

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

**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

85 Medinat Hayehudim, Building G, PO Box 4033

Herzliya Pituach 46140, Israel

Tel: +972-9-955-7080

Fax: +972-9-951-9727

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

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



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

Yes  No

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

Large accelerated filer  Accelerated filer  Non-accelerated filer

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

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

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

Item 17  Item 18

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

Yes  No

**XTL BIOPHARMACEUTICALS LTD.**

**ANNUAL REPORT ON FORM 20-F**

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Consolidated Financial Statements

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Report of BDO Ziv Haft Consulting & Management Ltd., dated March, 2012

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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.





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.

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.



## 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.



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 depository to vote the ordinary shares underlying their ADRs, but only if we ask the depository to ask for their instructions. If we do not ask the depository to ask for the instructions, our ADR holders are not entitled to receive our notices of general meeting or instruct the depository 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 depository will notify our ADR holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depository will try, as far as is practical, subject to the provisions of the deposit agreement, to vote the shares as our ADR holders instruct. The depository 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 depository 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 depositary 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 2<sup>nd</sup>, 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](http://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, \$16,000 and \$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.

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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<sup>1</sup>, 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<sup>2</sup>. Two independent clinical research groups in Manchester, UK, Maryland USA and Japan<sup>3</sup> 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.

<sup>1</sup> Levkovitz Y., Levi U., Braw Y., and Cohen H., (2007) Brain Research, 1154: 154-162

<sup>2</sup> Levkovitz Y, Mendlovic S, et al. J Clin Psychiatry. 2010 Feb;71(2):138-49

<sup>3</sup> Miyaoka T et al. Clinical Neuropharmacology 31, October 2008 Sep-Oct;31(5):287-92

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<sup>4</sup>. Schizophrenia is ranked as the third most disabling condition, higher than blindness, by the general global population<sup>5</sup>.

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<sup>6</sup>. The research company Decision Resources indicates that the Schizophrenia treatment industry in 2010 amounted to approximately \$6.4 billion<sup>7</sup>.

<sup>4</sup> 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>

<sup>5</sup> 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 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.*

## **DOS**

### *Market Opportunity*

We had been developing the DOS program for the treatment of Hepatitis C, prior to us out-licensing it to Presidio in March 2008. Chronic Hepatitis C is a serious life-threatening disease which affects around 130 to 170 million people worldwide, according to the World Health Organization. According to the BioSeeker Group, 20% to 30% of chronic hepatitis patients will eventually develop progressive liver disease that may lead to decomposition of the liver or hepatocellular carcinoma (liver cancer). According to the National Digestive Diseases Information Clearing House, of the U.S. population, 1.6 percent, or an estimated 4.1 million Americans, have antibody to HCV (anti-HCV), indicating ongoing or previous infection with the virus. Hepatitis C causes each year 10,000 to 12,000 people die from HCV in the US alone.

### *Development Status*

In March 2008, and as revised in August 2008, we signed an agreement to out-license the DOS program to 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 a royalty 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. DOS is a pre-clinical program focused on the development of novel Hepatitis C small molecule inhibitors. DOS applies proprietary, fully synthetic chemistry methodologies to rapidly synthesize and diversify complex chemical compounds such as natural products. Compounds in each family inhibited HCV replication in a pre-clinical cell-based assay with potencies against the most prevalent HCV genotypes comparable or superior to clinical stage drugs. They also retained their potency against isolates that are resistant to clinical stage drugs. Presidio is currently in the process of identifying drug leads to be tested in formal toxicological studies in anticipation of the commencement of clinical trials in humans thereafter. According to our knowledge, as of today, the DOS program compounds are still in preclinical development. See "Item 10. Additional Information -Material Contracts."

<sup>6</sup> <http://www.nimh.nih.gov/statistics/1SCHIZ.shtml>

<sup>8</sup> <http://www.cancer.org/Cancer/CancerBasics/economic-impact-of-cancer>

We gained access to the DOS program through a license and asset purchase agreement with VivoQuest that was completed in September 2005. Under this agreement, we licensed lead HCV molecules, a proprietary compound library and medicinal chemistry technologies. The DOS small molecule chemistry technology developed at VivoQuest was used to create these molecules. See “Item 10. Additional Information -Material Contracts.”

### *Intellectual Property and Patent*

#### **General**

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

Generally, patent applications in the US are maintained in secrecy for a period of 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. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. Granted patents can be challenged and ruled invalid at any time, therefore the grant of a patent is not of itself sufficient to demonstrate our entitlement to a proprietary right. The disallowance of a claim or invalidation of a patent in any one territory can have adverse commercial consequences in other territories.

If our competitors prepare and file patent applications in the US that claim technology also claimed by us, we may choose to participate in interference proceedings declared by the US 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 our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses



associated with that effort.

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

### **rHuEPO for the treatment of MM**

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. and Yeda Research and Development Company Ltd., Israeli corporations, in April 1998 and a PCT was filed in April 1999. The patent was granted in the United States, Europe (Austria, Belgium, France, Germany, Great Britain, Ireland, Italy, Netherlands, Spain, Sweden and Switzerland), Israel, Japan, Hong Kong and Canada. The issued patent will expire in 2019 (See “Item 4. Government and Industry Regulation” regarding our granted orphan drug designation). Pursuant to our agreement with Bio-Gal Ltd, we have exclusive worldwide rights to the above patent for the use of rHuEPO in MM.

The main claims of this issued patent are as follows: A method for the treatment of a multiple myeloma patient, comprising the administration of erythropoietin or recombinant human erythropoietin, as the case may be, for the inhibition of tumor growth, triggering of tumor regression or inhibition of MM cell metastasis in the said patient.

The original EPO patent for the treatment of anemia is currently owned by Amgen and Johnson & Johnson.

### **SAM-101 for the Treatment of Schizophrenia**

A patent titled “Combined therapies of antipsychotic drugs and tetracyclines in the treatment of psychiatric disorders” was submitted by Mor on October 2007 (International application number PCT/IL2007/001251). The patent is currently in National Phase and has been filed in USA, Canada, Europe, Japan, India, Australia and Israel.

The main claims of this patent include: 1. A pharmaceutical composition comprising as active ingredients at least one tetracycline and at least one antipsychotic drug; 2. The pharmaceutical composition with modified release formulation; 3. A method for treating a psychotic disorder comprising administering the pharmaceutical composition to a patient in need.

### **DOS**

The lead molecules that are included in the VivoQuest license are covered by four issued US patents and three pending US patent applications. As of April 8, 2011, the Company has determined to maintain these patents in the United States only. The patent applications describe both the structure of the compounds and their use for treating

HCV infection. The two issued VivoQuest patents will expire in 2023. Additional patent applications, if issued, will expire in 2023, 2024 and 2025. We have also filed additional patent applications that cover the lead compounds discovered since the licensing of the DOS from VivoQuest. These additional patent applications, if issued, will expire in 2026 and 2027. Based on the provisions of the Patent Term Extension Act, we currently believe that we would qualify for certain patent term extensions. Pursuant to the VivoQuest license, we will make royalty payments ranging from 2% to 8%, based on net sales of the compounds.

### **Other Intellectual Property Rights**

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

### ***Licensing Agreements and Collaborations***

Our current key strategic alliances are discussed below. See “Item 5. Operating and Financial Review and Prospects - Obligations and Commitments” which describes contingent milestone payments we have undertaken to make to certain licensors over the life of the licenses described below.

### **Bio-Gal Ltd./XTEPO**

We signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal, a private biotechnology company based in Gibraltar, in March 2009. In December, 2009, we amended the asset purchase agreement with Bio-Gal, so that XTL could acquire from the shareholders of XTEPO 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 successful completion 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 the 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).

### **MinoGuard License**

On March 24, 2011, the Company entered into a term sheet to acquire the assets of MinoGuard by an exclusive license to use MinoGuard's entire technology in return for royalties on sales and milestone payments throughout the clinical development process, without any other payments. MinoGuard was founded in 2007 in order to commercialize combination therapies for treating psychotic diseases, focusing on schizophrenia. The transaction was subject, among others, to completion of due diligence studies, examination of the regulatory track for the continued development of the drug and the approval of the Company's Board. On November 30, 2011, the agreement with MinoGuard was completed after all prerequisites abovementioned had fully met. In accordance with the terms of the license agreement we shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately \$2.5 million. In addition, we will pay MinoGuard royalty-based payments on products that are based on the Technology, equal to 3.5% of 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. The agreement states that 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.

