XTL BIOPHARMACEUTICALS LTD
Form 20-F
April 28, 2015

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, 2014

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: **000-51310**

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 43656, Israel

Tel: +972-9-955-7080

Fax: +972-9-951-9727

(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.

4,481,203 American Depositary SharesJ73,525,799 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 o No ý

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 o No ý

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 ý No o

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 ý No o

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 ý

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

£ US GAAP ý 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 o Item 18 £

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

Yes o No ý

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 as well as in our medical device 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, SAM-101 for the treatment of Schizophrenia, 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 prospectus.

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 signed. 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, 2014, 2013, 2012, 2011 and 2010. We have derived the selected financial data for the fiscal years ended December 31, 2014, 2013 and 2012, and as of December 31, 2014 and 2013, 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,				
	2014	2013	2012	2011	2010
	U.S Dollars in thousands				
Research and development expenses	(278)	(82)	(92)	(158)	(64)
General and administrative expenses	(1,744)	(1,329)	(2,448)	(1,078)	(1,222)
Other gains, net	-	1,059	802	12	30
Operating loss	(2,022)	(352)	(1,738)	(1,224)	(1,256)
Finance income	41	114	55	24	6
Finance expenses	(138)	(55)	(5)	(7)	(7)
Financial income (expenses), net	(97)	59	50	17	(1)
Earnings (losses) from investment in associate	-	(845)	569	-	-
Total loss from continuing operations	(2,119)	(1,138)	(1,119)	(1,207)	(1,257)
Other comprehensive income (loss):					
Items that might be classified to profit or loss:					
Foreign currency translation adjustments	-	108	114	-	-
Reclassification of foreign currency translation adjustments to Other gains, net	-	(221)	-	-	-
Total other comprehensive income	-	(113)	114	-	-
Total comprehensive loss from continuing operations	(2,119)	(1,251)	(1,005)	(1,207)	(1,257)

Total loss from discontinued operations	(746)	(2,575)	(623)	-	-
Total comprehensive loss for the year	(2,865)	(3,826)	(1,628)	(1,207)	(1,257)
Loss for the year attributable to:					
Equity holders of the Company	(2,527)	(2,476)	(1,390)	(1,207)	(1,257)
Non-controlling interests	(338)	(1,237)	(352)	-	-
	(2,865)	(3,713)	(1,742)	(1,207)	(1,257)
Total comprehensive loss for the year attributable to:					
Equity holders of the Company	(2,527)	(2,589)	(1,276)	(1,207)	(1,257)
Non-controlling interests	(338)	(1,237)	(352)	-	-
	(2,865)	(3,826)	(1,628)	(1,207)	(1,257)
Basic and diluted loss from continuing and discontinued operations (in US dollars)					
From continuing operations	(0.009)	(0.005)	(0.005)	(0.006)	(0.011)
From discontinued operations	(0.002)	(0.006)	(0.001)	-	-
Basic and diluted loss per share (in US dollars)	(0.011)	(0.011)	(0.006)	(0.006)	(0.011)
Weighted average number of issued ordinary shares	231,224,512	223,605,181	217,689,926	201,825,645	113,397,846

Consolidated Statements of Financial Position Data:

	Year ended December 31,				
	2014	2013	2012	2011	2010
	U.S Dollars in thousands				
Cash, cash equivalents and bank deposits	2,159	4,165	3,312	1,495	1,066
Working capital	2,102	3,870	2,143	955	259
Total assets	5,644	8,015	11,086	4,073	3,797
Long term liabilities	-	11	13	-	-
Total shareholders' equity	4,660	6,265	7,353	3,444	2,834
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 Business

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 incur losses in our medical device 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. As of December 31, 2014, we had an accumulated accounting deficit of approximately $148 million. 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.

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

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

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

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

As of the date hereof, XTL had three full-time employees and two part-time service providers (one of whom is an officer).

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 and medical device businesses; and

· the potential impairment of substantial 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 (drugs or medical devices), 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 drug development business

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.

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 Food and Drug Administration ("**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 lead product candidates, hCDR1 and Recombinant Human Erythropoietin (rHuEPO) are each planned for and/or ready for a Phase 2 clinical study. In order for our candidates to proceed to later stage clinical testing or marketing approval, they must show positive clinical.

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

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, rHuEPO or SAM-101. We currently do not have any drug candidates pending approval with the 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 US, 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 regulatory approval is obtained, our products and their manufacture will be subject to continual review, and there can be no assurance that such approval will not be subsequently withdrawn or restricted. Changes in applicable legislation or regulatory policies, or discovery of problems with the products or their manufacture, may result in the imposition of regulatory restrictions, including withdrawal of the product from the market, or result in increased costs to us.

