADS holders may not be able to exercise voting rights.

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 our 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 depository to make such distributions available to them.

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. 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. 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 Raanana, 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, since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria, Lebanon and Jordan which share common borders with Israel, and is affecting the political stability of those countries. This instability and any outside intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for causing additional conflicts in the region. 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. Additionally, a violent jihadist group named Islamic State of Iraq and Levant (IS or ISIL or ISIS) is involved in hostilities in Iraq, Syria and other countries and has been growing in influence. Although ISIL's activities have not directly affected the political and economic conditions in Israel, ISIL's stated purpose is to take control of the Middle East, including Israel. 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 and 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.

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.

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 mainly due to payment to Israeli employees and suppliers. 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.

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.

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.

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 unmet medical needs. Our current drug development program is focused on the treatment of SLE.

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. Until 1999, our therapeutic focus was on the development of human monoclonal antibodies to treat viral, autoimmune and oncological diseases. Our first therapeutic programs focused on antibodies against the hepatitis B virus, interferon – and the Hepatitis C virus. Our current drug development program is currently focused on the treatment of SLE.

In March 2009 we signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of Multiple Myeloma in exchange for the issuance of ordinary shares of XTL representing approximately 69.44% of our then issued and outstanding ordinary share capital. Under the agreement we are obligated to pay 1% royalties on net sales of rHuEPO, as well as a fixed royalty payment in the total amount of $350 thousand upon the success 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 Phase 2 or (ii) the completion of a successful fundraising by XTL at any time after the completion of Phase 2 of at least $2 million.

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 agreed 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 agreed to 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 its 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, as of June 30, 2013, and as XTL had not commenced a phase 2 clinical trial as of that date, XTL 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.

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. Lupus is a debilitating disease affecting approximately five million people worldwide, according to the Lupus Foundation of America. hCDR1 is a peptide, short chains of amino acid monomers, 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.

Prior to being licensed to the Company by Yeda, hCDR1 was licensed to Teva Pharmaceutical Industries Ltd. ("**Teva**"), which performed two placebo controlled Phase I trials and a placebo controlled Phase II trial (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. It is currently planned by the Company that such dose will be the focus of the clinical development plan moving forward. Following 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), the Company is planning to initiate a new Phase II clinical trial, which will include the 0.5 mg and a lower weekly dose of hCDR1.

On November 2, 2014, InterCure's Audit Committee and Board of Directors approved the signing of an agreement with Green Forest Global Ltd. (the "**Agreement**" and "**Green Forest**", respectively) a company wholly owned by Mr. Alexander Rabinovitch, an interested party in the Company.

Pursuant to the Agreement, Green Forest will be allotted 2,622,647 ordinary shares of InterCure (the "**First RoundAllotted Shares**") representing 34.23% of the issued and outstanding shares of InterCure at the time of the allotment for an investment of $ 230 thousand. Further, upon InterCure's shares' return to the main list of the TASE, an additional 2,622,648 ordinary shares of InterCure will be allotted to Green Forest for an additional investment of $ 230 thousand (the "**Second Round Allotted Shares**").

On December 23, 2014, the extraordinary general meeting of shareholders of InterCure approved the Agreement.

The Agreement was approved by the TASE and is effective as of February 12, 2015. After the execution of the Agreement and the conversion of an outstanding loan, the Company's holdings in InterCure's issued and outstanding share capital decreased to 36.53%.

On March 23, 2015, InterCure issued 37,804,012 ordinary shares as part of a rights offering, thus diluting the Company's holding in InterCure's issued and outstanding share capital to approximately 6.16%.

On April 2, 2015, InterCure issued the Second Round Allotted Shares, thus diluting the Company's holding in InterCure's issued and outstanding share capital to approximately 5.82%.

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.

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 HaCharoshet Street, Raanana 4365603, Israel, and our telephone number is +972-9-955-7080. Our primary internet address is www.xtlbio.com. None of the information on our website is incorporated by reference herein.

Since January 1, 2013 to the date hereof, our principal capital expenditures (divestitures) are as follows (in thousands of US dollars):

	Year ended December 31,		
	2015	2014	2013
InterCure			
Conversion of loan convertible into shares of InterCure	50	-	378
Sale of shares and rights to shares	(20)	-	-
Proteologics Ltd.			
Purchase of shares by means of equity issuance	-	-	912
Sale of investment in Proteologics Ltd.	-	(291)	(3,054)
Total	30	(291)	(1,764)

B. Business Overview

Introduction

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical drugs for the treatment of unmet medical needs. Our current drug development program is focused on the treatment of SLE.

Our lead 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 by Teva Pharmaceutical Industries, Ltd., or Teva, which had previously in-licensed hCDR1 from 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 (“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 and a lower weekly dose of hCDR1.

Our second drug candidate is recombinant human erythropoietin, or rHuEPO, which we have licensed from Yeda Research and Development ("Yeda"), and Mor Research Applications, or Mor, for the extension of survival of patients with advanced/end-stage multiple myeloma. Multiple myeloma is a severe and incurable malignant hematological cancer of plasma cells. Erythropoietin, or EPO is a glycoprotein hormone produced mainly by the kidney. It is the major growth regulator of the erythroid lineage. EPO stimulates erythropoiesis, the production of red blood cells, by binding to its receptor on the surface of erythroid progenitor cells, promoting their proliferation and differentiation and maintaining their viability. Over the last decade, several reports have indicated that the action of EPO is not restricted to the erythroid compartment, but may have additional biological, and consequently potential therapeutic, properties, broadly beyond erythropoiesis. Erythropoietin is available as a therapeutic agent produced by recombinant DNA technology in mammalian cell culture. rHuEPO is used in clinical practice for the treatment of various anemias including anemia of kidney disease and cancer-related anemia.

