XTL BIOPHARMACEUTICALS LTD
Form 20-F
March 29, 2012

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, 2011

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)

Herzliya Business Park

85 Medinat Hayehudim, Building G, PO Box 4033

Herzliya Pituach 46140, Israel

(Address of principal executive offices)

David Grossman

Chief Executive Officer

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Herzliya Pituach 46140, Israel

Tel: +972-9-955-7080

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(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 two Ordinary Shares, par value NIS 0.1	None
(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.

10,158,081 American Depositary Shares 204,031,550 Ordinary Shares

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

Yes ¨ No x

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

Yes ¨ No x

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

Yes x No ¨

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

Yes ¨ No x

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

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

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

£ U.S. GAAP x International Financial Reporting Standards as issued £ Other
by the International Accounting Standards Board

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

Item 17 ¨ Item 18 ¨

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

Yes ¨ No x

XTL BIOPHARMACEUTICALS LTD.

ANNUAL REPORT ON FORM 20-F

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This annual report on Form 20-F contains trademarks and trade names of XTL Biopharmaceuticals Ltd., including our name and logo.

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," 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. The words "expect," "anticipate," "intend," "plan," "believe," "seek, "estimate," and similar expressions are intended to identify such forward-looking statements. 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.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. 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," "we," "us" and "our" refer to XTL Biopharmaceuticals Ltd. and our wholly-owned subsidiaries, Xtepo Ltd, XTL Biopharmaceuticals, Inc. and XTL Development, Inc. 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

Selected Financial Data

The tables below present selected financial data for the fiscal years ended as of December 31, 2011, 2010, 2009, 2008 and 2007. We have derived the selected financial data for the fiscal years ended December 31, 2011, 2010 and 2009, 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"). Until 2009, we have presented our financial statements using the accounting standards and principles as set forth under United States Generally Accepted Accounting Principles ("US GAAP"). Since 2009 and effective since January 1, 2007, we have prepared our consolidated financial statements in accordance with IFRS. The selected financial data for the fiscal years ended as of December 31, 2011, 2010, 2009 2008 and 2007 are presented in accordance with IFRS. 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,				
	2011	2010	2009	2008	2007
	U.S Dollars in thousands				
Revenues	-	-	-	5,940	907
Cost of revenues	-	-	-	1,841	110
Gross profit	-	-	-	4,099	797
Research and development costs	158	64	-	11,722	11,500
General and administrative expenses (income)	1,078	1,222	*(2,429)	3,937	7,596
Impairment loss of intangible asset	-	-	-	7,500	-
Other gains (losses), net	12	30	139	288	(8)
Operating income (loss)	(1,224)	(1,256)	2,568	(18,772)	(18,307)
Finance income	24	6	6	331	668
Finance costs	7	7	10	17	30
Financial income (costs), net	17	(1)	(4)	314	638
Income (loss) before taxes on income	(1,207)	(1,257)	2,564	(18,458)	(17,669)
tax benefit	-	-	(23)	(31)	(206)
Net income (loss) for the year attributable to equity holders of the parent	(1,207)	(1,257)	2,587	(18,427)	(17,463)
Basic and diluted earnings (loss) per share (in U.S. dollars)	(0.006)	(0.011)	0.044	(0.315)	(0.382)
Weighted average number of issued ordinary shares	201,825,645	113,397,846	58,561,065	58,553,864	45,698,564

* Including reduced expenses which result from forfeiture of shares that were contingent on the performance of the former chairman and former CEO, see also Note 16b to the financial statements.

Consolidated Statements of Financial Position Data:

	Year ended December 31,				
	2011	2010	2009	2008	2007
	U.S Dollars in thousands				
Cash, cash equivalents, bank deposits and trading and marketable securities	1,495	1,066	412	2,924	12,977
Working capital	955	259	(151)	1,433	8,532
Total assets	4,073	3,797	715	3,402	23,378
Long term obligations	-	-	-	-	131
Total shareholders' equity	3,444	2,834	7	1,474	17,878

Exclusive License for the patent on SAM-101

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 engaged in a worldwide exclusive license with MinoGuard by which we shall develop and commercialize MinoGuard's technology for the treatment of psychotic disorders focusing on Schizophrenia. We will 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 (“the License”).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 of its shares to MinoGuard. In addition to the above payments, if we shall not commence a Phase 2 clinical trial by June 30, 2013, we will pay MinoGuard an annual license fee of $45,000 for the initial year, which will increase by $90,000 per year and up to $675,000 for the eighth year of license. According to the agreement receipt of an approval to commence such trial or continuance of clinical trials that were conducted or will be conducted by MinoGuard and/or its researchers, shall be deemed commencement of the Phase 2 clinical trial for this matter.

Exclusive License for the use patent on Erythropoietin

On March 18, 2009, we entered into an asset purchase agreement with Bio-Gal Ltd. (hereinafter “Bio-Gal”), a private company, for the rights to a use patent on Recombinant Human Erythropoietin, or rHuEPO, for the treatment of multiple myeloma, or "MM". On December 31, 2009, we amended the asset purchase agreement with Bio-Gal, so that XTL shall acquire all the issued and outstanding share capital of XTEPO Ltd. (a special purpose company that was established by Bio-Gal's shareholders who also transferred Bio-Gal's intellectual property rights on rHuEPO and will raise by way of a private placement approximately $1.5 million) (hereinafter “XTEPO”). We intend to develop rHuEPO for the prolongation of MM patients' survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. The course of the disease is progressive, and various complications occur, until death. In the United States alone, there are approximately 74,800 people living with MM, with about 20,520 new cases diagnosed in 2011 (Facts 2012. The Leukemia & Lymphoma Society), making MM the second most prevalent blood cancer.