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

The license may be terminated in by either XTL without cause upon 30 days notice, or by the licensor for no commercial progress in the event that by the date of June 30th, 2013 neither commencement of phase II Clinical Trial with respect to the licensed product has occurred, nor XTL has entered into a Sublicense Agreement with a substantial third party.

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

Countries in which application was filed	Priority Date	Application No.	Patent No.	Status	Expiration Date*
Canada	18.10.2007	2666796	-	Filed	18.10.2027
Europe	18.10.2007	07827225.9	-	Examination	18.10.2027
India	18.10.2007	3100/DELNP/2009	-	Filed	18.10.2027
Israel	18.10.2007	198134	-	Examination	18.10.2027
PCT	29.03.2007	PCT/IL2007/000414	-	Expired	
PCT-1	18.10.2007	PCT/IL2007/001251	-	Expired	
US Prov.	19.10.2006	60/852646	-	Expired	
USA	18.10.2007	12/446444	-	Examination	18.10.2027

\* assuming that the patent will be registered on the basis of the PCT (Patent Cooperation Treaty application).

### **VivoQuest License**

In August 2005, we entered into a license agreement with VivoQuest covering a proprietary compound library, including certain HCV compounds. Under the terms of the license agreement, we have exclusive worldwide rights to VivoQuest's intellectual property and technology in all fields of use. To date we have made approximately \$0.9 million in license payments to VivoQuest under the license agreement. The license agreement also provides for additional milestone payments triggered by certain regulatory and sales targets. These additional milestone payments total \$34 million, \$25 million of which will be due upon or following regulatory approval or actual product sales, and are payable in cash or ordinary shares at our election. In addition, the license agreement requires that we make royalty payments to VivoQuest on product sales.

### **Presidio License**

In March 2008, and as revised August 2008, we signed an agreement to out-license the DOS program to 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 a royalty 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.

### **Bicifadine License**

In January 2007, XTL Development had signed an agreement with DOV to in-license the worldwide rights for Bicifadine for the treatment of diabetic neuropathic pain. In accordance with the terms of the license agreement, XTL Development paid an initial up-front license fee of \$7.5 million in cash in 2007. In addition, XTL Development would have made milestone payments of up to \$126.5 million over the life of the license. These milestone payments may have been made in either cash and/or our ordinary shares, at our sole discretion, with the exception of \$5 million in cash, which would have been due upon or after regulatory approval. XTL Development was also obligated to pay royalties to DOV on net sales of Bicifadine. 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 in 2008 and all rights under the agreement reverted to DOV. Since the failure of the Bicifadine phase 2b clinical trial, XTL Development ceased the prosecution and maintenance of those patents relating to Bicifadine, in coordination with DOV. In March 2010, the agreement was formally terminated.

### ***Competition***

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

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

The anti-cancer drug market is very large. The National Institute of Health estimated that the total cost of cancer care in the United States in 2007 was \$226.8 billion<sup>8</sup>. In 2008, sales of anti-cancer drugs reached a total of approximately \$48 Billion<sup>9</sup> and are expected to grow to 80 billion dollars in 2011<sup>0</sup>. In 2003, a new anti-cancer drug for multiple myeloma called Velcade was approved for use and marketing.



In 2008, sales of drugs used to treat multiple myeloma in the US, France, Germany, Italy, Spain, England and Japan totaled \$2.1 billion (and is expected to rise to \$5.3 billion in 2018)<sup>11</sup>. According to their recent financial statements, actual sales of Velcade in 2011 by Johnson & Johnson<sup>12</sup> (which markets Velcade outside the US) amounted to \$1.27 billion. Also, based on the financial statements of the pharmaceutical Celgene<sup>13</sup> (which markets Revlimid), Revlimid sales in 2011 amounted to \$3.21 billion. Velcade sales by the Japanese pharmaceutical Takeda<sup>14</sup> (which markets velcade in the US) in 2010 amounted to \$0.59 billion.

<sup>9</sup> IMS Health <http://www.reuters.com/article/idUSN1453543620080515>

<sup>10</sup> IMS Health <http://www.thepharmaletter.com/file/46150/multiple-myeloma-market-will-more-than-double-to-53-billion-in-2018.html>

<sup>11</sup> According to IMS Health - <http://www.reuters.com/article/idUSN1453543620080515>

<sup>12</sup> <http://files.shareholder.com/downloads/JNJ/1746723755x0x552947/211DF99C-D473-47DA-B3AF-8EE1A05361D6/2011-An>  
(page 32)

<sup>13</sup> <http://ir.celgene.com/phoenix.zhtml?c=111960&p=irol-newsArticle&ID=1653011&highlight=>

<sup>14</sup> [http://www.takeda.com/pdf/usr/default/ar2011e\\_42865\\_3.pdf](http://www.takeda.com/pdf/usr/default/ar2011e_42865_3.pdf) (page 55)

### **Competing Products for Treatment of MM**

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

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

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

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

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

**High dose chemotherapy**, particularly melphalan, with autologous haematopoietic stem cell transplantation improves response rates and their duration and survival compared with conventional chemotherapy. It is now commonly used as consolidation treatment. Unfortunately, even after haematopoietic stem cell transplantation, relapse is only a matter of

time, although a minority of patients seems to survive over a decade in remission (“operational cure”). Maintenance treatment after transplantation with corticosteroids or interferon is often prescribed in an attempt to delay relapse. Although this probably does prolong the duration of remission, it is unclear if it confers a survival benefit.

**Allogeneic haematopoietic stem cell transplantation** might potentially cure a proportion of patients through immunologically mediated graft versus myeloma effect. However, this procedure remains highly experimental at the present time. High mortality related to treatment has been a problem historically, but the use of safer preparative regimens of reduced intensity could improve long term results.

### **Competing Products for Treatment of Schizophrenia**

SAM-101, if approved, will compete with currently available marketed atypical anti-psychotics from Eli Lilly, Johnson & Johnson, Bristol-Myers Squibb/Otsuka Pharmaceutical Co., Ltd., Pfizer Inc., AstraZeneca and others, as well as with generic brands of typical and atypical anti-psychotics. In addition there are a number of potentially competitive compounds under development, which includes: Cariprazine, which is being developed by Forest Laboratories, Inc.; Bifeprunox, which is being developed by Solvay Pharmaceuticals, Inc., and Lurasidone, which is being developed by Dainippon Sumitomo Pharma Co., Ltd.

### ***Supply and Manufacturing***

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

### **rHuEPO for the treatment of MM**

We believe that we will either be able to purchase Recombinant Erythropoietin (rHuEPO) from existing pharmaceutical companies or to enter into collaborative agreements with contract manufacturers or other third-parties to obtain sufficient inventory to satisfy the clinical supply needs for our planned development program for the treatment of MM.

### **SAM-101 for the Treatment of Schizophrenia**

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

### **DOS**

Under the terms of the license agreement, Presidio became responsible for all further development and commercialization activities and costs relating to the DOS program.

### **General**

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

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

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

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

### ***Government and Industry Regulation***

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

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

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

The Company may apply the European Medicines Agency in order to obtain Orphan-drug designation for its Recombinant Erythropoietin in Europe. Orphan designation is granted by the European Medicines Agency, following a positive opinion from the Committee for Orphan Medicinal Products, to a medicinal product that is intended for the

diagnosis, prevention or treatment of a life-threatening or a chronically debilitating condition affecting not more than five in 10,000 persons in the European Community when the application for designation is submitted. Orphan drug designation provides the sponsor with access to the Centralized Procedure for the application for marketing authorization, protocol assistance, up to a 100% reduction in fees related to a marketing authorization application, pre-authorization inspection and post-authorization activities, and could provide ten years of market exclusivity in the EU, once approved for the treatment of multiple myeloma.

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

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

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

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

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

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

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

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

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

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

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

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

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



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

- - insufficient supply of the drug candidates;

- - adverse medical events or side effects in treated patients; and

- - ineffectiveness of the drug candidates.

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

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

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

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

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

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

### **Organizational structure**

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

Our wholly-owned subsidiaries, XTL Biopharmaceuticals, Inc. and XTL Development, Inc., are each incorporated in Delaware. Since November 2008, these companies have not been active.