A clinical observation confirmed the high success rate of rHuEPO in treating the anemia in patients with multiple myeloma. Six patients with very poor prognostic features of multiple myeloma, whose expected survival was less than six months continued treatment with rHuEPO beyond the initial designed 12 week period, and they lived for 45-133 months cumulatively with the multiple myeloma diagnosis and 38-94 months with rHuEPO (with a good quality of life). We were granted an Orphan-drug designation from the FDA in May 2011, for rHuEPO.

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 before 2017 and are exploring opportunities to sell or license rHuEPO or collaborate with partners in its development.

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.

Under our current near-term strategy with respect to our pharmaceutical and biopharmaceutical products, 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;
- continually build our pipeline of therapeutic candidates; and

- develop collaborations with large pharmaceutical companies to sublicense/develop, and market our hCDR1 and rHuEPO drug development programs.

Recent Developments

Registered Direct Offering

In April 2015, we entered into security purchase agreements providing for the issuance of an aggregate of 1,777,778 ADSs representing 35,555,560 ordinary shares in a registered direct offering at $2.25 per ADS for aggregate gross proceeds of $4,000 thousand. In addition, we issued unregistered warrants to purchase 888,889 ADSs representing 17,777,778 ordinary shares in a private placement. At the closing, we also issued placement agent warrants to purchase up to 89,888 ADSs representing 1,797,760 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 $2.25 per ADS, subject to adjustment as set forth therein.

InterCure Transactions

In July 2012, we acquired control over InterCure Ltd, (“InterCure”), a public company whose shares are traded on the TASE and which develops a home therapeutic device for non-medicinal and non-invasive treatment of various diseases such as hypertension, heart failure, sleeplessness and mental stress and markets and sells a home therapeutic device for hypertension.

On November 2, 2014, Intercure's Audit Committee and Board of Directors approved the signing of an agreement with Green Forest Global Ltd. (the "**Agreement**" and "**Green Forest**", respectively) a company wholly owned by Mr. Alexander Rabinovitch, an interested party in the Company.

Pursuant to the Agreement, Green Forest will be allotted 2,622,647 ordinary shares of InterCure (the "**First RoundAllotted Shares**") representing 34.23% of the issued and outstanding shares of InterCure at the time of the allotment for an investment of $ 230 thousand. Further, upon InterCure's shares' return to the main list of the TASE, an additional 2,622,648 ordinary shares of InterCure will be allotted to Green Forest for an additional investment of $ 230 thousand (the "**Second Round Allotted Shares**").

On December 23, 2014, the extraordinary general meeting of shareholders of InterCure approved the Agreement.

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On April 2, 2015, InterCure issued the Second Round Allotted Shares, thus diluting the Company's holding in InterCure's issued and outstanding share capital to approximately 5.82%.

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 response. Mild forms of SLE may be treated with antimalarial medications, non-steroidal anti-inflammatory drugs, and topical and/or low-dose glucocorticoids, although more aggressive 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 cytotoxic drugs to block cell growth and 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 2015 sales of Benlysta were £230 million, up 25% on the year before.

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 the Company 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.

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), we intend to initiate an advanced, 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.

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, XTL plans to file its IND, and in the coming quarters initiate a global clinical trial for hCDR1 in the treatment of systemic lupus erythematosus (SLE).

rHuEPO for the Treatment of Multiple Myeloma

Market Opportunity

Currently incurable, multiple myeloma is a severe plasma cell malignancy characterized by the accumulation and proliferation of clonal plasma cells in the marrow, leading to the gradual replacement of normal hematopoiesis. The course of the disease is progressive, and various complications occur, until death. This devastating disease affects the bone marrow, bones, kidneys, heart and other vital organs. It is characterized by pain, recurrent infections, anemia and pathological fractures. In the course of the disease, many patients become gradually disabled and bed-ridden. The overall survival duration today with chemotherapy and other novel treatments is less than five years. These treatments have severe side effects, including the suppression of the immune system, susceptibility to infections, nausea, vomiting and bleeding disorders.

According to the Leukemia and Lymphoma Society, in the U.S. alone, there are approximately 81,000 people living with or are in remission from multiple myeloma and according to the National Cancer Institute, each year in the U.S., 20,000 people learn they have this disease. Most people are diagnosed with multiple myeloma after age 65 and it is more common in men than women and in African Americans than Caucasians.

rHuEPO: General & Mechanism of Action

rHuEPO, which stands for recombinant human erythropoietin, is a hormone, produced by the kidneys, and is responsible for red blood cell production in bone marrow. Erythropoietin (“EPO”), a glycoprotein hormone produced mainly by the kidney, is the major growth regulator of the erythroid lineage. EPO stimulates erythropoiesis by binding to its receptor on the surface of erythroid progenitor cells, promoting their proliferation and differentiation and maintaining their viability. The cloning of the EPO gene led to the introduction of rHuEPO into clinical practice for the treatment of various anemias including anemia of kidney disease and cancer-related anemia.