On August 3, 2010, the Bio-Gal transaction was completed according to the outline signed by the parties to the agreement on December 31, 2009, after all the closing conditions had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share swap transaction pursuant to Sections 104 and 103 to the Israeli Income Tax Ordinance (Revised), 1961.

In accordance with the terms of the amended asset purchase agreement, we issued to XTEPO's shareholders approximately 133 million ordinary shares representing 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a $10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are also 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 mentioned above shall be made to Yeda Research and Development Company Ltd. (“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 or XTEPO of a minimum amount of $2 million at any time after the completion of the Phase 2 (See notes 1b and 9a to the consolidated financial statements: General, Intangible Asset).

Risk Factors

Before you invest in our ordinary shares or American Depositary Receipts representing American Depositary Shares, which we refer to in this report as ADRs, 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 ADRs. 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 ADRs 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 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, 2011, we had an accumulated accounting deficit of approximately $143.3 million (our current carry forward tax losses are substantially lower - for our current carry forward tax losses, see “Item 5. Operating and Financial Review and Prospects - Governmental Economic, Fiscal, Monetary or Political Policies that Materially Affected or Could Materially Affect Our Operations”). 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 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. In addition, the multi-national nature of our studies adds another level of complexity and risk as the successful completion of those studies is subject to events affecting countries outside the United States. 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 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 depend on independent clinical investigators, and other third-party service providers to conduct the clinical trials of our drug candidates and technologies, and we expect to continue to do so. We also may, from time to time, engage a clinical research organization for the execution of our clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but we do 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 US Food and Drug Administration, or the FDA, and/or other foreign regulatory agencies/authorities relating to good clinical practices. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trial's plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products, or could result in enforcement action against us.

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

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

- difficulty in establishing or managing relationships with clinical research organizations and physicians;
- different standards for the conduct of clinical trials and/or health care reimbursement;
- our inability to locate qualified local consultants, physicians, and partners;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and
- general geopolitical risks, such as political and economic instability, and changes in diplomatic and trade relations.

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

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

Our drug candidates and technologies are either in preclinical or clinical stages. Specifically, our lead product candidates, Recombinant Human Erythropoietin (rHuEPO) and SAM-101, are planned for a Phase 2 clinical program and the Diversity Oriented Synthesis, or DOS program, and according to our knowledge based upon the most current reports we have received from Presidio Pharmaceuticals, Inc., has not yet been tested in humans (see “Item 10. Additional Information - Material Contracts”). In order for our candidates to proceed to later stage clinical testing, they must show positive clinical or preclinical data. While rHuEPO has shown promising preclinical data and has also shown promising clinical observation data for the extension and improvement of the quality of life of Multiple Myeloma terminal patients prior to it being licensed to us, 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. While SAM-101 has shown improvement in the positive symptoms of schizophrenia as well as the patients’ cognitive state, minimizes the negative symptoms (social parameters and patient cognition) and reduces weight gain side effects among patients, 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, 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 any of our products. We currently do not have any drug candidates or technologies 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 extensive pre-clinical testing and "adequate and well-controlled" clinical trials.

Pre-clinical testing and clinical development are long, expensive and uncertain processes. 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 contract research organizations, or 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;
- 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
- government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

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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 our ongoing clinical trials were not, and the designs of future 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 existing or future 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.

Specifically, in 2008, Amgen Inc. announced that US regulators added black box, or black label, warnings to its erythropoietin drugs, Epogen and Aranesp. Similar warnings were also added to Johnson and Johnson's Procrit which is also licensed from Amgen. In the United States, a black box warning is a type of warning that appears on the package insert for prescription drugs that 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. The warnings warn that the erythropoietin drugs increased death and accelerated tumor growth in patients with several types of cancer, including breast and cervical. Prior labeling warned of similar risks in other types of cancers.

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 all of our drug candidates and technologies. We have licensed the rights, patent or otherwise, to our drug candidates from third parties. Specifically, we have recently licensed a patent on SAM-101 for the treatment of psychotic disorders, focusing on Schizophrenia from MinoGuard, who in turn licensed it from Mor. Furthermore, we licensed a use patent for the use patent on Recombinant Human Erythropoietin (rHuEPO) for the prolongation of multiple myeloma patients' survival and improvement of their quality of life from Bio-Gal, who in turn licensed it from Mor and Yeda. and we have licensed DOS from VivoQuest, Inc. (see "Item 10. Additional Information-Material Contracts"), 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. For a further discussion on our license agreements, the patent rights related to those licenses, and the expiration dates of those patent rights, see "Item 4. Information on the Company - Business Overview - Intellectual Property and Patents" and "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations," below.

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.

For example, in 2008, we announced that we had out-licensed the DOS program to Presidio Pharmaceuticals, Inc., or Presidio. Under the terms of the license agreement, Presidio becomes responsible for the development and commercialization activities and costs related to the DOS program.

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 are 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 level of off-label use of our drug candidates;
- the availability of government or third-party pay or reimbursement for our products;
- the side effects or unfavorable publicity concerning our products or similar products; and
- the effectiveness of our and/or partners' sales, marketing and distribution efforts.