### **Property, Plant and Equipment**

Since August 2010 we lease offices of approximately 255 square meters, in Herzliya, Israel. The basic lease period is for 36 months with an option for an additional 24-month period. In addition, the Company has the right to terminate the agreement on the date of an alternative tenant in its place, pursuant to approval of the landlord.

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

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

None.

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## ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in “Item 3. Key Information–Risk Factors” and “Item 4. Information on the Company.” See also the “Special Cautionary Notice Regarding Forward-Looking Statements” set forth above.

You should read the following discussion and analysis in conjunction with our audited consolidated financial statements, including the related notes, prepared in accordance with IFRS (International Financial Reporting Standards) for the years ended December 31, 2011, 2010 and 2009, and as of December 31, 2011 and 2010, contained in “Item 18. Financial Statements” and with any other selected financial data included elsewhere in this annual report.

In April 2009, the Company was de-listed from NASDAQ after the Bicifadine trial did not meet its endpoints. At the same time, the Company became primarily listed on TASE (Tel Aviv Stock Exchange) and therefore is not entitled to the exemptions previously granted in Israel due to its listing on NASDAQ.

Pursuant to the requirement to comply with all the Israeli listing requirements, the Company adopted IFRS (International Financial Reporting Standards) as the accounting policy of the Company starting on 2009 and effective since January 1, 2007.

### *Selected Financial Data -*

The tables below present selected financial data for the fiscal years ended as of December 31, 2011, 2010 and 2009. 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 IFRS issued by the IASB. You should read the selected financial data in conjunction with “Item 3. Key Information” and “Item 8. Financial Information” and “Item 18. Financial Statements.”

### **Consolidated Statements of Comprehensive Income:**

Year ended December 31,		
2011	2010	2009

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U.S dollars in thousands (except per share data)

Research and development costs	158	64	-
General and administrative expenses (income)	1,078	1,222	*) (2,429 )
Other gains (losses), net	12	30	139
Operating income (loss)	(1,224 )	(1,256 )	2,568
Finance income	24	6	6
Finance costs	7	7	10
Financial income (costs), net	17	(1 )	(4 )
Income (loss) before taxes on income	(1,207 )	(1,257 )	2,564
tax benefit	-	-	(23 )
Net income (loss) for the year attributable to equity holders of the parent	(1,207 )	(1,257 )	2,587
Basic and diluted earnings (loss) per share (in U.S. dollars)	(0.006 )	(0.011 )	0.044
Weighted average number of issued ordinary shares	201,825,645	113,397,846	58,561,065

\*) 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 15b to the financial statements.

Consolidated Statements of Financial Position Data:

As of December 31,  
2011 2010 2009  
U.S dollars in thousands

Cash, cash equivalents and bank deposits	1,495	1,066	412
Working capital	955	259	(151 )
Total assets	4,073	3,797	715
Total shareholders' equity	3,444	2,834	7

**Overview**

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of unmet medical needs, particularly the treatment of multiple myeloma, or MM, schizophrenia and Hepatitis C. 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.

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

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

We did not generate revenues in 2011, 2010 and 2009 as we are a development stage company, and thus we did not have cost of revenues for those years.

Our research and development expenses in 2011 and 2010 consisted of primarily expenses related to the preparations for the rHuEPO drug clinical trial development plan. As part of the preparations, the Company is currently conducting 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. This collected research data will be integrated in the Phase 2 clinical trial. The costs of such preparations comprise of, among others, costs in connection with medical regulation, patent registration costs, medical consulting costs. Additionally, we had amortization expenses of the exclusive right to examine a medical technology in the field of the immune system. We did not have research and development expenses in 2009.



Our general and administrative expenses consist primarily of salaries, consultant fees, and related expenses for executive, finance and other administrative personnel, professional fees, director fees and other corporate expenses, including investor relations, and facilities related expenses. We expense our general and administrative expenses as they are incurred. In 2009, we recorded a reversal of non cash option compensation expenses that related to options granted to our former chairman and former CEO in an amount of approximately \$ 4.1 million according to IFRS 2 and as a result the net general and administrative expenses ended with negative expenses (see “non-cash option compensation” below).

Our business development costs consist primarily of salaries and related expenses for business development personnel, travel, professional fees and transaction advisory fees to third party intermediaries. Our business development activities are related to partnering activities for our drug programs, seeking new development collaborations and in-licensing opportunities. According to IFRS, business development expenses are presented based on the function of expense in general and administrative. We expense our business development expenses as they are incurred. The transaction advisory fee associated with the Bicifadine transaction in the form of a SAR was revalued based on the then current fair value, at each subsequent reporting date. On September 30, 2009, in accordance with IFRS 2 and after the Company's management examined the issue, in furtherance to the Company's financial condition, the classification of the transaction was modified to an equity-settled transaction.

Our results of operations include non-cash compensation expense as a result of the grants of stock options. Compensation expense for awards of options granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual stock options according to the Black-Scholes valuation model. The expense is included in the respective categories of expense in the statement of comprehensive income. In 2009 we reversed a significant amount of \$4.1 million related to the former Chairman's and former CEO's non-cash option compensation expenses granted in August 2005 and March 2006, respectively, and which were subject to a market capitalization/share price milestone(s) that were not achieved. According to IFRS 2, due to the fact that these options were linked to market capitalization/share price milestone(s), we were required to reverse the accumulated related expenses that were recorded over the years since the grant date, immediately after their termination from the company in March-April 2009 and after we acknowledged that the milestone(s) were not achieved. We experienced a reduction in non-cash compensation in the fiscal year ended December 31, 2009 (even excluding the reversal of the options related to the former Chairman and former CEO) due to the restructuring plan of the Company from November 2008 and the reduction in the number of employees (see note 16b to the consolidated financial statements). We expect to incur significant increase on the non-cash compensation for the future, primarily due to the increase in the number of employees and additional grants of options to current employees.

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

period.

Our planned clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our product candidates in the near future or generate licensing revenues from upfront payments associated with out-licensing transactions. In addition, we expect losses to continue as we continue to fund development of our drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. As a result, our periodical results may fluctuate and a period-by-period comparison of our operating results may not be a meaningful indication of our future performance.

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## Results of Operations

### *Years Ended December 31, 2011, 2010 and 2009*

*Revenues.* The Company did not produce any revenues for the years ended December 31, 2011, 2010 and 2009. We do not anticipate to recognize material revenue in 2012.

*Cost of Revenues.* There was no cost of revenues for the years ended December 31, 2011, 2010 and 2009 as we did not generate revenues in these years. .

*Research and Development Costs.* Research and development expenses in 2011 and 2010 amounted to \$158 thousand and \$64 thousand, respectively and derived mainly from costs related to the preparations to the rHuEPO drug clinical trial development plan. 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 costs of such preparations comprises of, among others, medical regulation, medical consulting , expenses relating to clinical insurance and amortization of the exclusive right to examine a medical technology in the field of the immune system. We had no research and development expenses in 2009. (see “2009 Restructuring” below and also see Note 10c to the financial statements). The increase in research and development expenses resulted mainly due to the fact that the Bio-Gal transaction was completed in August 2010, thus we incurred expenses relating to the preparations related to rHuEPO drug clinical trial development plan only thereafter. Also the increase in research and development expenses is due to amortization expenses in connection with the technology examination abovementioned which began in September 1, 2010 and ended in November 30, 2011.

Excluding non-cash compensation costs and amortization expenses, we expect to increase our level of research and development costs during 2012 mainly due to the plan to receive approval to initiate the phase 2 clinical trial on rHuEPO for the treatment of multiple myeloma, costs related to SAM-101 development, and costs related to new technologies, if in-licensed/acquired.