Clinical Trial History

Over the last decade, several reports have indicated that the action of EPO is not restricted to the erythroid compartment, but may have additional biological, and consequently potential therapeutic, properties, broadly beyond erythropoiesis. A clinical observation confirmed the high success rate of rHuEPO in treating the anemia in patients with multiple myeloma. Six patients with very poor prognostic features of multiple myeloma, whose expected survival

was less than six months continued treatment with rHuEPO beyond the initial designed 12 week period, and lived for 45-133 months cumulatively with the Multiple Myeloma diagnosis and 38-94 months with rHuEPO (with a good quality of life).

We were granted an Orphan-drug designation from the FDA in May 2011, for rHuEPO. 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 have begun regulatory work and have held preliminary discussions with potential drug suppliers, clinical sites and third party vendors for the planned study. As part of those preparations, we conducted a study which consists of collecting preliminary data on the existence of specific proteins in the blood of a group of multiple myeloma patients.

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 before 2017 and are exploring opportunities to sell or license rHuEPO or collaborate with partners in its development.

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.

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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.

hCDR1 for the Treatment of SLE

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, Hungary, Ireland, Italy, Liechtenstein, Spain, Sweden, Switzerland, The Netherlands and the UK), Australia, Canada, Hong Kong, India, Israel, Japan, Korea, Mexico, Norway, 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., China, India, Israel, Japan, and Mexico, and is under examination in Europe and Canada. The patent expires on January 14, 2024.

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, a Phase 2-ready asset for the treatment of SLE, among other 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 thousand. 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 thousand. The remaining installments of approximately $64 thousand each, payable in cash, are due every six months commencing on July 1, 2015, with the final payment due on January 1, 2017, provided that if we receive funding of at least $5,000 thousand then we shall be required to promptly pay Yeda any unpaid patent expense reimbursement in one lump-sum cash payment.

Under the license agreement, we are required to make milestone payments of up to $2.2 million: $200 thousand upon starting a Phase 3 clinical trial, $1 million upon FDA approval to market in the U.S., and $250 thousand 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.

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 thousand upon the successful completion of Phase 2. Such payment of $350 thousand 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.

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, efficacy has been tested 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 developed to treat SLE including, among others, anifrolumab developed by MedImmune, belimumab developed by GlaxoSmithKline, blisibimod developed by Anthera Pharmaceuticals, forigerimod acetate (lupuzor) developed by Immupharma, abatacept developed by Bristol-Myers Squibb, ACT-334441 developed by Actelion, atacicept 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 Multiple Myeloma

rHuEPO may be supplementary to the following drugs including, but not limited to, Thalidomid (thalomide), Revlimid (lenalidomide) Velcade (bortezomib), Krypolis (carfilzomib), and Pomalyst (pomalidomide). Other potential therapies are in clinical development for multiple myeloma. Vorinistat, being developed by Merck & Co., and panobinostat, being developed by Novartis AG, are being studied in combination with bortezomib for relapsed myeloma; and elotuzumab, being developed by Abbott Laboratories. In addition, in the future allogeneic haematopoietic stem cell transplantation might potentially cure a proportion of patients through immunologically mediated graft versus myeloma effect. However, this procedure remains highly experimental at the present time.

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.

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. 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.

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 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.

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.

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.

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 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.

Property, Plant and Equipment

Since April 2015 we lease offices in Ra’anana, Israel. The basic lease period is for 24 months with an option for an additional 12-month period.

To our knowledge, there are no environmental issues that affect our use of the properties that we lease.

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 IFRS (International Financial Reporting Standards) for the years ended December 31, 2015, 2014 and 2013, and as of December 31, 2015 and 2014, contained in “Item 18. Financial Statements” and with any other selected financial data included elsewhere in this annual report.

Selected Financial Data

The tables below present selected financial data for the fiscal years ended as of December 31, 2015, 2014 and 2013 and as of December 31, 2015 and 2014. The balance sheet information as of December 31, 2013 has been derived from audited financial statements not included elsewhere in this report. 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. Financial Statements.”

Consolidated Statements of Comprehensive income:

	Year ended December 31,		
	2015	2014	2013
	U.S. dollars in thousands		
	(except per share data)		
Continuing operations:			
Research and development expenses	(578)	(278)	(82)
General and administrative expenses	(1,419)	(1,744)	(1,329)
Impairment of intangible assets	(1,604)	-	-
Other gains, net	(10)	-	1,059
Operating loss	(3,611)	(2,022)	(352)
Finance income	4	10	65
Finance expenses	(15)	(107)	(6)
Finance income (expenses), net	(11)	(97)	59
Earnings (loss) from investment in associate	-	-	(845)
Loss from continuing operations	(3,622)	(2,119)	(1,138)
Loss from discontinued operations	(689)	(746)	(2,575)
Total loss for the year	(4,311)	(2,865)	(3,713)
Other comprehensive income (loss):			
Items that might be classified to profit or loss:			
Foreign currency translation adjustments	-	-	108
Reclassification of foreign currency translation adjustments to Other gains, net	-	-	(221)
Total other comprehensive income (loss)	-	-	(113)
Total comprehensive loss	(4,311)	(2,865)	(3,826)
Total loss attributable to:			
Equity holders of the Company	(4,313)	(2,527)	(2,476)
Non-controlling interests	2	(338)	(1,237)
	(4,311)	(2,865)	(3,713)
Total comprehensive loss attributable to:			

Equity holders of the Company	(4,313)	(2,527)	(2,589)
Non-controlling interests	2	(338)	(1,237)
	(4,311)	(2,865)	(3,826)
Basic and diluted loss per share from continuing and discontinued operations (in U.S. dollars):			
From continuing operations	(0.014)	(0.009)	(0.005)
From discontinued operations	(0.003)	(0.002)	(0.006)
Loss per share for the period	(0.017)	(0.011)	(0.011)

Consolidated Statements of Financial Position Data:

	As of December 31,		
	2015	2014	2013
	U.S Dollars in thousands		
Cash, cash equivalents and bank deposits	3,817	2,159	4,165
Working capital	3,829	2,081	3,870
Total assets	5,323	5,644	8,015
Long term liabilities	-	-	11
Total shareholders' equity	4,887	4,660	6,265
Non-controlling interests	-	19	520

Overview

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical drugs for the treatment of unmet medical needs. Our current drug development program is focused on the treatment of SLE.