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, a phase 2 clinical stage asset for the treatment of Systemic Lupus Erythematosus ("**SLE**") from Yeda Research and Development Company Ltd. ("**Yeda**"). We licensed a use patent for the use of Recombinant Human Erythropoietin (rHuEPO) for the prolongation of Multiple Myeloma patients' survival and improvement of their quality of life from Bio-Gal Ltd., or Bio-Gal, who in turn licensed it from Mor Research Applications Ltd., an Israeli corporation and licensing arm of Kupat Holim Clalit, one of the largest HMOs in Israel ("**Mor**") and Yeda. We have licensed a patent on SAM-101 for the treatment of psychotic disorders from MinoGuard Ltd., or MinoGuard, who in turn licensed it from Mor.

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 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 are an emerging company and 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 partners' sales, marketing and distribution efforts.

Specifically, each of hCDR1, rHuEPO or SAM-101, if successfully developed and commercially launched for the treatment of SLE, Multiple Myeloma or Schizophrenia, 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, or cGMP, in order to meet acceptable regulatory standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our drug candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our drug candidates. Any difficulties or delays in our contractors' manufacturing and supply of drug candidates could increase our costs, cause us to lose revenue or make us postpone or cancel clinical trials.

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

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.

Risks Related to Our Financial Condition

We fund our operations from our own capital and from external sources by way of issuing equity securities. If we need to raise additional capital and are unable to do so on terms favorable to us, or at all, we may not be able to continue our operations.

The Company depends on external financing resources to continue its activities. The actual amount of cash that the Company will need to fund its operations is subject to many factors, including, but not limited to, the timing, design and conduct of the clinical trials of our existing drug candidates, any future projects which may be in-licensed or any other business development activities. For example, changing circumstances and/or in-licenses of new technologies may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control.

The Company will incur additional losses in 2015 from research and development activities and from current operations which will be reflected in negative cash flows from operating activities. Accordingly, in order to complete the clinical trials to bring a product to market, the Company will be required to raise additional cash through the issuance of equity securities. However, if the Company is not able to raise additional capital at acceptable terms, the Company may be required to sell tradable securities held by it or reduce operations or sell or out-license to third parties some or all of its technologies. If the Company is unable to raise capital, the Company will be required to delay some of its planned research and development activities as well as curtail, cease or discontinue operations.

The financial condition of our drug development business depends on a number of factors, some of which are beyond our control. These factors include, among other things:

- the progress of our planned research activities;
- the accuracy of our financial forecasts;
- the number and scope of our planned development programs;
- our ability to establish and maintain current and new licensing or acquisition arrangements;

- our ability to achieve our milestones under our licensing arrangements;
- the costs involved in enforcing patent claims and other intellectual property rights;
- the costs and timing of the clinical trials according to regulatory requirements;
- rHuEPO patent expiration in 2019 and failure to obtain orphan drug designation in Europe;
- hCDR1 patent expiration in 2024 and failure to obtain patent term extension or obtain data exclusivity in the US and Europe;
- SAM-101 patent expiration in 2027; and
- The costs and timing of regulatory approvals.

The global capital markets have been experiencing extreme volatility and disruption for the last several years. Given recent market conditions, additional financing may not be available to us when we need it. In order to complete the clinical trials to bring a product to market we will need to raise additional capital. However we may be unable to do so on terms favorable to us, or at all, and we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our technologies. If we raise additional funds by selling ordinary shares, ADSs, or other securities, the ownership interests of our shareholders will be diluted. If we need to raise additional funds through the sale or license of our drug candidates or technology, we may be unable to do so on terms favorable to us or at all.

Risks Related to Our Intellectual Property

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 US 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 US 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 US 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.

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

- developments concerning our drug candidates or medical devices;
- 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 the Company's products;

· failure to obtain renewal of the required licenses for marketing and sales of the Company's products in the main markets in which the Company's products are sold;

· changes in the market valuations of similar companies; and

· additions or departures of key personnel.

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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 hold more than 5% of our outstanding ordinary shares (approximately 35.56% 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, the Company will deem these two shareholders as controlling shareholders in the Company, for as long as such individuals are interested parties in the Company. 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, the Company 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 ("**Nasdaq**") and our ordinary shares are traded on the TASE. Trading in our securities on these markets is made in different currencies and at different times, including as a result of different time zones, different trading days and different public holidays in the US 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 US citizens or residents may be required to pay additional income taxes.

There is a risk that we will be classified as a passive foreign investment company, or PFIC, for certain tax years. If we are classified as a PFIC, a US 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 that we were likely not a PFIC for the taxable years ended December 31, 2010, 2011, 2012 and 2013. Although such a determination is fundamentally factual in nature and generally cannot be made until the close of the applicable taxable year, based on our current operations, we believe that we were likely not a PFIC for the taxable year ended December 31, 2014, but we may be a PFIC in subsequent years. 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, US shareholders are urged to consult their own tax advisors for guidance as to our status as a PFIC.