*General and Administrative Expenses.* General and administrative expenses in 2011 totaled approximately \$1,078 thousand, compared to \$1,222 thousand in 2010 and income (decrease in expenses) of approximately \$2,429 thousand in 2009. The decrease in general and administrative expenses in 2011 compared to 2010 and the increase in general and administrative expenses in 2010 compared to 2009 were due mainly to the following reasons:



The decrease in general and administrative expenses in 2011, compared to 2010, is mainly due to decline in options expenses which were accounted for by the graded vesting method under which the expenses are declined over the vesting period, as explained above, decrease in Directors and Officers Liability Insurance expenses which reflects the decrease in the annual premium in view of the improvement in Company's parameters, decline in professional services expenses and decline in expenses for maintenance of patents principally for the EPO drug following registration of patents in all countries where it was filed in 2010, offset by a growth in salary costs/consulting fees of senior officers which are updated in the second half of 2010 according to the agreements and a growth in rent expenses which reflect the lease agreement of our permanent offices since August 2010. During 2009, the Company recorded a decrease in general and administrative expenses after expenses from previous years in respect of options of the former chairman and former CEO of the Company were reversed because the terms of the options that were contingent on the performance were not met. The effect of the options which were forfeited immediately after their departure amounted to approximately \$4.1 million. General and administrative expenses in 2009 less the effect of the reverse of expenses in respect of options of the former chairman and former CEO of the Company totaled approximately \$1,672 thousand, compared to approximately \$ 1,222 thousand in 2010, a decrease of approximately \$450 thousand (27%) which mainly arises from the decrease in salary expenses following the restructuring plan in the Company in 2009, decrease in office lease expenses (terminating the US office lease agreement, changing the Israeli offices while reducing office space) and decrease in the Company's operating expenses as part of the restructuring plan performed by the Company immediately after announcing the failure to achieve the Bicifadine drug clinical trial endpoints at the end of 2008.

Excluding non-cash compensation costs, we expect to increase our level of general and administrative costs during 2012 compared to 2011. This is due to the fact that in 2011, we have broadened our product pipeline by in-licensing SAM-101 (see "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations") and we may license additional technologies in the upcoming year.

*Other gains (losses), net.* The Company derived other gains in the year ended December 31, 2011 of approximately \$ 12 thousand which primarily originated from reduced allowance for suppliers in foreign subsidiaries for previous years based on the aging and condition of the debt, compared to other gains in the amount of approximately \$ 30 thousand for the year ended December 31, 2010.. The Company derived other gains in 2009 of approximately \$ 139 thousand which originated from agreements entered into with different suppliers mainly in the U.S. in respect of previous years relating to the activity of the clinical trial of Bicifadine which was terminated at the end of 2008 and which derived to the Company reduced costs.

*Net Financial expenses.* Finance income (expenses) for the years ended December 31, 2011, 2010 and 2009 totaled approximately \$ 17 thousand, \$ (1) thousand and \$ (4) thousand, respectively. The increase in finance income in 2011 compared to 2010 and 2009 derives mainly from interest income on short-term bank deposits whose carrying amount during 2011 was significantly higher compared to 2010 and 2009 and this as a result of effecting the issuance in March 2011 (see cash flow report to the consolidated financial statements and note 16a).

*"Income Taxes"* We had no income tax expense for the years ended December 31, 2011 and 2010 due to the losses incurred and we did not recognize any deferred tax benefits, since it is not "more likely than not" that we will be able

to generate profits in the future to realize the deferred taxes.

Tax benefit for the year ended December 31, 2009, amounted to \$23 thousand. In November 2009 Congress passed the Worker Homeownership & Business Assistance Act of 2009 which allows businesses to carryback operating losses for up to 5 years. AS a result of this Act the company was able to carry back its 2009 losses to tax years ended December 31, 2003. This benefit was partially offset by New York State Franchise tax.

### ***2009 Restructuring***

Following the failure of the Bicifadine trial in November 2008, we terminated the employment of most of our employees. As a result, we incurred a payment of \$420 thousand during 2009 related to employee dismissal costs, all of which were accrued in 2008. In February 2009, we appointed a Chief Executive Officer whose terms of employment have been approved in March 2010, effective August 3, 2010, upon the completion of the Bio-Gal transaction. In July 2009, we appointed a Chief Financial Officer.

### **Critical Accounting Policies**

*Basis of presentation of the financial statements.* The financial statements of the Group as of December 31, 2011 and 2010 and for each of the three years in the period ended December 31, 2011 have been prepared in accordance with International Financial Reporting Standards which are standards and interpretations issued by the International Accounting Standards Board ("IFRS") and include the additional disclosure required in accordance with the Israeli Securities Regulations (Annual Financial Statements), 2010.

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

The consolidated financial statements have been prepared under the historical cost convention.

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

The Group's operating cycle is 12 months.

The Group analyses the expenses recognized in the statement of comprehensive income by classification based on the function of expense.

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with IFRS (International Financial Reporting Standard). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

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



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

Non-market vesting conditions are included in the assumptions used in estimating the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions of the share-based payment arrangement are to be satisfied. In each reporting date, the Company revises its estimates of the number of options that are expected to vest based on the non-market vesting conditions and recognizes the impact of the revision to original estimates, if any, in the statement of comprehensive income (loss) with a corresponding adjustment in equity.

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

Share-based payments for share appreciation rights with settlement alternatives, at the Company's sole discretion, which were granted to the Company's service provider, were accounted in the past as a cash-settled grant. The Company re-measured the value of the liability at each reporting date. On September 30, 2009, in accordance with IFRS 2 and after the Company's management examined the issue, in furtherance to the Company's financial condition (see Note 1c to the financial statements), the classification of the transaction was modified to an equity-settled transaction. The Company is not obligated to settle the transaction in cash.

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

The fair value of stock options granted with service conditions is determined using the Black-Scholes valuation model. Such value is recognized as an expense over the service period, net of estimated forfeitures, using the graded vesting method under IFRS 2. The fair value of stock options granted to the former Chairman and former CEO with market conditions was determined using a Monte Carlo Simulation method. Such value is recognized as an expense using the accelerated method under IFRS 2. The options of the former Chairman and former CEO mentioned above expired after their departure from the Company in March and April, 2009 respectively and the accumulated expenses related to these options recorded over the years were reversed in year 2009 (see note 16b to the consolidated financial statements).

The estimation of stock awards that will ultimately vest requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period those estimates are revised. We consider many factors when estimating expected forfeitures, including types of awards, employee class, and historical experience. Actual results, and future changes in estimates, may differ substantially from our current estimates.

*Research and development expenses:* research expenditure is recognized as an expense when incurred. Costs arising from a development project are recognized as intangible assets when the following criteria are met:

- It is technically feasible to complete the intangible asset so that it will be available for use;
- Management intends to complete the intangible asset and use or sell it;
- There is an ability to use or sell the intangible asset;

- It can be demonstrated how the intangible asset will generate probable future economic benefits;
- Adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and
- The expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as an expense as incurred. During the reported period, the Group did not capitalize development costs to intangible assets.

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

Acquired development assets are not systematically amortized and are tested for impairment annually in accordance with the provisions of IAS 36, "Impairment of Assets".

The Company recognizes at fair value an intangible asset relating to research and development costs acquired from third parties.

Amortized intangible assets - an exclusive right to examine an acquired technology in the field of the immune system with a finite life of 15 months starting September 1, 2010 that is amortized on a straight-line basis over the useful life of this right. On November 30, 2011, the amortization of this right ceased.

Government grants for approved projects were deducted from the relevant expense.

#### **New and amended IFRS standards and IFRIC interpretations:**

Below are standards and amendments to existing standards that have been issued and are effective for reporting periods after January 1, 2011:

Amendment to IFRS 7, "Financial Instruments: Disclosures". This amendment represents part of the improvements to IFRSs published in May 2010. This amendment changes part of the quantitative and qualitative disclosures required for the nature and extent of risks associated with financial assets and clarifies the interaction between these quantitative and qualitative disclosures. This amendment is applied for annual reporting periods beginning on or after January 1, 2011. The Group adopted this amendment on January 1, 2011 and its initial adoption had no material impact on the Group's financial statements.

Below are standards and amendments and interpretations to existing standards that are not yet effective and have not been early adopted by the Group:

a) IFRS 9, "Financial Instruments" ("IFRS 9"). The first part of IFRS 9 which deals with classification and measurement of financial assets was published in November 2009 and the second part of IFRS 9 which includes guidance on financial liabilities and derecognition of financial instruments was published in October 2010. IFRS 9 replaces the parts of IAS 39, "Financial Instruments: Recognition and Measurement" ("IAS 39") that relate to the classification and measurement of financial instruments. IFRS 9 requires financial assets to be classified into one of the two following categories: financial assets measured after initial recognition at fair value and financial assets measured after initial recognition at amortized cost. The decision to which category a financial asset should be classified is made on initial recognition. This classification is driven by the model the entity manages its financial instruments (its business model) and the contractual characteristics of the cash flows from the instrument. For financial liabilities, IFRS 9 retains most of the IAS 39 requirements. The main change is that, in cases where an entity has a financial liability that is designated at fair value through profit or loss, the part of a change in fair value due to changes in the liability's credit risk (an entity's own credit risk) is recorded directly in other comprehensive income rather than the statement of income, unless this creates an accounting mismatch. There is not subsequent recycling of the amounts in other comprehensive income to profit or loss. But, accumulated gains or losses may be transferred within equity.