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 are a development stage company. We have had no drug product sales to date and the sales of our medical devices are as yet insufficient to generate operating income. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, our initial public offering, our placing and open offer transaction, and private investments in public equities.

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, marketing efforts of our medical devices and potential in-licensing and acquisition opportunities.

Our research and development expenses in 2015, 2014 and 2013 primarily consisted of expenses related to the hCDR1, and to a lesser degree, rHuEPO development plans. As part of the preparations for hCDR1 in 2015, the Company engaged regulatory and clinical consultants and commenced work on Chemistry, Manufacturing and

Control, or CMC, including production and testing of the drug substance.

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 expenses 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 2m to the consolidated financial statements). We record compensation expenses based on the fair value of the award at the grant date according to the Black-Scholes valuation model. According to the IFRS 2, in non-performance-based options, the Company recognizes 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. The Company treats 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.

A. **Results of Operations**

Year ended December 31, 2015 compared to the year ended December 31, 2014

Research and Development Expenses. Research and development expenses in the years ended December 31, 2015 and 2014 totaled approximately $578 thousand and $278 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 patients. The increase in expenses in 2015 compared to 2014 is mainly due to expenses related to our hCDR1 drug. Expenses incurred in 2015 include, among other things, chemistry, manufacturing and control (CMC) costs for production of the drug substance and drug product, as well as clinical and regulatory consulting fees related to the preparation and submission to the U.S. FDA of our pre-IND meeting package for our planned clinical study of the hCDR1 drug for the treatment of SLE patients.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2015 and 2014 totaled approximately $1,419 thousand and $1,744 thousand, respectively. The decrease in 2015 compared to 2014 is mainly due to the Company's efforts to reduce overhead costs as well as lower share-based compensation expenses.

Impairment of intangible assets. The Company is required to determine, 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, 2015, the Company recognized an impairment in the amount of $1,604 thousand with regard to the rHuEPO intangible asset. For further information, see note 11 of the financial statements for the year ended December 31, 2015.

Finance expenses, net. Finance expenses, net for the years ended December 31, 2015 and 2014 totaled approximately $11 thousand and $97 thousand, respectively. The decrease in finance expenses in 2015 compared to 2014 derives mainly from a reduced exposure to NIS/USD exchange rate fluctuations due to lower NIS cash balances in 2015 compared to 2014.

Total loss from discontinued operations. Total loss from discontinued operations of approximately $689 thousand and $746 thousand, is derived from the Company’s investment in InterCure, a former subsidiary. Such loss for the year ended December 31, 2015 represents a loss from the deconsolidation of InterCure.

Income Taxes. We had no income tax expense for the years ended December 31, 2015 and 2014 due to losses incurred and we did not recognize any deferred tax benefits, since it is not "more likely than not" that we will be able to generate profits in the future to realize the deferred taxes.

Years Ended December 31, 2014 and 2013

Research and Development Expenses. Research and development expenses in the years ended December 31, 2014 and 2013 totaled approximately $278 thousand and $82 thousand, respectively. Research and development expenses are comprised mainly of expenses related to preparations for initiating the phase 2 clinical trials of the hCDR1 and, to a lesser extent, rHuEPO drugs designed to treat SLE and multiple myeloma patients, respectively. The increase in expenses in 2014 compared to 2013 is mainly due to expenses related to our hCDR1 drug, in-licensed in January 2014.

General and Administrative Expenses. General and administrative expenses for the years ended December 31, 2014 and 2013 totaled approximately $1,744 thousand and $1,329 thousand, respectively. The increase in 2014 compared to 2013 is mainly due to a $0.5 million reversal of expenses in 2013 due to forfeitures of stock options by a director who resigned from the Company.

Finance income (expenses), net. Finance income (expenses), net for the years ended December 31, 2014 and 2013 totaled approximately ($97 thousand) and $59 thousand, respectively. The decrease in finance income in 2014 compared to 2013 derives mainly from an increase in the NIS/USD exchange rate during 2014.

Total loss from discontinued operations. Total loss from discontinued operations totaled approximately $746 thousand and $2,575 thousand, and represents InterCure's net results for the years ended December 31, 2014 and 2013, respectively. Such loss in 2013 includes an impairment of $1.7 million in intangible assets recognized in the acquisition of InterCure in 2012.

Income Taxes. We had no income tax expense for the years ended December 31, 2014 and 2013 due to losses incurred and we did not recognize any deferred tax benefits, since it is not "more likely than not" that we will be able to generate profits in the future to realize the deferred taxes.

Significant Accounting Policies

Basis of presentation of the financial statements. The financial statements of the Company and its subsidiaries (the "**Group**") as of December 31, 2015 and 2014, and for each of the three years in the period ended December 31, 2015

have been prepared in accordance with International Financial Reporting Standards which are standards and interpretations issued by the International Accounting Standards Board ("**IFRS**").

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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.

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

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

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 in g 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.