Specifically, Recombinant Human Erythropoietin or SAM-101, if successfully developed and commercially launched for the treatment of 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. See “Item 4. Information on the Company – Business Overview - Supply and Manufacturing,” below. 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.

We believe that we will either be able to purchase rHuEPO and the components of the SAM-101 combination 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 programs for the treatment of multiple myeloma and schizophrenia, respectively. 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.

If our competitors develop and market products that are less expensive, more effective or safer than our products, 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. For a discussion of these competitors and their drug candidates, see "Item 4. Information on the Company - Business Overview – Competition," below. 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.

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

As of March 29, 2012, we had three full-time employees (one of whom is an officer, who is engaged with the Company as a service provider) and three 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.

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 in us 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.

Specifically, as per the terms of our amended agreement with Bio-Gal Ltd. and XTEPO, we issued approximately 133 million ordinary shares par value NIS 0.10 representing 69.44% of our then issued and outstanding ordinary share capital. Also, on November 30, 2011 we entered into a license agreement with MinoGuard by which we received an exclusive license to use SAM-101 in return for royalties on sales and milestones that may be paid in cash or our ordinary shares. (see "Item 4. Information on the Company - Business Overview - Intellectual Property and Patents" and "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations," below). 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 core business; 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. In addition, we may be required to pay third parties substantial transaction fees, in the form of cash or ordinary shares, in connection with such transactions.

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

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

The use of our drug candidates and technologies in clinical trials, and the sale of any approved products, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, 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;
- injury 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 Financial Condition

The Company has no revenues from operations and it funds its operations from its own capital and from external sources by way of issuing equity instruments. 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 incurred losses amounting to approximately $ 1.2 million and negative cash flows from operating activities amounting to approximately $ 1.3 million in the year ended December 31, 2011 (approximately $ 1.3 million and approximately $ 0.75 million, respectively, in the year ended December 31, 2010). The Company has no revenues from operations at this stage and it is dependent on external financing sources. The Company's management believes that giving the Company's current business plan, the cash and short term investment together with the proceeds from the private placement and the exercise of warrants in March 2012, totaled approximately $3.8 million (see note 24 to the consolidated financial statements), will enable it to fund its activities through at least into 2014. However, 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 2012 from research and development activities and from current operation which will be reflected in negative cash flows from operating activities. Accordingly, the Company will need to raise additional cash in the future thru the issuance of equity securities. However, if the Company is not be able to raise additional capital at acceptable terms, the Company may need to reduce operations or sell or license to third parties some or all of our technologies.

Our business depends on a number of factors, some of which are beyond our control. These factors include, among others:

· 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 regulatory approvals;

- 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; and

- SAM-101 patent expiration in 2027.

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The global capital markets have been experiencing extreme volatility and disruption for the last five years. In recent months, the volatility and disruption has increased mainly due to the financial instability and debt of some European countries, the uprisings against the regime in some Middle Eastern and North African countries, and the tension with Iran. Given recent particularly adverse market conditions for small biotechnology companies, 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, 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, ADRs, 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.

We may not be able to utilize our accumulated net losses owned by the Company in Israel and/or offsetting the tax liability of the Subsidiaries.

We have had a "permanent establishment" in the United States, or US, which began in 2005 and ended in 2009. As a result, any income attributable to such US permanent establishment for the years 2005-2009 was subject to US corporate income tax in the same manner as if we were a US corporation. If this is the case, we may not be able to utilize any of the accumulated Israeli loss carry forwards mentioned in our notes to the 2010 financial statements since these losses were not attributable to the US permanent establishment. However, we would be able to utilize losses attributable to the US permanent establishment to offset such US taxable income. As of December 31, 2011, US net operating loss carry forwards are approximately $23 million. These losses are subject to certain significant limitations and/or reductions due to, among other; the shifts in ownership of XTL, resulting from the Bio-Gal transaction (see "Item 8. Financial Information-Material Contracts") and subject to further limitations in case of a future offering or capital raise, resulting in more than 50 percentage point change over a three year look back period, and expiring through 2029. US corporate tax rates are higher than those to which we are subject in the State of Israel, and if we are subject to US corporate tax, it would have a material adverse effect on our results of operations. Currently we do not have any activity in the US subsidiaries. However, if the subsidiaries commence operations in the future, they will be subject to the tax rules mentioned above.

We may not be able to utilize our accumulated net losses owned by our Subsidiaries in the US or offsetting any tax liabilities we may incur in the next years.

As of December 31, 2011, the net operating tax losses ("NOL") of the US subsidiaries amounted to approximately $20 million. The utilization of these NOLs is subject to significant limitations and/or reductions to offset income in the future, if any, due to, among other, the shifts in ownership of XTL resulting from the Bio-Gal transaction (see "Item 8. Financial Information-Material Contracts") and subject to further limitations pursuant to a US tax rule, in case of a future offering or capital raise, resulting in more than 50 percentage point change over a three year look back period, and expiring through 2029.

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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. See “Item 4. Information on the Company - Business Overview - Intellectual Property and Patents,” below regarding our patent position with regard to our product candidates. 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 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 18 months or more. 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 choose to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, 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 adequately protect our trade secrets or other proprietary information. 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 receive patent protection or protect our proprietary information will be at risk.