In December 2011, an amendment to IFRS 9 and to IFRS 7, "Financial Instruments: Disclosures" ("the amendment") was published. The amendment deferred the mandatory effective date of IFRS 9 and the transitional provisions upon implementation and added certain transition disclosure requirements ("the additional disclosures").

According to IFRS 9, after its amendment, as above, both parts of IFRS 9 will apply for annual periods beginning on or after January 1, 2015. Entities may elect to apply IFRS 9 early but it is not possible to apply the second part of IFRS 9 early without applying at the same time the first part of IFRS 9. However, the first part of IFRS may be applied earlier without being required to apply at the same time the second part of IFRS 9.

Entities that adopt IFRS 9 for reporting periods:

1. Beginning before January 1, 2012 - are not required to restate prior periods upon or provide the additional disclosures upon initial adoption.
2. Beginning on or after January 1, 2012 and before January 1, 2013 - may elect to either restate its prior periods or provide the additional disclosures.
3. Beginning on or after January 1, 2013 - are not required to restate prior periods but are required to provide the additional disclosures.

The Group is assessing the possible impact of IFRS 9 on its financial statements and the timing of its implementation.

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b) IFRS 10, "Consolidated Financial Statements" ("IFRS 10"). IFRS 10 replaces all the guidance on control and consolidation of financial statements in IAS 27, "Consolidated and Separate Financial Statements" ("IAS 27") and SIC-12, "Consolidation - Special Purpose Entities". IFRS 10 redefines "control". The new definition focuses on the requirement that control and variable returns should exist in order for control to exist. "Power" is the current ability to direct the activities which significantly affect the returns. IFRS 10 contains, inter-alia, guidance relating to differentiating between participating rights and protective rights as well as guidance relating to cases where an investor is acting on behalf of another party or on behalf of a group of parties (agent/principal relationships). The core principle that a consolidated entity presents a parent company and its subsidiaries as if they are a single entity remained unchanged as well as the mechanics of consolidation. IFRS 10 will be applied for annual periods beginning on or after January 1, 2013. Earlier application is permitted. If an entity elects to apply earlier, it shall disclose this fact and early apply IFRS 11, "Joint Arrangements" ("IFRS 11"), IFRS 12, "Disclosures of Interests in Other Entities" ("IFRS 12"), IAS 27 (Revised), "Separate Financial Statements" ("IAS 27R"), IAS 28 (Revised), "Associates and Joint Ventures" ("IAS 28R") simultaneously. The initial adoption of this amendment is not expected to have a material impact on the Group's financial statements.

c) IAS 28R - IAS 28R replaces IAS 28, "Investments in Associates" ("IAS 28") and the key changes contained therein compared to IAS 28 relate to adding explicit references to the application of the equity method when accounting for investments in joint ventures as a result of the new guidance prescribed by IFRS 11. IAS 28R will be applied for annual periods beginning on or after January 1, 2013. Earlier application is permitted. If an entity elects to apply earlier, it shall disclose this fact and early apply IFRS 10, IFRS 11, IFRS 12 and IAS 27R simultaneously. The Group is assessing the possible impact of IAS 28R on its financial statements and the timing of its implementation.

d) IFRS 13, "Fair Value Measurements" ("IFRS 13") - focuses on improving consistency and reducing complexity of fair value measurement by providing a precise definition of "fair value" and a single source of fair value measurement and disclosure requirements for use across IFRSs. The requirements of IFRS 13 do not extend the use of fair value accounting but provide guidance on how it should be applied where its use is already required or permitted by other standards within IFRSs. IFRS 13 will be applied for annual periods beginning on or after January 1, 2013. Earlier application is permitted while disclosing this fact. IFRS will be applied prospectively as of the beginning of the annual period in which it is initially applied. The disclosure requirements of IFRS 13 do not need to be applied in comparative information for periods before initial application of IFRS 13. The Group is assessing the possible impact of IFRS 13 on its financial statements and the timing of its implementation.

e) The amendment to IAS 32, "Offsetting Financial Assets and Financial Liabilities" ("the amendment to IAS 32") and the amendment to IFRS 7, "Disclosures: Offsetting Financial Assets and Financial Liabilities" ("the amendment to IFRS 7") were published in December 2011. The amendment to IAS 32 does not modify the existing model in IAS 32, "Financial Instruments: Presentation" regarding offsetting financial assets and financial liabilities ("offsetting") but clarifies that in order for the criteria of offsetting to exist in the financial statements it is required, inter alia, that the right of set-off must be available today namely, it should not be contingent on a future event and, in addition, it is required that the right of set-off will be legally enforceable in all of the following circumstances: in the normal course of business and in the event of default, insolvency or bankruptcy of the entity and all counterparties. The amendment to IAS 32 also clarifies the circumstances in which the right of set-off through gross settlement mechanism will meet the criteria of right to set-off by net settlement.

The amendment to IFRS 7 adds new disclosure requirements that focus on quantitative information about recognized financial instruments that are offset in the statement of financial position as well as recognized financial instruments that are subject to certain netting arrangements (irrespective of whether they are offset in the statement of financial position). The amendment to IAS 32 will be retrospectively applied for annual periods beginning on or after January 1, 2014. Earlier application is permitted. The amendment to IFRS 7 will be retrospectively applied for annual and interim periods beginning on or after January 1, 2013.



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

We generate all of our revenues and hold most of our cash, cash equivalents and bank deposits in US dollars. While a substantial amount of our operating expenses are in US dollars, we incur a portion of our expenses in New Israeli Shekels. In addition, we also pay for some of our services and supplies in the local currencies of our suppliers. Since 2009 (after the Bicifadine trial did not meet its endpoints) the Company's head office moved to Israel and thus the portion of our expenses in New Israeli Shekels ("NIS") and our cash held in NIS has increased, mainly due to payment to Israeli employees and suppliers. As a result, we are exposed to the risk that the US dollar will be devalued against the New Israeli Shekel or other currencies, and as result our financial results could be harmed if we are unable to guard against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the dollar or that the timing of any devaluation may lag behind inflation in Israel. To date, our business has not been materially adversely affected by changes in the US dollar exchange rate or by effects of inflation in Israel. Additionally, our future activities could lead us to perform a clinical trial in Israel, which may lead us to reassess our use of the US dollar as our functional currency.

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

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

On July 14, 2009, the "Knesset" (Israeli Parliament) passed the Law for Economic Efficiency (Amended Legislation for Implementing the Economic Plan for 2009 and 2010), 2009, which prescribes, among 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%.

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

As of December 31, 2011, XTL Biopharmaceuticals Ltd. did not have any taxable income. As of December 31, 2011, our net operating loss carry forwards for Israeli tax purposes registered on behalf of XTL Biopharmaceuticals Ltd

amounted to approximately \$24 million. Under Israeli law, these net-operating losses may be carried forward indefinitely and offset within XTL Biopharmaceuticals Ltd only, against future taxable income, including capital gains from the sale of assets used in the business, with no expiration date.

In order to obtain tax exemption for the share swap transaction with Bio-Gal pursuant to Sections 104 and 103 to the Israeli Income Tax Ordinance (Revised), 1961, we signed an agreement with the Israeli Tax Authority on July 15, 2010. Below is the summary of the principal conditions for the share swap and the transfer of the intangible asset:

1. The balance of the Company's business losses and capital losses for tax purposes was reduced to approximately NIS 80 million (approximately \$ 22 million) and approximately NIS 0.7 million (approximately \$ 0.19 million), respectively. This item is not to derogate from the Tax Assessing Officer's authority to establish that the balance of losses is actually lower than the abovementioned amounts.

- Any losses incurred to the Company prior to the share swap, after their reduction as discussed in paragraph 1 above,
2. will not be offset against any income originating from Xtepo (the transferred company) or against a capital gain from the sale of shares of Xtepo.
  3. Xtepo shareholders will not be allowed to sell their shares in the Company for a period of two years from the end of the year of completion of the transaction (“the Lock-up Period”), subject to any changes in legislation.
  4. The Company and Xtepo both undertake to maintain their main economic activity as it was prior to the transaction during the Lock-up Period.
  5. The Company will not be permitted to sell its holdings in Xtepo for the duration of the Lock-up Period.