Intangible assets

1. Brand name and technology:

Brand name and technology acquired in a business combination are recognized at fair value on the acquisition date. Brand name and technology have a finite useful life and are presented at cost net of accumulated amortization and impairment losses. The amortization is calculated using the straight-line method over the expected useful life (9-10 years).

2. Computer software:

Acquired licenses to use computer software are capitalized based on costs incurred in acquiring the specific software and preparing it for use. These costs are amortized using the straight-line method over the estimated useful life (five

years). Costs relating to computer software upkeep are recognized as expenses as incurred.

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3. 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”.

4. 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, 2015, the Group did not capitalize development costs to intangible assets.

Impairment of non-financial 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.

As for testing impairment of acquired intangible assets, see *intangible assets* above.

Inventories

Inventories are measured at the lower of cost and net realizable value. The cost of inventories comprises costs of purchase and costs incurred in bringing the inventories to their present location and condition. Net realizable value is the estimated selling price in the ordinary course of business less the estimated costs of completion and the estimated selling costs. The Company periodically evaluates the condition and age of inventories and makes provisions for slow moving inventories accordingly.

Cost of inventories is determined as follows:

Raw materials - at cost of purchase using the “first-in, first-out” method.

Purchased merchandise and products - using the “first-in, first-out” method.

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.

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.

Revenue recognition

Revenues are recognized in profit or loss when the revenues can be measured reliably, it is probable that the economic benefits associated with the transaction will flow to the Company, and the costs incurred or to be incurred in respect of the transaction can be measured reliably. Revenues are measured at the fair value of the consideration received less any trade discounts, volume rebates and returns.

Following are the specific revenue recognition criteria which must be met before revenue is recognized:

Revenues from sale of goods to retail customers:

Revenues from the sale of goods are recognized when all the significant risks and rewards of ownership of the goods have passed to the buyer and the seller no longer retains continuing managerial involvement. The delivery date to the customer is usually the date on which ownership passes.

Revenues from sale of goods to distributors:

InterCure sells its products to distributors as well. Revenues from such sales are recognized when InterCure or its subsidiaries deliver the goods to the distributor, when sales channel and selling price are at the distributor's sole discretion, and when there are no ongoing obligations to prevent the distributor from receiving the goods. Revenue is only recognized when goods were delivered to the designated site, risks of loss and damage are transferred to the distributor and distributor had received the goods in accordance with the sales agreement, conditions for receipt of goods had expired or InterCure holds objective evidence that goods receipt criteria had been met.

Sales do not include a finance component, as they are made with a 60 days credit period, considered as consistent with the market in which InterCure operates.

Non-current assets (or disposal groups) held for sale

Non-current assets (or disposal groups) are classified as held for sale when their carrying amount will be recovered principally through a sale transaction rather than through continuing use.

Discontinued operations

A discontinued operation is a component of an entity that either has been disposed of, or is classified as held for sale, and represents a separate major line of business or geographical area of operations, or is part of a single coordinated plan to dispose of a separate major line of business or geographical area of operations or is a subsidiary acquired exclusively with a view to resale.

Revenues and expenses attributable to discontinued operations are presented in the statement of comprehensive loss under the item "*Total loss from discontinued operations*", for all years presented.

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.

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

(i) 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.

(ii) The Group is required to determine at the end of each reporting period whether there is any indication that an asset 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. The value-in-use calculations require management to make estimates of the projected future cash flows. Determining the estimates of the future cash flows is based on management past experience and best estimate for the economic conditions that will exist over the remaining useful economic life of the CGU.

- Share-based payments – in evaluating the fair value and the recognition method 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 Company's results and the number of options that will vest.

2. Judgments that have a critical effect on the adoption of the entity's accounting policies:

- The existence of control over InterCure – As of December 31, 2014, and effective as of May 16, 2013, the Company held 54.72% of InterCure's issued and outstanding share capital, following the conversion of the loan granted to InterCure into 7,620,695 shares of InterCure. In the reporting period ended December 31, 2012, the Group's management had estimated the degree of effect it had in InterCure and had determined that it was able to govern InterCure's financial and operating policies despite holding less than 50% of InterCure's issued and outstanding share capital at the time, through de-facto control, this following an examination of InterCure's entire equity instruments. This conclusion was reached mainly since the Company was able to convert the aforementioned loan into shares of InterCure, a conversion which will have conferred the Company a stake of approximately 54.72% of InterCure's issued and outstanding share capital.

- During the year ended December 31, 2015, events pertaining to the investment in InterCure reduced the Company's stake in InterCure to 5.82%. Considering the Company's diluted voting rights in InterCure, the Company's management determined that a loss of control in InterCure occurred on February 12, 2015.

Impact of Inflation and Currency Fluctuations

We generate most of our revenues and 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, 2015, 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 $ 20 thousand lower (2014 – post-tax loss approximately $ 85 thousand lower; 2013 - post-tax loss approximately $ 157 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. Loss was less sensitive to fluctuations in the exchange rate in relation to the NIS in 2015 than in 2014 mainly because of the decreased amount of the NIS-denominated balances in the items of cash, receivables and payables of the Group.

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

The income of the Company is subject to corporate tax at the regular rate; the guidance of the amendment to the Israeli Income Tax Ordinance, 2005 from August 2005 prescribes a gradual reduction in the corporate tax rates and the resulting corporate tax rates starting 2009 are as follows: 2009 - 26% and 2010 and thereafter - 25%.