Provisions of Israeli corporate law may delay, prevent or affect a potential acquisition of all or a significant portion of our shares or assets and thereby depress the price of our ADSs and ordinary shares.

We are incorporated in the State of Israel. Israeli corporate law regulates acquisitions of shares through tender offers. It requires special approvals for transactions involving significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay or prevent an acquisition, or make it less desirable to a potential acquirer and therefore depress the price of our shares. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders.

Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of such acquisition, the purchaser would become a 25% or greater shareholder of the company. This rule does not apply if there is already another 25% or greater shareholder of the company. Similarly, Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of the acquisition, the purchaser's shareholdings would entitle the purchaser to over 45% of the shares in the company, unless there is a shareholder with 45% or more of the shares in the company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received the approval of the company's

shareholders, (2) was from a 25% or greater shareholder of the company which resulted in the purchaser becoming a 25% or greater shareholder of the company, or (3) was from a 45% or greater shareholder of the company which resulted in the acquirer becoming a 45% or greater shareholder of the company. These rules do not apply if the acquisition is made by way of a merger.

Finally, in general, Israeli tax law treats specified acquisitions less favorably than does US tax law.

Our 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. Our 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 our ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. Our shareholders have shareholder rights prescribed by Israeli law. Israeli law and our Articles of Association, or Articles, govern such shareholder rights. Our 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. Our 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, our ADS holders are not entitled to receive our notices of general meeting or instruct the depositary how to vote. Our ADS holders will not be entitled to attend and vote at a general meeting unless they withdraw the ordinary shares from the depository. However, our ADS holders may not know about the meeting far enough in advance to withdraw the ordinary shares. If we ask for our ADS holders' instructions, the depositary will notify our 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 our 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 our 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 our ADS holders may not be able to exercise voting rights.

Our 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 our 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. Our 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 our 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, our 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 our 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 headquarters and some of our planned clinical sites and suppliers are located in Israel. Political, economic and military conditions in Israel directly affect our operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors, as well as incidents of civil unrest, military conflicts and terrorist actions. There has been a significant increase in violence since September 2000, which has continued with varying levels of severity through to the present. This state of hostility has caused security and economic problems for Israel. To date, Israel is facing political tension in its relationships with Iran and other Arab neighbor countries. Specifically, the hostilities along Israel's border with the Gaza Strip have increased, escalating to wide scale military operations in December 2008, November 2012 and July 2014 amid continuous rocket attacks into the south and center of Israel. In addition, in recent years there have been violent uprisings against the regimes in some Arab countries in the Middle East and North Africa. Consequently, there is a concern for the stability in the region which may affect the political and security situation in Israel. We cannot ensure that the political and security situation will not impact our business. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations and could make it more difficult for us to raise capital.

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

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

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

We have generated most of our revenues and hold most of our cash, cash equivalents, bank deposits and marketable securities in US dollars. Until 2008, a substantial amount of our operating expenses were in US dollars (approximately 96% in 2008). In 2009 the Company's head office moved back to Israel, and thus the portion of our expenses in New Israeli Shekels ("**NIS**") and our cash held in NIS has increased, mainly due to payment to Israeli employees and

suppliers. As a result, we could be exposed to the risk that the US 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 US dollar or that the timing of any devaluation may lag behind inflation in Israel.

Our results of operations may be adversely affected by changes in tax policy by the Israeli government.

The income of the Company is subject to corporate tax at the regular rate; the guidance of the amendment to the Income Tax Ordinance, 2005 from August 2008 prescribes a gradual reduction in the corporate tax rates and the resulting corporate tax rates starting 2008 are as follows: 2008 - 27%, 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%.

On December 6, 2011 the reduction in the corporate tax rates outlined above was revoked by the Knesset and it was also resolved that the corporate tax rate will be 25% for the tax year 2012 and thereafter.

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. 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%).

We cannot guarantee that there will be no additional changes in the corporate tax rate in the future that may adversely affect our results of operations and financial condition.

It may be difficult to enforce a US judgment against us, our officers or our directors or to assert US 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 US, may be difficult to obtain within the US. In addition, because substantially all of our assets and most of our directors and officers are located outside the US, any judgment obtained in the US against us or any of our directors and officers may not be collectible within the US. 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 US court for monetary damages in civil matters may be enforced by an Israeli court.

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 products for the treatment of unmet medical needs, currently for the treatment of SLE, Multiple Myeloma and Schizophrenia.

Recent Developments

License for hCDR1

On January 7, 2014, the Company entered into a licensing agreement with Yeda to research, develop and commercialize hCDR1, a Phase II-ready asset for the treatment of SLE ("**Lupus**"), 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). 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 0.25 mg) weekly dose of hCDR1.