It is indicated that the guidance to Sections 104 and 103 to the Israeli Income Tax Ordinance which deal with restructuring and mergers impose statutory limitations and various conditions on the entities participating in the change in structure/merger, among others, restrictions on dilution of holdings from raising by a prospectus or by private placements. The summary of the principles detailed above does not constitute a substitute to the overall articles. On February 1, 2012, the Tax Authority published a position circular regarding the limitations in sections 103 and 104 according to which a relief is granted in the issue of the various limitations under the sections mentioned above during the lock-up period, inter alia, in instances of allocation of rights to "new" shareholders by private placements.

Since April 7, 2009, we did not have a “permanent establishment” and activity in the US, and our subsidiaries do not perform any activity. Our board of directors consists of a majority of Israeli residents and our management is domiciled in Israel. However, for the period we did have a “permanent establishment” in the US, any income attributable to such US permanent establishment would be subject to US corporate income tax in the same manner as if we were a US corporation. The maximum US corporate income tax rate (not including applicable state and local tax rates) is currently at 35%. In addition, if we had income attributable to the permanent establishment in the US, we may be subject to an additional branch profits tax of 30% on our US effectively connected earnings and profits, subject to adjustment, for that taxable year if certain conditions occur, unless we qualified for the reduced 12.5% US branch profits tax rate pursuant to the United States-Israel tax treaty. We would be potentially able to credit any foreign taxes that may become due in the future against its US tax liability in connection with income attributable to its US permanent establishment and subject to both US and foreign income tax.

### **Liquidity and Capital Resources**

We have financed our operations from inception primarily through various private placement transactions, our initial public offering, a placing and open offer transaction, option and warrant exercises, and private investments in public equities. As of December 31, 2011, we had received net proceeds of approximately \$77.8 million from various private

placement transactions, including net proceeds of approximately \$ 1.5 million from the Bio-Gal transaction in August 2010, net proceeds of approximately \$45.7 million from our initial public offering in September 2000, net proceeds of approximately \$15.4 million from the 2004 placing and open offer transaction, net proceeds of approximately \$1.75 million from our public offering on the Tel Aviv Stock Exchange (TASE) in March 2011 and proceeds of approximately \$2.1 million from the exercise of options and warrants.

As of December 31, 2011, we had approximately \$1.5 million in cash, cash equivalents, and short-term bank deposits, an increase of \$0.4 million from December 31, 2010. Cash used in operating activities for the year ended December 31, 2011, was \$1.3 million, as compared to \$0.7 million for the year ended December 31, 2010. This increase in cash used in operating activities is explained by the payment of debt to suppliers, service providers and other payables in the current period and in previous periods according to the payment terms. For the year ended December 31, 2011, the net cash used in investing activities totaled at approximately \$1.4 million, as compared to net cash used in investing activities of \$0.1 million for the year ended December 31, 2010. The increase in cash used in investment activities was primarily due to the cash received from the fundraising completed on March 7, 2011 that were invested in short-term deposits. For the year ended December 31, 2011, net cash provided by financing activities totaled approximately \$1.7 million and was primarily due to the mentioned Israeli public fundraising. For the year ended December 31, 2010, net cash provided by financing activities totaled approximately \$1.5 million and was primarily due to the completion of the Bio-Gal transaction under which we received this mentioned amount.

Continuation of our current operations is dependent upon the generation of additional financial resources through agreements for the monetization of our rHuEPO for multiple myeloma, SAM-101 for schizophrenia, and residual in the DOS program or through external financing. 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 through the issuance of equity securities. However, if the Company is not 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 forecast of the period of time through which our cash, cash equivalents and short-term investments will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need in future to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the accuracy of our financial forecasts;

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

- the timing of expenses associated with product development and manufacturing of the proprietary drug candidates that we have acquired rHuEPO for the treatment of MM, SAM-101 for the treatment of schizophrenia, and those that may be in-licensed, partnered or acquired;

- our ability to achieve our milestones under licensing arrangements; and

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

We have based our estimate on assumptions that may prove to be inaccurate. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing may be obtained through strategic relationships, public or private sales of our equity or debt securities, and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of our ordinary shares or other securities convertible into shares of our ordinary shares, the ownership interest of our existing shareholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan and which would raise substantial doubt about our ability to continue as a going concern. As a result, we may have to significantly limit our operations, and our business, financial condition and results of operations would be materially harmed. See “Item 3. Key Information - Risk Factors - Risks Related to Our Financial Condition.”

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

Research and development costs in 2011 and 2010 substantially derived from costs related to the preparations to the rHuEPO drug clinical trial development plan. As part of the preparations, the Company is currently conducting 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. This collected research data will be integrated in the Phase 2 clinical trial. The costs of such preparations comprise of, among others, costs in connection with medical regulation, patent registration costs, medical consulting costs. Additionally, we had amortization expenses of the exclusive right to examine a medical technology in the field of the immune system. We had no research and development expenses in 2009 (see also Note 17 to the financial statements).

### ***rHuEPO for the Treatment of MM***

According to the clinical trial’s preliminary plan we received as part of the Bio-Gal transaction we are planning on performing a prospective, multi-center, double blind, placebo controlled, 50-patient phase 2 study intended to assess safety of rHuEPO when given to patients with advanced MM and demonstrate its effects on survival, biological markers related to the disease, immune improvements and quality of life. We intend to receive approval to commence such trial in the second half of 2012 and we expect it to last two-and-a-half years and its cost is estimated at \$1-1.5 million. We have not yet submitted the preliminary plan, which may be updated, to the authorities and/or the applicable IRB.

While we have begun preliminary discussions with potential clinical sites and third party vendors for the planned study, we have not yet determined the final size and scope of the study, and as a result, we cannot certify the above estimations regarding the clinical trial period and cost to complete the study.

***SAM-101 for the Treatment of Schizophrenia***

According to the preliminary development plan we received as part of the MinoGuard transaction, it is planned to perform a multi-center phase 2b clinical trial under the FDA, using our proprietary combination. This preliminary plan is subject to changes in accordance with our regulatory advisors and the FDA/other regulatory agencies requirements.

***DOS Program for the Treatment of Hepatitis C***

Under the terms of the license agreement, Presidio became responsible for all further development and commercialization activities and costs relating to the DOS program. According to our knowledge, as of today, the DOS program compounds are still in preclinical development. The timing and results of pre-clinical studies are highly unpredictable. Due to the nature of pre-clinical studies and our inability to predict the results of such studies, we cannot estimate when such pre-clinical development will end.

The information above provides estimates regarding the costs associated with the current estimated range of the time that will be necessary to complete the development phase for rHuEPO for the treatment of MM and develop SAM-101 for the treatment of schizophrenia. We also direct your attention to the risk factors which could significantly affect our ability to meet these cost and time estimates found in this report in Item 3 under the heading “Risk Factors-Risks Related to our Business.”

The following table sets forth the research and development costs for the years 2009-2011 including all costs related to the clinical-stage projects, our pre-clinical activities, and all other research and development. We did not carry any research and development activity and costs in 2009, after the failure of the phase 2b clinical trial in November 2008. We have started preparations for rHuEPO clinical development in the last quarter of 2010 (after the completion of the Bio-Gal transaction on August 2010). We in-licensed SAM-101 in November 2011 (see "Item 4. Licensing Agreements and Collaborations") and we estimate that incur significant costs on its development in the upcoming years. Whether or not and how quickly we commence and complete development of our clinical stage projects is dependent on a variety of factors, including the rate at which we are able to engage clinical trial sites and the rate of enrollment of patients. As such, the costs associated with the development of our drug candidates will probably increase significantly.

For a further discussion of factors that may affect our research and development, see “Item 3. Risk Factors - Risks Related to Our Business,” and “Item 4. Information on the Company - Business Overview - Products Under Development” above.

	Research and development Expenses in thousand US\$		
	Years ended December 31,		
	2011	2010	2009
rHuEPO	70	32	-
SAM-101	-	-	-
Anti TNF (Yeda Option)	88	32	-
Total Research and development	158	64	-

### **Trend Information**

Please see “Item 5. Operating and Financial Review and Prospects” and “Item 4. Information on the Company” for trend information.