On July 14, 2009, the "Knesset" (Israeli Parliament) passed the Law for Economic Efficiency (Amended Legislation for Implementing the Economic Plan for 2009 and 2010), 2009, which prescribes, among other things, an additional gradual reduction in the corporate tax rates starting 2011 to the following tax rates: 2011 - 24%, 2012 - 23%, 2013 - 22%, 2014 - 21%, 2015 - 20%, 2016 and thereafter - 18%.

In December 2011, following the enactment of the Law for the Changing the Tax Burden (Legislative Amendments), 2011 (hereafter – "Tax Burden Distribution Law"), the phased reduction in the corporate tax was eliminated, and corporate tax rate in 2012 and thereafter was set to 25%.

On August 5, 2013, the Law for Changing National Priorities (Legislative Amendments for Achieving Budget Targets for 2013-2014), 2013 (the "Law") was published in the Government's records. The Law prescribes, among other things, the Law prescribes from the 2014 tax year and thereafter, an increase in the Israeli corporate tax rate to 26.5% (instead of 25%).

On January 5, 2016, the Israeli Parliament officially published the Law for the Amendment of the Israeli Tax Ordinance (Amendment 216), that reduces the corporate tax rate from 26.5% to 25%, effective for the year beginning January 1, 2016.

As of December 31, 2015, XTL Biopharmaceuticals Ltd. did not have any taxable income. As of December 31, 2015, our net operating loss carry forwards for Israeli tax purposes registered on behalf of XTL Biopharmaceuticals Ltd. amounted to approximately $ 28 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.

Since April 7, 2009, we have not had a "permanent establishment" or activity in the US, and our subsidiaries do not perform any activities in the US. Our board of directors consists of a majority of Israeli residents and our management

is domiciled in Israel.

B. Liquidity and Capital Resources

We have financed our operations from inception primarily through various private placement transactions, our initial public offering, a placing and open offer transaction, option and warrant exercises, and private investments in public equities. As of December 31, 2015, we had received net proceeds of approximately $80.2 million from various public offerings and private placement transactions, including net proceeds of approximately $45.7 million from our initial public offering in September 2000, net proceeds of approximately $15.4 million from the 2004 placement and open offer transaction, net proceeds of approximately $1.5 million from the Bio-Gal transaction in August 2010, net proceeds of approximately $1.75 million from our public offering on TASE in March 2011, net proceeds of $2.4 million from our private placement in March 2012, net proceeds of approximately $3.4 million from our public offering on Nasdaq in April 2015, and proceeds of approximately $4.0 million from the exercise of options and warrants.

As of December 31, 2015, we had approximately $3.8 million in cash and cash equivalents, an increase of $1.7 million from December 31, 2014.

Cash flows used in operating activities for the year ended December 31, 2015 totaled approximately $1.9 million, compared to cash flows used in operating activities of approximately $2.5 million for the year ended December 31, 2014. The decrease in cash used in operating activities compared to the corresponding period last year mainly arises from the Company’s divestment of InterCure, as cash flows in 2015 exclude any cash flows incurred in InterCure.

Cash flows used in investing activities in the year ended December 31, 2015 totaled approximately $35 thousand compared to cash flows provided by investing activities of approximately $1.5 million in the previous year. Cash flows in 2015 mainly originated from payment made to Yeda in connection with the hCDR1 asset, offset by cash received from the sale of a small portion of InterCure shares held by the Company. Activities in 2014 included withdrawal of short-term deposits in a total amount of $1.2 million, as well as receipt of the final payment from the sale of Proteologics in the amount of $0.3 million.

Cash flows provided by financing activities in the year ended December 31, 2015 totaled approximately $3.6 million compared to cash flows provided by investing activities of approximately $0.3 million in the previous year. Amount for the year ended December 31, 2015 reflects net cash flows during the period in connection with the April 2015 public offering, while the amount for the year ended December 31, 2014 mostly reflects the sale of treasury shares held by InterCure.

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, including short-term deposits, will allow the Company to finance its activities for a period of at least twelve months from the date hereof. 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 2016 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 may be required to raise additional funds in the future by issuing securities. Should the Company fail to raise additional capital in the future under standard terms, it will be required to minimize its 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 2015, 2014 and 2013 substantially derived from costs related to the hCDR1 and, to a lesser degree, rHuEPO, development plans. As part of the preparations for a planned clinical study of hCDR1, the Company engaged regulatory and clinical consultants in 2015 and commenced work on CMC, including production and testing of the drug substance and drug product.

hCDR1 for the Treatment of SLE

The Company intends to initiate a new Phase II clinical trial, which will include the 0.5 mg and a lower weekly dose. 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.

rHuEPO for the Treatment of Multiple Myeloma

The clinical trial's preliminary plan received as part of the Bio-Gal transaction, planned a prospective, multi-center, phase 2 study intended to assess safety of rHuEPO when given to patients with advanced Multiple Myeloma and demonstrate its effects on survival, biological markers related to the disease, immune improvements and quality of life. We have not yet submitted the preliminary plan, which may be updated, to the authorities and/or the applicable IRB. 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 before 2017 and are exploring opportunities to sell or license rHuEPO or collaborate with partners in its development.

The following table sets forth the research and development costs for the years 2015, 2014 and 2013 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,		
	2015	2014	2013
hCDR1	549	206	9
rHuEPO	29	37	57
SAM-101	-	25	16
Other	-	10	-
Total Research and Development	578	278	82

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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, 2015, we had known contractual obligations, commitments and contingencies of approximately $40 thousand which relate to lease obligations for our offices, all of which is due within the next year. In April 2015, we signed an operational lease agreement for our new offices in Ra'anana. Under the new lease agreement, we will pay a monthly rent of approximately $2,500.