Investment in InterCure

On November 3, 2014, InterCure announced that on November 2, 2014, its 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, following a reverse split in InterCure shares at a 10:1 ratio, Green Forest will be allotted 2,622,647 ordinary shares of InterCure (the "**First Round Allotted 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**").

In addition, the Agreement grants Green Forest the following three options:

a. Option to purchase up to an additional 3,416,818 ordinary shares of InterCure for $ 300 thousand (representing an exercise price of $ 0.0878 per share), exercisable within 12 months of the Transaction Completion Date, as defined in the Agreement.

b. Option to acquire the Company shares held by InterCure at a price of NIS 0.35 per share, exercisable within 6 months of the Transaction Completion Date.

c. Option to acquire InterCure's assets, rights and obligations relating to the "Resperate" business at the cost of inventory held at the time of the exercise of the option, exercisable within 6 months of the Transaction Completion Date.

Under the Agreement, Green Forest provided InterCure with a qualifying, non-secured, non-guaranteed, non-interest bearing and non-indexed loan of $ 40 thousand for a period of 60 days. At the time of the completion of the transaction, the loan will be repaid by the sale of shares of the Company held by InterCure to Green Forest for the value of the loan ($ 40 thousand) at a price of NIS 0.30 per share.

InterCure is granted the right to a Put option to sell all or part of the Company's shares held by InterCure at the Put option exercise date, for an exercise price of NIS 0.30 per share, exercisable within 6 months of the Transaction Completion Date.

In addition, at the time of and as a condition for the completion of the transaction, the outstanding loan of $ 50 thousand owed by InterCure to the Company will be converted to 569,470 ordinary shares of InterCure.

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. Consequently, on February 15, 2015, the outstanding loan of $ 50 thousand owed by InterCure to the Company was converted into 569,470 ordinary shares of InterCure, as mentioned above. After the conversion 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%.

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.

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 $350,000 upon the success of Phase 2. Such payment of $350,000 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 shall 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 shall develop and commercialize MinoGuard's technology for the treatment of psychotic disorders focusing on schizophrenia. Under the agreement, we are to conduct clinical trials, develop, register, market, distribute and sell the drugs that will emerge from MinoGuard's technology, with no limitations for a specific disorder. In consideration, we shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately $2.5 million. In addition, we will 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 has 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 $45,000, 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 $135,000, for the 12 month period between July 1, 2014 and June 30, 2015. Such annual payments will increase by $90,000 per annum, up to $675,000 for the eighth year of license or until the above agreement is terminated.

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.

Our 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 “XTL.” We operate under the laws of the State of Israel under the Israeli Companies Law, and in the US, the Securities Act and the Exchange Act.

Our principal offices are located at 5 HaCharoshet Street, Raanana 43656, 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.

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, currently for the treatment of SLE, Multiple Myeloma and Schizophrenia.

Our lead program is hCDR1, a Phase II-ready asset for the treatment of SLE. Only one new treatment, Benlysta, has been approved 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 the normal organs and causing irreversible damage. According to 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. The majority of patients are women of childbearing years.

hCDR1, is a peptide that is administered subcutaneously and acts as a disease-specific treatment to modify the SLE-related autoimmune process 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 II trial, the PRELUDE trial, were conducted by Teva, which had previously in-licensed hCDR1 from Yeda. 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. 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). Given the FDA's recommendation and the positive findings from the PRELUDE trial (which showed a substantial effect in the BILAG index), XTL intends to initiate a new Phase II clinical trial, which will include the 0.5 mg (and a 0.25 mg) weekly dose of hCDR1.

Our second compound is rHuEPO, which we intend to develop for the extension of survival of patients with advanced/end-stage Multiple Myeloma.

Erythropoietin ("**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

("**EPO-R**") 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.

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.

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).

Our third program, SAM-101, is based on the technology we in-licensed from MinoGuard - the development of combination drugs for psychotic diseases, with focus on Schizophrenia. MinoGuard completed a phase 2a study on SAM-101 in accordance with the Helsinki guidelines under the Shalvata Medical Center in Israel. SAM-101 is a unique proprietary combination of antipsychotic drugs and a known medicinal compound (minocycline). Schizophrenia is a chronic disorder that requires lifelong medication. While most of the available drugs are effective in remitting Schizophrenia's "positive symptoms" (hallucinations, delusions, agitation), even the best available drug is only partially effective in remitting several of the most disturbing features of the disease, referred to as "negative symptoms" (apathy, poverty of speech, emotional withdrawal, depression) and severe cognitive impairment. This deficiency results in schizophrenic patients' poor quality of life. In addition, noncompliance results in aggravation of symptoms, which frequently causes lengthy hospitalization periods.