We pursue patent protection in the US and in certain foreign countries relating to our development and commercialization of rHuEPO for the prolongation of multiple myeloma patients' survival and improvement of their quality of life. A main use patent (United States Patent 6,579,525 “Pharmaceutical Compositions Comprising Erythropoietin for Treatment of Cancer”) was submitted by Mor Research Applications Ltd., an Israeli corporation and Yeda Research and Development Company Ltd., an Israeli corporation, in April 1998 and PCT was filed in April 1999. The patent was granted in the United States, certain countries in Europe (major countries), Israel, Japan, Hong Kong and Canada and will expire in 2019. However we were granted an Orphan Drug Designation from the FDA in May 2011 in the US, (see “Item 4. Information on the Company - Government and Industry Regulation”). Currently, under the license agreement which is held by XTEPO, we have the exclusive worldwide rights to the above patent for the use of rHuEPO in multiple myeloma. See “Item 4. Information on the Company – Business Overview - Intellectual Property and Patents.” However, we cannot guarantee the scope of protection of any issued patents, or that such patents will survive a validity or enforceability challenge.

A PCT application (#PCT/IL2007/001251) relating to our development and commercialization of SAM-101 for the treatment of schizophrenia was filed in October 2007. The patent will expire in 2027. Currently, under the license agreement with MinoGuard, we have the exclusive worldwide rights to the above patent for the use of SAM-101 in schizophrenia. See "Item 4. Information on the Company – Business Overview - Intellectual Property and Patents." However, we cannot guarantee the scope of protection of any issued patents, or that such patents will survive a validity or enforceability challenge.

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 Ordinary Shares and ADRs

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

The trading volume of our ADRs has historically been low. Even if the trading volume of our ADRs 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 ADRs in desirable volume and you may be unable to sell your ADRs 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 ADRs at a desirable or stable price at any one time. You should be prepared to own our ordinary shares and ADRs 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 ADRs representing our ordinary shares is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- developments concerning our drug candidates;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- 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;
- changes in the market valuations of similar companies; and
- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our ordinary shares or ADRs, 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 ordinary shares could depress the market for our ordinary shares and ADRs.

Future issuances of a substantial number of our ordinary shares, or the perception by the market that those issuances could occur, could cause the market price of our ordinary shares or ADRs to decline or could make it more difficult for us to raise funds through the sale of equity in the future.

The Company has no revenues from operations at this stage and it is dependent on external financing sources. The Company's management believes that given the Company's current business plan, the cash and short term investment together with the proceeds from the private placement and the exercise of warrants in March 2012, totaling approximately $3.8 million (see note 24 to the consolidated financial statements), will enable it to fund its activities through at least into 2014. However, 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 2012 from research and development activities and from current operation which will be reflected in negative cash flows from operating activities. Accordingly, the Company will need to raise additional cash in the future thru the issuance of equity securities. However, if the Company is not be able to raise additional capital at acceptable terms, the Company may need to reduce operations or sell or license to third parties some or all of our technologies.

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. In addition, pursuant to a license agreement with MinoGuard, we may elect to execute any payment under the agreement resulting from milestone achievements, royalties, and sublicensing by way of issuing ordinary shares in lieu of cash payments. Also, according to the license agreement with VivoQuest, Inc., or VivoQuest, a privately held biotechnology company based in the US, we licensed (in all fields of use) certain intellectual property and technology related to VivoQuest's HCV program. Pursuant to the license agreement, we may elect to issue up to an additional $34 million in ordinary shares to VivoQuest in lieu of cash upon achievement of certain milestones. In the future, we may also enter into additional arrangements with other third-parties permitting us to issue ordinary shares in lieu of certain cash payments. Also, in connection with our agreement with DOV Pharmaceutical Inc., or DOV, which was terminated (see "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations," below), XTL Development committed to pay a transaction advisory fee to certain third party intermediaries. The advisory fees can be paid in cash or by issuance of shares, at our sole discretion. Pursuant to the agreement with the certain third party intermediaries, and after we examined the settlement issue, in furtherance to our financial condition, it is possible that the advisory fees will be paid by way of issuing 1,659,945 shares (equity-settled).

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

There are 3 shareholders (Mssrs. Alex Rabinovitch, David Bassa and Shalom Manova) who hold more than 5% each of our outstanding ordinary shares (approximately 37.21% cumulative). As a result, these persons/companies, either acting alone or together, may have the ability to significantly influence the outcome of all matters submitted to our stockholders 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/companies, 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 ADRs or ordinary shares.

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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 3 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 3 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 the aforementioned situations, the Company will consider any of the aforesaid 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 of majority (50%) of the votes who are not interested parties in such transaction.

Our ordinary shares and ADRs trade on more than one market, and this may result in price variations and regulatory compliance issues.

ADRs representing our ordinary shares are quoted on the Pink Sheets Market and our ordinary shares are traded on the Tel Aviv Stock Exchange, or 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 shares 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.

Our ADRs are quoted on the Pink Sheets market, which may result in them being classified as "Penny Stock."

Our ADRs may become subject to the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our securities. If our ADRs become considered penny stock, the ability of broker-dealers to sell our ADRs and the ability of our shareholders to sell their ADRs in the secondary market would be limited and, as a result, the market liquidity for our ADRs would be adversely affected. We cannot assure you that trading in our securities will not be subject to these or other regulations in the future.

Holders of our ordinary shares or ADRs 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 ADRs 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, 2008, 2009 and 2010. However, we believe that we were a PFIC for the taxable year ended December 31, 2007, 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, 2011 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. For further discussion of tax consequences of being a PFIC, see “US Federal Income Tax Considerations - Tax Consequences If We Are A Passive Foreign Investment Company,” below.