We entered into an agreement with subtenants to lease part of the office space in exchange for approximately $ 1,200 per month. The agreement is in effect until April 2017.

We do not carry any contractual obligations, commitments or contingencies relates to research and development operations.

Payment due by period as of December 31, 2015 (in thousands of US$)			
Contractual obligations	Total	Less than 1 year	More than 1 year
Operating lease obligations	40	30	10

Total	40	30	10

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.

According to the agreement with MinoGuard we were obligated to pay milestone payments to MinoGuard of up to $2.5 million based on development and marketing milestones as well as 3.5% royalty of our net sales of the product and 7.5%-20% from our third-party out-license receipts, depending on the phase of the drug at the time of an out-license transaction. 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 were obligated to pay MinoGuard an annual license fee representing a value of $45 thousand, for the 12 month period between July 1, 2013 and June 30, 2014. On September 3, 2014, we 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.

According to our strategic collaboration master agreement with the Institute and Mor, we are obligated to pay the Institute for the services provided by them the cost basis related to the Institute’s activity in the framework of any project plus an additional 10% of the total royalties to which Mor is entitled pursuant to its agreements with the Company in connection with each technology for which rights were granted to the Company.

According to the licensing agreement signed 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, 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 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
Shlomo Shalev	54	Chairman of the Board of Directors
Osnat Hillel Fain	50	Non-Executive and External Director
Oded Nagar	47	Non-Executive and External Director
David Bassa	54	Non-Executive Director
Doron Turgeman	47	Non-Executive Director
Dr. Jonathan Schapiro	55	Non-Executive Director
Dr. Dobroslav Melamed	38	Non-Executive Director
Josh Levine	51	Chief Executive Officer
David Kestenbaum	51	Chief Financial Officer

Shlomo Shalev joined our Board of Directors in December 2014 and in August 2015 was appointed to serve as Chairman. 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.

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, as the CEO of Galaxy Properties and Real Estate LTD and as a board member of Bunkersec Ltd. In addition to serving as a board member on a number of TASE listed companies, including 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.

David Bassa joined our Board of Directors in November 2013 and served as Chairman from June 2014 until August 2015. He is the CEO and co-founder of Sela Software Ltd., a leading knowledge center and software house for the high-tech and IT industry, since 1990. In 2000, Mr. Bassa founded Bio-Gal, a biopharmaceutical company which subsequently merged into XTL, for the purpose of developing Erythropoietin (EPO) for the treatment of Multiple Myeloma. Mr. Bassa graduated with a B.A in Economics from Bar-Ilan University and an M.Sc in Computer Science studies (without thesis), also from Bar-Ilan University. Mr. Bassa was twice awarded the President Excellency Award (1981, 2002) and managed the Israeli branch of the international AIESEC organization, of which he is a Hall of Fame member.

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 B Communications (BCOM) and Internet Gold (IGLD), both of which are 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. 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.

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. 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.

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.

David Kestenbaum was appointed our Chief Financial Officer in January 2014. Before joining XTL, he served as CFO of Zenith Solar Ltd., from 2010 to 2012. Prior positions include Finance Director of Colbar Lifescience Ltd., a medical device/biotech company and division of Johnson and Johnson (NYSE:JNJ) from 2007 to 2010, CFO of ZAG Industries Ltd., a division of The Stanleyworks (NYSE:SWK) from 2003 to 2007, and CFO and other senior financial positions at affiliates of Unilever NV (NYSE: UN) in the U.S. and Israel. He worked in public accounting at PriceWaterhouseCoopers in NY from 1986 to 1990. Mr. Kestenbaum is a U.S. Certified Public Accountant and holds a BSc in Accounting from Yeshiva University (NY), and a MBA in Finance and International Business from Columbia University (NY).

B. Compensation

The aggregate compensation paid by us to all persons who served as directors or officers for the year 2015 (11 persons) was approximately $0.6 million. This amount includes payments of approximately $0.1 million 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, who is a significant shareholder 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 March 2012, we granted to each of our former external directors, Jaron Diament and Dafna Cohen, options to purchase 150,000 ordinary shares exercisable at an exercise price of NIS 0.58633 per share (which is the average of the three-day closing price on TASE prior to the issuance). 33% of the options are vested and the remaining 67% shall vest and be exercisable on a monthly basis, commencing from the date of the mentioned shareholders meeting, for the duration of two years. Ms. Cohen and Mr. Diament ceased serving on the Board of Directors on March 18, 2015 and the 300,000 vested options granted to them expired on March 17, 2016.

On December 30, 2014, we granted to each of four of our directors – Mr. Doron Turgeman, Mr. Shlomo Shalev, Dr. Jonathan Schapiro and Dr. Dobroslav Melamed - options to purchase 150,000 ordinary shares exercisable at an exercise price of NIS 0.4325 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 the respective director provides services to us. The options have a term of ten years.

On March 25, 2015, we granted to each of two of our directors - Osnat Hillel Fain and Oded Nagar - options to purchase 150,000 ordinary shares at an exercise price of NIS 0.40 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 the respective director provides services to us. The options have a term of ten years.

In March 2015, we fixed the monetary compensation for non-executive directors as follows: annual consideration of $10 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 744 for meetings held by teleconference, NIS 620 for unanimous written board resolutions and reimbursement of reasonable out-of-pocket expenses.