Following in-vivo studies demonstrating the efficacy of minocycline treatment in a Schizophrenia murine mode, MinoGuard demonstrated in a successful phase 2a clinical study that the combination of atypical antipsychotic drugs and minocycline improves treatment efficacy and reduces side effects associated with current therapy as compared to antipsychotic treatment alone. Two independent clinical research groups in Manchester, UK and Japan have replicated these results, further supporting MinoGuard's hypothesis.

The Company's strategy does not include the investment of significant resources in the development of SAM-101 in the foreseeable future and as noted below the Company intends to seek collaboration with large pharmaceutical companies to sublicense/develop and market the SAM-101 program.

Our Strategy

Our objective is to be a leading biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of unmet clinical needs, currently for the treatment of SLE, Multiple Myeloma and Schizophrenia. We continuously identify and in-license therapeutic candidates in order to maximize our potential for commercial success.

Under our current strategy with respect to our pharmaceutical and biopharmaceutical products, we plan to:

- initiate an international, prospective phase 2 clinical study intended to assess the safety and efficacy of hCDR1 when given to patients with SLE;

- initiate a prospective phase 2 clinical study intended to assess the safety and efficacy of rHuEPO when given to patients with advanced Multiple Myeloma;

· continually build our pipeline of therapeutic candidates; and

· develop collaborations with large pharmaceutical companies to sublicense/develop, and market our hCDR1, rHuEPO and SAM-101 programs.

With regard to our medical device business, we plan to maximize the value of our asset and focus on our core business.

Products Under Development

hCDR1 for the treatment of Systemic Lupus Erythematosus

Market Opportunity

hCDR1 is a Phase II-ready asset for the treatment of SLE. Lupus is a debilitating disease affecting approximately five million people worldwide according to the Lupus Foundation of America. hCDR1, a peptide, is given by subcutaneous administration, 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. The approval of GlaxoSmithKline's Benlysta in 2011, the first product to gain marketing approval for patients with SLE in more than 50 years, paved the way for the introduction of new disease-modifying therapies and reignited the interest of pharmaceutical developers in this therapy area. GlobalData estimates the drug sales for SLE in 2012 were over $473 million across the seven major markets covered in its forecast: US, France, Germany, Italy, Spain, UK and Japan. By the end of the forecast period of 2022, sales are estimated to grow to over $1.1 billion with a CAGR of 9.36%. This growth will be driven by improved uptake of Benlysta, and the introduction of new biological therapies and the overall increase in prevalent cases of SLE, mainly due to the increasing population in these markets.

Regarding products in the pipeline, there are five advanced biological therapies. a number of pharmaceutical companies including Anthera Pharmaceuticals and Merck Serono, which are developing anti-BLyS therapies to directly compete with Benlysta (also an anti-BLyS therapy). All new anti-BLyS therapies are being developed for subcutaneous administration. Benlysta is currently given intravenously, even though GSK is currently developing a version for subcutaneous administration. UCB and ImmuPharma are developing biologic drugs with novel MOAs (UCB's drug is an antibody which is given intravenously). In addition, Bristol-Myers Squibb is developing its RA drug Orencia for the treatment of patients with Lupus Nephritis.

Development Status

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 II trial (the "**PRELUDE trial**"). The Phase I and Phase II studies consisted of over 400 patients, demonstrating that hCDR1 is well tolerated by patients and has a favorable safety profile. The PRELUDE trial did not achieve its primary efficacy endpoint based on the SLEDAI scale, resulting in Teva returning the asset to Yeda. However, the PRELUDE trial showed encouraging results in its secondary clinical endpoint, the BILAG index, and, in fact, the 0.5 mg weekly dose showed a substantial effect. Multiple post-hoc analyses also showed impressive results for this dose using the BILAG index. The Company plans such dose

to be the focus of clinical development moving forward. Subsequent to Teva's return of the program to Yeda, the FDA directed that the primary endpoint in future trials for Lupus therapies, including those for hCDR1, should be based on either the BILAG index or the SRI. Given the FDA's recommendation and the positive findings from the PRELUDE trial (which showed a substantial effect in the BILAG index), the Company intends to initiate a new Phase II clinical trial, which will include the 0.5 mg (and a 0.25 mg) weekly dose of hCDR1.

rHuEPO for the treatment of Multiple Myeloma

Market Opportunity

We intend to develop rHuEPO for the prolongation of Multiple Myeloma patients' survival. In the United States alone, there are approximately 74,800 people living with Multiple Myeloma. Multiple Myeloma is the second most prevalent blood cancer representing approximately 1% of all cancers in white US residents and 2% of all cancers in African Americans. The average age at diagnosis is 65-70 and it is more common in men than women and in African Americans than Caucasians.

Erythropoietin, 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.

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).

Development Status

As of the date hereof, the Company is in stages of planning and preparing for the implementation of a phase 2 clinical trial of rHuEPO for treating Multiple Myeloma patients. As part of those preparations, the Company 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. The data which was collected in the framework of the preliminary study will be combined, as necessary, in planning and preparing for the implementation of the phase 2 clinical trial which the Company expects to obtain the approval to commence in the second half of 2015.