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 depressing the price of our 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. See “Item 10. Additional Information - Taxation - Israeli Tax Considerations,” below.

Our ADR holders are not shareholders and do not have shareholder rights.

The Bank of New York, as depositary, executes and delivers our ADRs on our behalf. Each ADR is a certificate evidencing a specific number of ADSs. Our ADR 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 ADRs. Holders of our ADRs will have ADR holder rights. A deposit agreement among us, the depositary and our ADR holders, and the beneficial owners of ADRs, sets out ADR holder rights as well as the rights and obligations of the depositary. New York law

governs the deposit agreement and the ADRs. Our shareholders have shareholder rights. Israeli law and our Articles of Association, or Articles, govern shareholder rights. Our ADR 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 ADR holders may instruct the depositary to vote the ordinary shares underlying their ADRs, but only if we ask the depositary to ask for their instructions. If we do not ask the depositary to ask for the instructions, our ADR holders are not entitled to receive our notices of general meeting or instruct the depositary how to vote. Our ADR holders will not be entitled to attend and vote at a general meeting unless they withdraw the ordinary shares from the depository. However, our ADR holders may not know about the meeting enough in advance to withdraw the ordinary shares. If we ask for our ADR holders' instructions, the depositary will notify our ADR 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 ADR holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADR holders. We cannot assure our ADR 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 ADR holders may not be able to exercise voting rights.

Our ADR 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 ADR 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 ADR holders will receive these distributions in proportion to the number of shares their ADRs represent. In addition, there may be certain circumstances in which the depositary may not pay to our ADR holders amounts distributed by us as a dividend or distribution. See the risk factor “There are circumstances where it may be unlawful or impractical to make distributions to the holders of our ADRs,” below.

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

The deposit agreement with the depositary allows the depositary to distribute foreign currency only to those ADR 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 ADR 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 ADR 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 ADR holders. This means that our ADR 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 most 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 Turkey, Iran and other Arab neighbor countries. In addition, recently in some Arab countries in the Middle East and North Africa there were

violent uprisings against the regimes in these countries. Consequently, there is a concern for the stability in the region which may affect the political and security situation in Israel. We cannot insure 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 all 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). Commencing from 2009 (after the Bicifadine trial did not meet its endpoints) 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. Additionally, our future activities could lead us to perform a clinical trial in Israel, which may lead us to reassess the US Dollar as our functional currency. 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 if we are unable to guard against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may decide in the future 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 to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. 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 others, 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 outline abovementioned 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. We cannot ensure that the "Knesset" will re-implement its plan for reducing the corporate tax rate in the future and therefore it may

adversely affect our results if we will be profitable. Moreover, we cannot guarantee that there will be no additional changes in the corporate tax rate in the future that may harm the Company's results.

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 and our Israeli auditors, most of whom reside outside the US, may be difficult to obtain within the US. In addition, because substantially most 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. For more information regarding the enforceability of civil liabilities against us, our directors and our executive officers, see “Item 10. Additional Information - Memorandum and Articles of Association - Enforceability of Civil Liabilities,” below.

ITEM 4. INFORMATION ON THE COMPANY

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 MM, schizophrenia and Hepatitis C. Our lead compound is Recombinant Human Erythropoietin, or rHuEPO, a known compound that we are planning to develop for the prolongation of MM patients’ survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. 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 median duration of survival with chemotherapy and other novel treatments is about five years. Most of these treatments have severe side effects.

Recent Developments

On November 2nd, 2011, the Company entered into a term sheet by which it will acquire a technology ("NiCure") from Mor, the Technology Transfer Office (TTO) of Clalit Health Services, by obtaining an exclusive license to use the entire technology and intellectual property in return for royalties on sales and milestone payments throughout the clinical development process. The agreement that will be signed by the parties is subject to, among others, the completion of due diligence, examination of the regulatory environment for the continued development of the drug, and the approval of the Company's board. NiCure's technology is based on the local administration of renin-angiotensin inhibitors (known drugs for the treatment of hypertension, i.e "Enalaprilat"), as novel treatment for the symptoms of cartilage-related diseases, such as Osteoarthritis. Osteoarthritis is one of the most frequent causes of

physical disability in adults. The disease involves progressive deterioration of articular cartilage; being loss of the major polysaccharides glycosaminoglycan (GAGS) a main cause of the disease. The current invention offers a novel therapy focused on increasing or replenishing the level of GAGs in the synovial fluid and cartilage, thereby relieving or even reversing symptoms of such diseases. Moreover, as GAGs are an important component of the dermis, the same technology can be used in order to treat skin wrinkles.

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 completed our engagement in a worldwide exclusive license with MinoGuard under which we shall develop and commercialize MinoGuard's technology for the treatment of psychotic disorders focusing on Schizophrenia. We will 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 (“the License”).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 of its shares to MinoGuard. In addition to the above payments, if we shall not commence a Phase 2 clinical trial by June 30, 2013, we will pay MinoGuard an annual license fee of $45,000 for the initial year, which will increase by $90,000 per year and up to $675,000 for the eighth year of license. According to the agreement receipt of an approval to commence such trial or continuance of clinical trials that were conducted or will be conducted by MinoGuard and/or its researchers, shall be deemed commencement of the Phase 2 clinical trial for this matter.

In March 2011, we raised by public issuance of 12,305,000 Ordinary shares of NIS 0.1 par value each, 6,152,500 warrants (series 1) and 18,457,500 warrants (series 2) on the Tel-Aviv Stock Exchange an immediate net amount of approximately $ 1.75 million (approximately NIS 6.3 million) (See “Item 5. Operating and Financial Review and Prospects-Liquidity and Capital Resources”).