We previously granted to each of our three former directors, Mr. Yonay, Mr. Shweiger and Mr. Allouche, options to purchase 150,000 ordinary shares exercisable at NIS 0.298 per share (which is the average of the three-day closing price on TASE prior to the issuance). 33% of the options are vested and the remaining 67% vest on a monthly basis from March 2, 2010 over two years. On November 22, 2010, Mr. Shweiger ceased serving on our Board of Directors and therefore 63,747 of the total options granted to him were forfeited. Upon his departure, Mr. Shweiger exercised the vested 86,253 options. Mr. Allouche ceased serving on our Board of Directors on May 18, 2014, and during August 2014 he exercised the 150,000 vested options granted to him. Mr. Yonay ceased serving on our Board of Directors on December 30, 2014 and the 150,000 vested options granted to him expired on December 29, 2015.

On March 31, 2016, 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 of September 1, 2015. The terms include monthly remuneration in the amount of NIS 20 thousand, as well as the allocation of 1,500,000 stock options, exercisable into 1,500,000 ordinary shares of NIS 0.1 par value each of the Company, for an exercise price of NIS 0.6 per stock option. The exercise period of the stock options is a maximum of ten years from the grant date. The stock options vest in twelve equal portions each quarter over a period of three years from the grant date.

For further details regarding share options granted to our employees, directors and service providers, see Note 18 to the consolidated financial statements for the year ended December 31, 2015.

Employment Agreements

Joshua Levine

We entered into an employment agreement dated as of September 11, 2013, as amended on January 30, 2014, with Mr. Joshua Levine, our Chief Executive Officer, or CEO. Mr. Levine commenced his term as CEO on October 15, 2013 and is entitled to a monthly gross base salary of NIS 40 thousand (NIS 480 thousand annually), paid retroactively, effective from said commencement date.

The employment agreement provides that upon the successful completion of 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 of the Company or any entity under its control (which for this purpose means ownership by the Company of greater than 50% of the outstanding voting securities), as long as Mr. Levine is appointed as such entity’s CEO, during the thirty six month period from the date of the agreement, the Company will pay Mr. Levine a bonus equal to 1% of the above fund raising amount, up to a maximum aggregate amount of $200 thousand in any calendar year. The employment agreement further provides that in the event the Company or any of its wholly-owned subsidiaries or any entity under

its control, as long as Mr. Levine is appointed as such entity's CEO, receives payment in connection with any collaboration or other transaction relating to their respective products or technologies, excluding payments made to finance specific research and development activity and royalty payments, Mr. Levine shall be entitled to payment of 1% of the cash actually received by the Company in such transaction, up to an aggregate maximum amount of $200 thousand in any calendar year. Furthermore, the employment agreement provides that in the event the Company or any of its wholly-owned subsidiaries or any entity under its control, as long as Mr. Levine is appointed as such entity's CEO, receives payment in connection with payments made to finance specific research and development activity, Mr. Levine shall be entitled to receive payment of 0.5% of such funding actually received by the Company up to an aggregate maximum of $200 thousand in any calendar year and per single research and development funding. The aggregate of all such bonuses payable to Mr. Levine in any calendar year cannot exceed $300 thousand. In addition, the employment agreement provides that Mr. Levine shall be entitled to an annual bonus of NIS 66 thousand upon meeting goals set by the Board of Directors. 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.

In consideration for his service as our CEO, under the employment agreement, on March 17, 2014, Mr. Levine was granted options to purchase 1,500,000 ordinary shares. 600,000 of the options are exercisable at NIS 0.60 each and 900,000 of the options are exercisable at NIS 0.90 each. The options vest over 36 months from October 20, 2013 in 12 equal installments at the end of each calendar quarter for as long as Mr. Levine's employment with us has not terminated. The options have a term of ten years.

The employment agreement is in effect as of the date of approval at our general meeting of shareholders on March 17, 2014, and continues for a three-year term as of that date. Either party may terminate the employment agreement without cause upon three months' advance written notice during the first year of the agreement and four months' advance written notice thereafter. In the case of death or disability, as such terms are defined in the employment agreement, Mr. Levine or his heirs shall be entitled to four months' salary in addition to any severance pay under applicable law.

On March 25, 2015, a special meeting of shareholders approved a grant to Mr. Levine of an additional bonus of 0.5% of any funds raised by us from any non-existing shareholder of ours up to $36 thousand as well as options to purchase 100,000 ordinary shares exercisable at NIS 0.40 per share. Half the options vest upon grant and half vest in equal quarterly installments over 36 months provided Mr. Levine remains employed or provides services to us. The options have a term of ten years. Such grant was made in consideration of Mr. Levine's consent to waive 10% of his monthly compensation until the later of a qualified financing and December 31, 2015.

On March 31, 2016, a general meeting of shareholders of the Company approved the allocation of 1,000,000 stock options to the Company's Chief Executive Officer, exercisable into 1,000,000 ordinary shares of NIS 0.1 par value each of the Company, for an exercise price of NIS 0.6 per stock option. The exercise period of the stock options is a maximum of ten years from the grant date. 33.33% of the stock options vest following the lapse of 12 months from the grant date, and the remaining 66.67% vest in eight equal portions each quarter over a period of two years from the first anniversary.

David Kestenbaum

We entered into an employment agreement dated as of January 9, 2014 with Mr. David Kestenbaum, our Chief Financial Officer, or CFO. Mr. Kestenbaum is entitled to a monthly gross base salary of NIS 33 thousand (NIS 396 thousand annually).

The employment agreement provides that upon t