We plan on performing a prospective, multi-center, open-label, one arm phase 2 study intended to demonstrate its effects on survival, biological markers related to the disease, immune improvements and quality of life. We have begun regulatory work and have held preliminary discussions with potential drug suppliers, clinical sites and third party vendors for the planned study.

Given that we intend to develop a new indication for rHuEPO, which is already approved for other uses, and we intend to use a commercially available rHuEPO as part of the study, and the fact that the pre-clinical and phase 1 phases are intended to assess drug toxicity and safety, we may be exempted from carrying out these steps and the drug development process may begin with a Phase 2 clinical trial.

Intellectual Property and Patent

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. It is our intention 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 US and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and compositions and improvements in each of these. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any commercial advantage or financial value attributable to the patent.

Generally, patent applications in the US 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 US 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

The basic patent family (WO 2002/067848) covers the active pharmaceutical agent, the Edratide peptide. The patent has been granted in a large number of jurisdictions: US, Europe (validated in 13 countries), Australia, Canada, Hong Kong, Hungary, India, Israel, Korea, Mexico, Norway, and Russia. The patent expires on February 26, 2022. The basic patent for Edratide, in the US, did receive a patent term adjustment of 213 days (to September 27, 2022). The patent family for the formulation (WO 2004/064788) covers a very specific pharmaceutical composition comprising Edratide. It has been granted in the US, China, India, Israel, Japan, and Mexico, and is under examination in Europe and Canada. The formulation patent expires on January 14, 2024.

rHuEPO for the treatment of Multiple Myeloma

A main use patent, United States Patent 6,579,525 “Pharmaceutical Compositions Comprising Erythropoietin for Treatment of Cancer,” was filed by Mor and Yeda in Israel on April 8, 1998. 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 in 2019 (See “Government and Industry Regulation” regarding our granted orphan drug designation). Pursuant to our agreement with Bio-Gal, we have exclusive worldwide rights to the above patent for the use of rHuEPO in Multiple Myeloma.

The main claims of this US issued patent are 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.

SAM-101 for the Treatment of Schizophrenia

An international patent application entitled “Combined therapies of antipsychotic drugs and tetracyclines in the treatment of psychiatric disorders” was filed by Mor on October 18, 2007 (International application number PCT/IL2007/001251). The patent is currently pending in National Phase in the US, Canada, Europe, India, and Israel.

The main claims of this patent include a pharmaceutical composition comprising as active ingredients at least one tetracycline and at least one antipsychotic drug, the pharmaceutical composition with modified release formulation, and a method for treating a psychotic disorder comprising administering the pharmaceutical composition to a patient in need.

The patent applications are pending as National Phase in Israel, US, Canada, Europe, and India. The table below details the current status of the patent applications:

Countries in which application was filed	**Filing Date**	**Application No.**	**Patent No.**	**Status**	**Expiration Date***
Canada	18.10.2007	2666796	-	Filed	18.10.2027
Europe	18.10.2007	07827225.9	-	Examination	18.10.2027
India	18.10.2007	3100/DELNP/2009	-	Filed	18.10.2027
Israel	18.10.2007	198134	-	Examination	18.10.2027
PCT	29.03.2007	PCT/IL2007/000414	-	Expired	
PCT-1	18.10.2007	PCT/IL2007/001251	-	Expired	
US Prov.	19.10.2006	60/852646	-	Expired	
USA	18.10.2007	13/733130	-	Examination	18.10.2027

* assuming that the patent will be registered on the basis of the PCT.

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, the Company entered into a licensing agreement with Yeda to research, develop, and commercialize hCDR1, a Phase II-ready asset for the treatment of SLE, among other indications. In consideration, the Company is responsible for a patent expense reimbursement in six installments totaling approximately $400,000. The Company is required to make milestone payments of $2.2 million: $200,000 upon starting Phase III, $1 million upon U.S. Food and Drug Administration approval and $250,000 for regulatory approval in each of China and three of the European Union's Group of Six. In addition, the Company will pay 2-3% royalties of annual net sales and sublicense fees of 15-20% of whatever the Company receives from any sub-licensee.

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

the treatment phase, and additional time to analyze the results for a total of approximately two and a half years. We intend to request an interim analysis be conducted as well.

On May 14, 2014, the Company issued 222,605 Ordinary shares of the Company of NIS 0.1 par value each to Yeda, as the first of six installments for the aforementioned patent expenses reimbursement, representing a value of approximately $ 38 thousand.

On January 21, 2015, the Company issued Yeda 802,912 Ordinary shares of the Company of NIS 0.1 par value each, as the second of six installments for the aforementioned patent expenses reimbursement, representing a value of approximately $ 89 thousand.