On September 1, 2010, the Company and Yeda Research and Development Co. Ltd. (“Yeda”) entered into an option agreement granting an exclusive right to examine a medical technology in the field of the immune system, comprising of two proteins through which target molecules are examined and may serve as a basis for the development of therapeutics for diseases relating to the immune system, such as acute hepatitis, rheumatoid arthritis, Chron’s disease and psoriasis. Under the agreement, the Company purchased this exclusive option right to examine the medical technology for a 15-month period in consideration for $120,000 payable by the Company in the following manner and at the earlier of:

(i) In the event of raising funds by a prospectus to the public for more than $2 million, the Company is obligated to settle the payment in cash; or (ii) if 12 months after the date of closing of the agreement an amount of more than $2 million was not raised, the liability to Yeda can be satisfied, at the Company’s sole discretion and after obtaining Yeda’s approval to the timing, in cash or by issuance of options with equivalent value in lieu of that payment.

On December 2011 we notified Yeda that we do not intend to exercise the right given to us under this option agreement.

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 January 2007, XTL Development, Inc., our wholly owned subsidiary (“XTL Development”), had signed an agreement with DOV Pharmaceutical, Inc. (“DOV”), to in-license the worldwide rights for Bicifadine, a serotonin and norepinephrine reuptake inhibitor (SNRI) (“the Bicifadine transaction”). XTL Development was developing Bicifadine for the treatment of diabetic neuropathic pain - a chronic condition resulting from damage to peripheral nerves. In November 2008, we announced that the Phase 2b clinical trial failed to meet its primary and secondary endpoints, and as a result we ceased development of Bicifadine for diabetic neuropathic pain, and all rights under the agreement reverted to DOV. Since the failure of the Bicifadine phase 2b clinical trial, XTL Development has ceased the

prosecution and maintenance of those patents relating to Bicifadine, in coordination with DOV. In March 2010, the agreement was formally terminated.

In 2008, we signed an agreement to out-license the DOS program to Presidio Pharmaceuticals, Inc., or Presidio, a specialty pharmaceutical company focused on the discovery, in-licensing, development and commercialization of novel therapeutics for viral infections, including HIV and HCV. Under the terms of the license agreement, as revised, Presidio becomes responsible for all further development and commercialization activities and costs relating to our DOS program. In accordance with the terms of the license agreement, we received a $5.94 million, non-refundable, upfront payment in cash from Presidio and will receive up to an additional $59 million upon reaching certain development and commercialization milestones. In addition, we will receive royalties on direct product sales by Presidio, and a percentage of Presidio’s income if the DOS program is sublicensed by Presidio to a third party.

In March 2009, we signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal Ltd., a private biotechnology company based in Gibraltar. In December 2009, we amended the asset purchase agreement with Bio-Gal Ltd. so that XTL could acquire from the shareholders of XTEPO Ltd. ("XTEPO"), a special purpose company that was established by Bio-Gal Ltd.'s shareholders who shall receive from Bio-Gal all of Bio-Gal's right on rHuEPO and raised approximately $1.5 million, all of their shares in XTEPO in exchange for the issuance to XTEPO's shareholders of ordinary shares of XTL representing approximately 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a $10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are also 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 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 or XTEPO at any time after the completion of Phase 2 of an amount of minimum $2 million. On August 3, 2010, the Bio-Gal transaction was completed according to the outline signed by the parties to the agreement on December 31, 2009, after all the closing conditions had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share swap transaction pursuant to Section 104 and 103 to the Israeli Tax Ordinance (Revised), 1961 (See note 10a to the consolidated financial statements: Intangible Asset).

Our ADRs are quoted on the Pink Sheets, an inter-dealer electronic quotation and trading system in the over-the-counter (OTC) securities market, under the symbol "XTLBY.PK." Our ordinary shares are traded on the Tel Aviv Stock Exchange under the symbol "XTL." We operate under the laws of the State of Israel, under the Israeli Companies Act, and in the US, the Securities Act and the Exchange Act.

Our principal offices are located at Herzliya Business Park, 85 Medinat Hayehudim Street, Building G, PO Box 4033, Herzliya 46140, Israel, and our telephone number is +972-9-955-7080. XTL Biopharmaceuticals, Inc., our wholly-owned US subsidiary and agent for service of process in the US, can be reached at XTL Biopharmaceuticals, Inc c/o Corporation Trust Company, Corporation Trust Center, 1209 N. Orange Street, Wilmington, Delaware 19801, or by telephone at (800) 677-3394. Our primary internet address is www.xtlbio.com. None of the information on our website is incorporated by reference into this annual report.

In March 2011, we raised by public issuance of 12,305,000 Ordinary shares of NIS 0.1 par value each, 6,152,500 warrants (series 1) and 18,457,500 warrants (series 2) on the Tel-Aviv Stock Exchange an immediate net amount of approximately $ 1.75 million (approximately NIS 6.3 million). Since inception and until the date of the statement of financial position, we have raised net proceeds of approximately $139.2 million to fund our activities, including the net proceeds from the public issuance abovementioned.

For the years ended December 31, 2011, 2010, and 2009 our capital expenditures were $12,000, $16,000and $0 respectively. During 2011 and 2009, proceeds from disposition of certain unused assets were immaterial (less than $1,000). In 2010 we did not dispose any of our assets

Business Overview

Introduction

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 MM, schizophrenia, and Hepatitis C.