### **Off-Balance Sheet Arrangements**



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

### **Obligations and Commitments**

As of December 31, 2011, we had known contractual obligations, commitments and contingencies of \$216 thousands which relate to our offices and vehicle operating lease obligations, of which \$122 thousands is due within the next year, with the remaining balance due as per the schedule below.

According to the vehicle operating lease agreements we have the sole right to terminate these agreements with 1-2 months paid notice. We also have the sole right to extend such office lease period by additional 24 months.

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

		Payment due by period as of December 31, 2011 (in thousands of US\$)			
		Less than	1-3	3-5	More than
Contractual Obligations	Total	1 year	years	years	5 years
Operating lease obligations	216	122	94	—	—
Total	216	122	94	—	—

Additionally, the VivoQuest license agreement provides for contingent milestone payments triggered by certain regulatory and sales targets. These milestone payments total \$34 million, \$25 million of which will be due upon or following regulatory approval or actual product sales, and are payable in cash or ordinary shares at our sole discretion. In addition, the license agreement requires that we make royalty payments on product sales. Pursuant to our out-licensing agreement with Presidio, Presidio is obligated to pay us for any contingent milestone consideration owed to VivoQuest pursuant to the XTL and VivoQuest license agreement.

We have undertaken to make contingent milestone payments to DOV Pharmaceutical, Inc. of up to approximately \$126.5 million over the life of the license. These milestone payments may be made in either cash and/or our ordinary shares, at our election, with the exception of \$5 million in cash, which would due upon or after regulatory approval. We were also obligated to make royalty payments on future product sales net sales. We ceased development of Bicifadine in November 2008 and since then both XTL Development and DOV ceased the prosecution and maintenance of those patents relating to the Bicifadine. In March 2010, we formally terminated the license agreement. Therefore, we will not be obligated to make any of the aforesaid payments.

Pursuant to our asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal Ltd., we are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 upon the successful 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 the Phase 2 of an amount of minimum \$2 million.

According to the agreement with MinoGuard we are obligated to pay milestone payments to MinoGuard of up to \$2.5 million based on development and marketing milesotnes as well as 3.5% royalty of our net sales of the product and

7.5%-20% from our third-party out-license receipts, depends on the phase of the drug at the time of an out-license transaction. It should be noted we have the sole discretion to pay any of the above amounts in cash or by way of issuing of our shares to MinoGuard.

In addition, in January 2007, XTL Development and the company committed to pay a transaction advisory fee to certain third party intermediaries in connection with the in-license of Bicifadine from DOV. In October 2007, XTL Development entered into definitive agreements with the third party intermediaries with respect to the binding term sheets signed in 2007 (the "Definitive Agreements"). Under the terms of the Definitive Agreements, the transaction advisory fee was structured in the form of SARs, in the amount equivalent to (i) 3% of our fully diluted ordinary shares at the close of the transaction (representing 1,659,944 ordinary shares NIS 0.1 par value), vesting immediately and exercisable one year after the close of the transaction, and (ii) 7% of our fully diluted ordinary shares at the close of the transaction (representing 3,873,203 ordinary shares NIS 0.1 par value), vesting on a certain milestone event. Payment of the SARs by XTL Development can be satisfied, at our discretion, in cash and/or by issuance of our registered ordinary shares. Upon the exercise of a SAR, the amount paid by XTL Development will be an amount equal to the amount by which the fair market value of one ordinary share on the exercise date exceeds the \$1.7 grant price for such SAR (fair market value equals (i) the greater of the closing price of an "ADR" on the exercise date, divided by two, or (ii) the preceding five day ADR closing price average, divided by two). Any vested SARs will expire on January 15, 2017. As of December 31, 2011, the 3% tranche was vested and recorded in our financial statements as capital reserve according to IFRS 2 (see note 2m to the financial statements). The 7% tranche was not vested. In March 2010, we formally terminated the license agreement and therefore all unvested SAR (the 7% tranche) have automatically expired. See also "Item 10. Additional Information - Material Contracts."

## Item 6. Directors, Senior Management and Employees

### Directors and Senior Management

The following sets forth information with respect to our directors and executive officers as of March 29, 2012.

Name	Age	Position
Amit Yonay	42	Chairman of the Board of Directors
Dafna Cohen	42	Non Executive and External Director
Jaron Diament	44	Non Executive and External Director
Marc Allouche	38	Non Executive Director
David Grossman	37	Director and Chief Executive Officer
Ronen Twito	37	Chief Financial Officer
Moshe Mittelman	57	Medical Director

Amit Yonay has served as a director in our company since March 2009. Since 2007, he has been actively involved in independent investments primarily in the real estate and capital markets with an emphasis toward distressed asset opportunities. Mr. Yonay had served from 2000 to January 2007, as the Head Israeli Sell-Side Analyst with ING Financial Markets (NYSE: ING, Euronext: INGA) in Israel. Mr. Yonay received a BSc in Electrical Engineering from Binghamton University and an MBA from Tel Aviv University in Finance and International Business.

Dafna Cohen has served as a director in our company since March 2009. From 2010-2011 she served as director of Global Treasury at Mediamind Technologies (Nasdaq: MDMD), From 2005 to 2009 she served as Director of Investment and Treasurer of Emblaze Ltd. (LSE: BLZ). From 2000 to December 2004, Ms. Cohen was an Investment Manager for Leumi Partners.. From 1994-2000, Ms. Cohen worked in the derivatives sector of Bank Leumi. In addition, Ms. Cohen serves as a director of Formula Systems Ltd (Nasdaq: FORTY, TASE: FORTY) since November 2009. Ms. Cohen serves as a director of Inventech Central (TASE: IVTC) since March 2011 and serves as a Director at Europort (TASE: ERPT.B1) since January 2012. Ms. Cohen received a BA in economics and political science and an MBA in finance and accounting from Hebrew University, Jerusalem.

Jaron Diament has served as a director in our company since March 2009. He has served as the founding partner and Chief Executive Officer of Tagor Capital Ltd., a public real estate investment company (TASE: TGCP), and a board member of all of its non-Israel real estate investments since December 2009. From September 2006 to December 2009, Mr. Diament served as Chief Financial Officer of Tagor Capital Ltd. and a board member of all of its non-Israel real estate investments. From 2003 to September 2006, Mr. Diament was an independent financial advisor focused on risk management and corporate finance transactions. From 1994 to February 2005 Mr. Diament was CFO of H.G.I.I. Ltd. (TASE: HGII, today a private company) and a member of the board of certain wholly owned subsidiaries. In

addition, Mr. Diament serves as an external director of Mega Or Holdings Ltd. (TASE: MGOR) since September 2007 and as an independent director in Danidav Investments Ltd. since May 2011 (TASE: DNDV). Mr. Diament received a BA in economics and accounting from Tel Aviv University.

Marc Allouche has served as a director in our company since March 2009. He is the founder and managing partner of NFI Consulting, an investment banking & business advisory firm. NFI focuses on creating and advising investment and business opportunities between Europe and Israel, notably within two asset classes: private equity and real estate. Previously, he served as the head of the Alternative Investments Division of Harel Insurance Investments & Financial Services Ltd., from 2008 to 2009, focusing on private equity and real estate investments. From 2006 to 2007, Mr. Allouche served as Executive Vice President of investments & strategic development of SGPA, a French private equity group and, concurrently, was CEO of one of its portfolio companies, operating in the retail sector in France, for turnaround purposes. From 2002 to 2005, from Paris, Mr. Allouche was founder and managing director of the Private Equity Advisory Group of Russel Bedford International, in charge of international corporate finance, transaction services and restructuring advisory services. From 2000 to 2001, Mr. Allouche served as Vice President at Nessuah Zannex Venture Capital Company Ltd., in strategic alliance with US Bancorp Piper Jaffray, managing a life sciences venture capital fund and, concurrently, was also managing director of one of its med-tech portfolio companies for turnaround purposes. From 1998 to 2000, Mr. Allouche was involved in the creation and the management of the Technology Group of KPMG International - Somekh Chaikin in Israel, a corporate finance division dedicated to high-tech and biotech companies. From 1996 to 1998, Mr. Allouche was a Senior Consultant at the Audit and the Transaction Services divisions of Price Waterhouse in Paris. Mr. Allouche received a BA in economics and a MBA with major in corporate finance and accounting from Dauphine University, Paris. He is also a Chartered Public Accountant in France.