Bio-Gal/XTEPO

In March 2009 we signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of Multiple Myeloma. We are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of $350,000 upon the successful completion of Phase 2. Such payment of $350,000 is payable to Yeda upon the earlier of (i) six months from the successful completion of Phase 2 or (ii) the completion of a successful fundraising by XTL at any time after the completion of the Phase 2 of at least $2 million.

MinoGuard License

In November 2011, the Company acquired the assets of MinoGuard by an exclusive license to use MinoGuard's entire technology in return for royalties on sales and milestone payments throughout the clinical development process, without any other payments. MinoGuard was founded in 2007 in order to commercialize combination therapies for treating psychotic diseases, focusing on Schizophrenia. Under the terms of the license agreement we shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately $2.5 million. In addition, we will pay MinoGuard royalty-based payments on products that are based on the technology, equal to 3.5% of net sales and/or a percentage of our 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 has the sole discretion to pay any of the above amounts in cash or by way of issuing of its shares to MinoGuard. In addition to the above payments, since as of June 30, 2013, XTL had not commenced a phase 2 clinical trial, we paid MinoGuard an annual license fee, by way of issuance of 175,633 ordinary shares of the Company, representing a value of $45,000, 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 $135,000, for the 12 month period between July 1, 2014 and June 30, 2015. Such annual payments will increase by $90,000 per annum, up to $675,000 for the eighth year of the license.

The term of the license commenced upon the signing of the license agreement and will be effective for an unlimited time. Upon the expiration of the last payment obligation of XTL the license will be considered perpetual and fully paid up.

URL addresses

XTL maintains the www.xtlbio.com URL address.

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 product that has been approved for SLE in the last 50 years, GlaxoSmithKline's Benlysta which was approved in 2011. Regarding products in the pipeline, there are five advanced biological therapies. a number of pharmaceutical companies including Anthera Pharmaceuticals and Merck Serono, which are developing anti-BLyS therapies to directly compete with Benlysta (also an anti-BLyS therapy). All new anti-BLyS therapies are being developed for subcutaneous administration. Benlysta is currently given intravenously, even though GSK is currently developing a version for subcutaneous administration. UCB and ImmuPharma are developing biologic drugs with novel MOAs (UCB's drug is an antibody which is given intravenously). In addition, Bristol-Myers Squibb is developing its RA drug Orencia for the treatment of patients with Lupus Nephritis.

Competing Products for Treatment of Multiple Myeloma

Although there are commercially available drugs for the treatment of Multiple Myeloma, we plan to conduct our clinical trial so that rHuEPO will be tested and given only to patients who have been treated with and either failed treatment or need to stop taking, all standard therapy. Thus, the drugs below are not in direct competition to our drug. However, rHuEPO may improve the current treatments and therefore may be supplementary to them, as follows:

Thalidomide is effective in approximately one-third of patients (for a certain period of time) with advanced disease and is synergistic with other agents active in Multiple Myeloma. Its exact mechanism of action is unclear, but inhibition of angiogenesis, modulation of cytokines, and immunological effects are probably involved. Thalidomide, as a single agent or in combination with steroids, is now the standard first line treatment for relapsed or refractory myeloma (if not used before) and is also being used as frontline and maintenance treatment. Newer derivatives of thalidomide, such as revlimid or lenalidomide (formerly CC5013), have potentially greater biological activity and fewer adverse effects, including teratogenicity. Preliminary studies show a response in 30-50% of patients with refractory disease. Thalidomide has severe side effects such as flu-like symptoms, constipation, neuropathy and thrombophilia, and has not yet demonstrated survival advantage.

Lenalidomide (Revlimid) is used with dexamethasone to treat patients with Multiple Myeloma who have already had another treatment. It is a small molecular analog of thalidomide that was originally found based on its ability to effectively inhibit tumor necrosis factor production. Lenalidomide is 50,000 times more potent than thalidomide in inhibiting tumor necrosis factor-alpha, and has less severe adverse drug reactions. Nonetheless, lenalidomide, like its parent compound thalidomide, causes venous thromboembolism (VTE), a potentially serious complication with their use.

Bortezomib (Velcade) inhibits the proteasome, an intracellular organelle responsible for protein disposal. The response rate to bortezomib in extensively treated myeloma is around 50%. The drug has recently been approved by the FDA based on phase 2 clinical results. The drug has several serious side effects, including neuropathy.

Carfilzomib (Kyprolis): This is a new generation or a novel derivative of proteasome-inhibitor, i.e. the new modern "Bortezomib". It was already approved by the FDA as a second or third line therapy for relapsed or resistant myeloma. This was based on phase 2 clinical trials, and trials, including in Israel, are going on. According to the information gained so far, it appears that some of the previously resistant Multiple Myeloma patients to Velcade (Bortezomib) might respond to Carfilzomib. It is still too early to determine whether the novel drug indeed prolongs life (overall survival) or only prolongs the progression-free survival.