Our lead compound is rHuEPO, which we intend to develop for the survival extension of MM terminal patients' lives.

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, MM 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 median overall survival duration today with chemotherapy and other novel treatments is about five years. These treatments have severe side effects, including the suppression of the immune system, susceptibility to infections, nausea, vomiting and bleeding disorders.

Our second 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 in accordance with the Helsinki guidelines under the Shalvata Medical Center in Israel on SAM-101, 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 in symptoms, which frequently causes lengthy hospitalization periods.

Following in-vivo studies demonstrating the efficacy of minocycline treatment in a schizophrenia murine mode[1], 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[2]. Two independent clinical research groups in Manchester, UK, Maryland USA and Japan[3] have replicated these results, further supporting MinoGuard's hypothesis.

Our third program is the Diversity Oriented Synthesis, or DOS, program, which is focused on the development of novel pre-clinical Hepatitis C small molecule inhibitors. Compounds developed to date inhibit HCV replication in a pre-clinical cell-based assay with potencies comparable to clinical stage drugs. On March 20, 2008, we announced that we had out-licensed the DOS program to Presidio.

[1] Levkovitz Y., Levi U., Braw Y., and Cohen H., (2007) Brain Research, 1154: 154-162

[2] Levkovitz Y, Mendlovic S, et al. J Clin Psychiatry. 2010 Feb;71(2):138-49

[3] Miyaoka T et al. Clinical Neuropharmacology 31, October 2008 Sep-Oct;31(5):287-92

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On September 1, 2010, the Company and Yeda entered into an option agreement granting an exclusive right to examine a medical technology in the field of the immune system, comprising of two proteins through which target molecules are examined and may serve as a basis for the development of therapeutics for diseases relating to the immune system, such as acute hepatitis, rheumatoid arthritis, Chron's disease, and psoriasis. Under the agreement, the Company purchased this exclusive option right to examine the medical technology for a 15-month period in consideration for $120,000. In December 2011 we notified Yeda that we do not intend to exercise the right given to us under this option agreement.

To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any commercial revenues from the sales of our drug candidates. Moreover, preliminary results of our pre-clinical or clinical tests do not necessarily predict the final results, and acceptable results in early preclinical or 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.

Our Strategy

Our objective is to be a leader in developing novel pharmaceutical and biopharmaceutical products. We continuously identify and in-license therapeutic candidates in order to maximize our potential for commercial success.

Under our current strategy, we plan to:

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

- initiate a prospective clinical study intended to assess the safety and efficacy of SAM-101 when given to patients with schizophrenia;

- continually build our pipeline of therapeutic candidates, and

- develop collaborations with large pharmaceutical companies to market rHuEPO and SAM-101.

Products Under Development

rHuEPO for the treatment of MM

Market Opportunity

We intend to develop the use of rHuEPO for the prolongation of MM patients' survival. In the United States alone, there are approximately 74,800 people living with MM, with about 20,520 new cases diagnosed in 2011 (Facts 2012. The Leukemia & Lymphoma Society). MM 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 is also 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 (EPO-R) 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 (Mittelman PNAS 2001, Mittelman European Journal of Hematology 2004; Katz Acta Haematol 2005; Prutchi-Sagiv BJH 2006; Prutchi-Sagiv Exp Hematol 2008; Brines PNAS 2001; Baz Acta Haematol 2007; Prutchi-Sagiv Medical Hypothesis and Research 2005, Katz Eur. J. Immunol 2007) 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 made by Professor Moshe Mittelman and colleagues (Mittelman M, Zeidman A, Kanter P, Katz O, Oster H, Rund D, Neumann D. Erythropoietin has an anti-myeloma effect - a hypothesis based on a clinical observation supported by animal studies. Eur J Haematol. 2004 Mar;72(3):155-65) confirmed the high success rate of rHuEPO in treating the anemia in patients with MM. Six patients continued treatment with rHuEPO beyond the initial designed 12 week period with very poor prognostic features of MM, whose expected survival was less than 6 months, and surprisingly, they lived for 45–133 months cumulatively with the MM diagnosis and 38–94 months with rHuEPO (with a good quality of life).

This clinical observation was further supported by pre-clinical animal studies. These animal studies not only confirmed the anti-myeloma effect of rHuEPO but also detected a new unrecognized hitherto immune-mediated effect to rHuEPO, probably mediated via T cells (Mittelman M., Neumann D., Peled A., Kanter P. and Haran- Ghera N. (2001) Erythropoietin induces tumor regression and antitumor immune responses in murine myeloma models. (PNAS, vol. 98: 9. 5181 - 5186; Katz O, Barzilay E, Skaat A, Herman A, Mittelman M, Neumann D.Erythropoietin induced tumour mass reduction in murine lymphoproliferative models. Acta Haematol. 2005; 114 (3):177-9). Recently, it was also shown that treatment of stage II-III MM patients with rHuEPO is associated with a significant improvement of various immunological parameters and functions (Prutchi-Sagiv British Journal of Hematology 2006; Prutchi-Sagiv Experimental Hematology 2008; Lifshitz Molecular Immunology 2009).

Furthermore, several studies have been published by other investigators addressing survival and/or prognosis in cancer patients treated with rHuEPO. For example:

Baz R et al: A team from the Cleveland Clinic Myeloma Program analyzed their experience with rHuEPO in MM patients. This retrospective analysis provides data on 292 MM patients enrolled on different protocols between 1997 and 2003. The authors concluded that “rHuEPO was associated with improved overall survival in this population of anemic MM patients with SWOG stages II, III and IV.” They summarized by saying that “a prospective randomized trial is warranted to corroborate this finding” (Baz R et al: Recombinant human erythropoietin is associated with increased overall survival in patients with multiple myeloma (Acta Haematol 2007; 117: 162-7)).

Development Status

We plan on performing a prospective, multi-center, double blind, placebo controlled phase 2 study intended to demonstrate its effects on survival, biological markers related to the disease, immune improvements and quality of life. We intend to initiate the clinical trial/receive approvals to commence such clinical trial in the second half of 2012. The trial will enroll approximately 50 MM patients over a period of 2 and a half years. We have begun preliminary discussions with potential clinical sites and third party vendors for the planned study. The study is expected to cost $1-1.5 million. As part of the preparations, the Company conducts a research which includes collection of data relating to the level of specific proteins in the blood of a group of patients with multiple myeloma, which will assist in focusing the Phase 2 clinical trial protocol. These collected research data will be integrated in the Phase 2 clinical trial.

The drug development process is a multi-step process, including the following steps: pre-clinical, Phase 1, Phase 2, and Phase 3 clinical trials.

Given that we intend to develop a new indication for rHuEPO, which is already approved for another use, 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 Phase 2 clinical trial.

This is an estimation only and based on information our group has at the time of writing this report. Actual results may differ from the results implied in this report. There is no certainty that we may receive an exemption from carrying out one or more phases, nor is there certainty about the results of these experiments.

SAM-101 for schizophrenia

Market Opportunity

We intend to develop SAM-101, a patent-protected combination of minocycline and antipsychotic drugs for the treatment of schizophrenia. According to the US National Institute of Mental Health (NIMH), schizophrenia is the most prevalent severe mental disease in the USA, affecting 1.1% of the adult population[4]. Schizophrenia is ranked as the third most disabling condition, higher than blindness, by the general global population[5].

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, known as "negative symptoms" (apathy, poverty of speech, emotional withdrawal, depression) and severe cognitive impairment. SAM-101 is expected to overcome major limitations of currently available treatments for schizophrenia by providing an effective treatment, affecting both negative and positive symptoms, therefore preventing further deterioration in schizophrenic patients. In addition, SAM-101 showed lower side effects in the clinical trial mentioned below, which is expected to allow for higher compliance and improved patient quality of life. We believe that our innovative combination drug may open an opportunity for manufacturers to extend ethical drugs marketing time.

The global schizophrenia market in 2010 reached $6.4 billion. The market declined thereafter owing to the launch of generic versions of the leading antipsychotics – risperidone, olanzapine, quetiapine and ziprasidone, in 2011. According to Datamonitor, pipeline products in phase 3 and 2 clinical trials are not expected to drive market growth, since most of them offer no or little significant advantage over current medications, which will shortly become generic. Nevertheless, a number of new companies will enter the schizophrenia market during the upcoming years. Combination therapies are recognized for clinical advantages including facilitated patient compliance and convenience, along with increased efficacy. Such developments play a key role in terms of pharmaceutical market contenders' business strategy, allowing for extended exclusivity rights. According to DataMonitor (2005), "If a combination treatment is shown to be clinically superior, pharmaceutical companies will be racing to have the first combination product".

Development Status

We in-licensed SAM-101 after it successfully completed a Phase 2a prospective, randomized, double-blind, placebo-controlled clinical trial conducted on about 70 schizophrenics in accordance with the Helsinki guidelines under the Shalvata Medical Center in Israel. The trial met its endpoints showing that SAM-101 improves the positive symptoms of the disease as well as the patients' cognitive state, minimizes the negative symptoms (social parameters and patient cognition) and reduces weight gain side effects among patients. Schizophrenia is a severe and chronic (psychotic) mental disorder and one of the most common. It affects the majority of social and mental functions, mood, perception, thought and cognitive functions. According to the United States National Institute of Mental Health, about 1.1% of the adult population in the United States has Schizophrenia[6]. The research company Decision Resources indicates that the Schizophrenia treatment industry in 2010 amounted to approximately $6.4 billion[7].

[4] The schizophrenia prevalence estimations ranges from 0.5%-1.5% as reported by DSM-IV(2000). The US Surgeons General reports a prevalence of 1.3% worldwide, regardless of race (1999) http://www.nimh.nih.gov/statistics/1SCHIZ.shtml

[5] Ustun et al (1999) The Global Burden of Mental Disorders. *American Journal of Public Health,* 89(9), 1315-1318 this is ok

Since minocycline and antipsychotics have been approved in the United States, a combination of the two should be eligible for market approval using the 505(b)(2) route. This allows the FDA to rely on their own previous finding of safety and efficacy of the active pharmaceutical ingredients for the purposes of marketing approval of SAM-101.

The phase 2 trial that was conducted in Israel has shown that SAM-101 has additional clinical benefit compared to the available antipsychotic drug alone. We plan to perform a multi-center phase 2 clinical trial under the FDA, using our proprietary combination. In order to confirm the scope of work required for product market approval (New Drug Approval, NDA) and to identify the specific requirements for filing an Investigational New Drug (IND) application with the FDA and for eventual market approval of the combination drug, we will request a Pre-IND meeting with the FDA.

This is an estimation only and based on information our group has at the time of writin