Pomalidomide (Pomalyst) has been approved by the FDA just recently, also for the treatment of relapsed/resistant Multiple Myeloma, as a second-third line treatment. This agent belongs to the INIDs family of drugs, and in essence, is considered as the novel lenalidomide.

It is important to emphasize that studies with Carfilzomib and Pomalidomide are ongoing and their real role in the treatment of Multiple Myeloma has not been completely clarified.

Traditional chemotherapy treatment includes melphalan and prednisone, now used sparingly because of its propensity to compromise collection of haematopoietic stem cells, other combinations, and regimens containing high dose corticosteroids. The latter-including dexamethasone; vincristine, doxorubicin, and dexamethasone; and cyclophosphamide, vincristine, doxorubicin, and methylprednisolone -are preferred for transplant candidates.

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High dose chemotherapy, particularly melphalan, with autologous haematopoietic stem cell transplantation improves response rates and their duration and survival compared with conventional chemotherapy. It is now commonly used as consolidation treatment. Unfortunately, even after haematopoietic stem cell transplantation, relapse is only a matter of time, although a minority of patients seems to survive over a decade in remission ("operational cure"). Maintenance treatment after transplantation with corticosteroids or interferon is often prescribed in an attempt to delay relapse. Although this probably does prolong the duration of remission, it is unclear if it confers a survival benefit.

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. High mortality related to treatment has been a problem historically, but the use of safer preparative regimens of reduced intensity could improve long term results.

Supply and Manufacturing

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

hCDR1 for the treatment of SLE

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.

rHuEPO for the treatment of Multiple Myeloma

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 to obtain sufficient inventory to satisfy the clinical supply needs for our planned development program for the treatment of Multiple Myeloma.

SAM-101 for the Treatment of Schizophrenia

We believe that we will either be able to purchase the selected antipsychotic and minocycline from existing pharmaceutical companies or to enter into collaborative agreements with contract manufacturers or other third-parties to obtain sufficient inventory to satisfy the clinical supply needs for our future development for the treatment of Schizophrenia.

General

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 US 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.

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 US, 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.

The Company was granted an Orphan-drug designation from the FDA in May 2011, for rHuEPO. In the US, 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 US. The designation provides the drug developer with a seven-year period of US 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.

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

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

- is intended to treat a serious or life-threatening condition;
- is intended to treat a serious aspect of the condition; and
- has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

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

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

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

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

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

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

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 US, 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 wholly-owned subsidiary, XTEPO, is an Israeli privately-held company incorporated in November 2009 for the execution of the Bio-Gal transaction and which holds the exclusive license of the use patent of rHuEPO drug for Multiple Myeloma.

Our wholly-owned subsidiary, XTL Biopharmaceuticals, Inc. and its wholly-owned subsidiary XTL Development, Inc., were each incorporated in Delaware. Since November 2008, these companies have not been active. Both companies were dissolved in 2014.

Our subsidiary, InterCure Ltd., is an Israeli public company, incorporated in November 1994. As of December 31, 2014, we held approximately 54.72% of InterCure’s issued and outstanding ordinary shares. As of the date hereof, we hold approximately 5.82% of InterCure’s issued and outstanding ordinary shares.

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 24-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, 2014, 2013 and 2012, and as of December 31, 2014 and 2013, 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, 2014, 2013 and 2012 and as of December 31, 2014 and 2013. The balance sheet information as of December 31, 2012 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.”

	Year ended December 31,		
	2014	2013	2012
	U.S. dollars in thousands (except per share data)		
Research and development expenses	(278)	(82)	(92)
General and administrative expenses	(1,744)	(1,329)	(2,448)
Other gains, net	-	1,059	802
Operating loss	(2,022)	(352)	(1,738)
Finance income	41	114	55
Finance expenses	(138)	(55)	(5)
Finance income, net	(97)	59	50
Earnings (loss) from investment in associate	-	(845)	569
Total loss for the year	(2,119)	(1,138)	(1,119)
Other comprehensive income (loss):			
Items that might be classified to profit or loss:			
Foreign currency translation adjustments	-	108	114
Reclassification of foreign currency translation adjustments to Other gains, net	-	(221)	-

Total other comprehensive income (loss)	-	(113)	114
Total comprehensive loss from continuing operations	(2,119)	(1,251)	(1,005)
Total comprehensive loss from discontinued operations	(746)	(2,575)	(623)
Total comprehensive loss for the year	(2,865)	(3,826)	(1,628)
Total loss for the year attributable to:			
Equity holders of the Company	(2,527)	(2,476)	(1,390)
Non-controlling interests	(338)	(1,237)	