David Grossman has served as a director in our company and as Chief Executive Officer of our company since February 2009. He served as a Vice President of Eurocom Investments LP, a private equity fund, from March 2006 to December 2008. Also from March 2006 to December 2008, Mr. Grossman was Vice President of Sahar Investments Ltd, (TASE: SAIN, today Enlight Energy: ENLT) which focused on investments in the Life Sciences arena. From July 2003 to March 2006, Mr. Grossman was a Senior Analyst at Israel Health Care Ventures (IHCV), an Israeli healthcare venture capital fund. Since August 2011, Mr. Grossman serves as an external director and member of the audit committee of Rosetta Green Ltd. (TASE: RSTG). From January 2009 to April 2011, Mr. Grossman was a director and member of the audit committee of Bio Light Israeli Life Science Investments Ltd. (TASE: BOLT), and from May 2007 to July 2008 was a Director and member of the audit committee of Gilat Satcom Ltd. (AIM: GLT). Mr. Grossman received a BA business administration with a focus on information technology, from the Interdisciplinary Center Herzliya.

Ronen Twito has served as Chief Financial Officer in our company since July 2009. Prior to joining XTL, he served as Corporate Finance Director at Leadcom Integrated Solutions Ltd., an international telecommunications company, specializing in management and implementation of network deployment services (then listed on the AIM and TASE) from November 2004 to May 2009. Previously he served as an Audit Manager at Ernst & Young Israel from January 2000 to November 2004. Mr. Twito possesses over 12 years of finance experience in both publicly traded and private companies, which includes IPOs, dual listings, bonds placement, public fund raising, consolidated financial statement and M&As. Mr. Twito is an Israeli Certified Public Accountant and is a member of the Institute of CPAs in Israel. He holds a BSc in Business & Management – Accounting, and a B.Ed in Teaching of accounting, both from the Collman Management College.

Prof. Moshe Mittelman has served as the Medical Director at our company since August 2010. He is also a Hematology consultant and Director of the Department of Medicine at the Tel Aviv Sourasky (Ichilov) Medical Center, Israel. Since 1997, Moshe has been Clinical Associate Professor of Medicine at the Sackler School of Medicine, Tel Aviv University. A well-known hematologist focusing on cancer and erythropoietin (EPO) research, Prof. Mittelman was one of the first hematologists to apply rHuEPO in the clinical practice, which allowed him to make the pioneering observation of prolonged survival in multiple myeloma (MM) rHuEPO -treated patients . This led to extensive research both in the lab as well as with patients, showing hitherto unrecognized immune effects to EPO. This research project has resulted in a series of scientific papers published in prestigious journals. Prof. Mittelman is also a well-known speaker in international conferences. Prof. Mittelman's work led to the founding of Bio-Gal, Ltd. which has now merged with XTL. Prof. Mittelman has also served as President of the Israel Society of Internal Medicine, Secretary of the Israel Society of Hematology and a Hematology Consultant for the Israel Ministry of Health. Prof. Mittelman is also a consultant to various biotech companies. During the years 2008-2010, he has been a member of the national committee of the Health Basket in Israel. Since 2007, Prof. Mittelman serves as director in Gaon Holdings Ltd. (TASE: GAON), a public holding company.

## **Employment Agreements**

We have an agreement dated January 18, 2010, which came into effect upon the completion of the Bio-Gal transaction, and effective as of January 1, 2010, with David Grossman, our Chief Executive Officer. Mr. Grossman is currently entitled to an annual base fee of NIS 480,000. Upon the successful completion of cash fund raising of at least US\$ 10 million in equity on NASDAQ or any other recognized and approved stock exchange (the "Fund Raising"), Mr. Grossman's Annual fees shall be raised to NIS 580,000. In the event that the Company completes the Fund Raising and also Another Transaction (as defined below), then Mr. Grossman's annual fee shall be raised to NIS 630,000. ("Another Transaction" shall mean any business combination transaction, merger or acquisition, intellectual property licensing transaction or joint venture e.t.c.). In the event that we completed a Fund Raising of a cash amount of more than US\$3 million within 24 months of the signing date, Mr. Grossman would have been entitled to receive a one time bonus equal to 1% of the Fund Raising amount but not more than US\$150,000. However, such an event did not occur and therefore on March 19, 2012 the shareholder meeting approved a board resolution that if the Company effects any fund raising during the thirty six (36) month period from the date of this resolution, the Company will pay to Mr. Grossman a bonus equal to 1.2% of the above fund raising amount, up to a maximum amount of \$200 thousand. Mr. Grossman is also entitled to receive benefits comprised of managers' insurance as commonly acceptable for officer holders, and the use of a company car. There is a non-compete clause surviving one year after termination of employment. The agreement is not limited in time and may be terminated by either party on a four months prior written notice. In March 2010, our shareholders approved the agreement and the granting of options to Mr. Grossman to purchase a total of 1,610,000 ordinary shares at an exercise price equal to NIS 0.075 per share. These options shall vest over a two-year period, with 33.33% having vested on the grant date, and the remaining 66.67% shall vest on a monthly basis, commencing from the effective date, over a period of 2 years thereafter for as long as Mr. Grossman's agreement with us is not terminated. Due to the fact that Mr. Grossman served as a CEO from February, 2009 without any consideration, Mr. Grossman received a one time signing payment of NIS 430,000. On 26 and 27 February 2011, the company's audit committee and board of directors approved, respectively, the company CEO's request and in accordance with the terms of the Agreement that they signed with him that the contractual arrangement of the CEO will be that of providing management services as an independent contractor and only if the financial consideration that will be paid to him does not exceed the cost to the company for his employment as an employee as stipulated above and that the company CEO undertakes to indemnify the company if an employer-employee relationship will be

established between himself and the company.

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We have an employment agreement dated July 29, 2009, and effective as of June 24, 2009, with Ronen Twito, our Chief Financial Officer. Mr. Twito is currently entitled to an annual base salary of NIS 456,000. Upon the successful completion of cash fund raising of at least US\$ 10 million in equity on NASDAQ or any other recognized and approved stock exchange (the "Fund Raising"), Mr. Twito's Annual Salary shall be raised to NIS 550,000. In the event that the Company completes Fund Raising and also Another Transaction (as defined below), then Mr. Twito's annual salary shall be raised to NIS 600,000. ("Another Transaction" shall mean any business combination transaction, merger or acquisition, intellectual property licensing transaction or joint venture e.t.c.). In the event of a Fund Raising which is of a cash amount more than US\$3 million but less than US\$10 Million, Mr. Twito's annual salary shall be raised, to an amount based on a linear calculation of US\$3 Million – US\$10 Million applied to the annual salary increase of NIS 456,000 – NIS 550,000 (or in the event Another Transaction is achieved, NIS 600,000). In the event that we complete a Fund Raising of a cash amount of US \$15 million, then Mr. Twito shall be entitled to a cash bonus in a NIS amount equal to US\$ 200,000 In the event that the actual fundraising is of an amount of more than US\$3 million but less than US \$15 million, then Mr. Twito shall be entitled to a linear portion of the cash bonus calculated based on the actual fundraising between US\$3 Million and US\$15 Million. On February 12, 2012 our board of directors passed a resolution that if the Company effects any fund raising during the thirty six (36) months period from the date of this resolution, the Company will pay to Mr. Twito a bonus equal to 1.2% of the above fund raising amount, up to a maximum amount of \$200 thousand. Mr. Twito is also entitled to receive benefits comprised of managers' insurance (pension and disability insurance), as commonly acceptable for officer holder, and the use of a company car. There is a non-compete clause surviving one year after termination of employment. The employment agreement is not limited in time and may be terminated by either party on three months prior written notice. In July 2009, our Board of Directors granted options to Mr. Twito to purchase a total of 1,400,000 ordinary shares at an exercise price equal to NIS 0.075 per share. These options shall vest over a three-year period, with 33.33% having vested after 5 month from the agreement date, and the remaining 66.67% shall vest on a monthly basis, commencing from the effective date, over a period of 3 years thereafter for as long as Mr. Twito's employment with the Company is not terminated.

We have an agreement dated on July 12, 2010, and effective as of August 27, 2010, with Prof. Moshe Mittelman, our Medical Director. Prof. Mittelman is entitled to a monthly fee of \$ 2,500. His entitlement began 90 days after the date of completion of the Bio-Gal transaction, i.e., November 3, 2010. The agreement is limited to the date of successful completion of the phase 2 clinical trial on the rHuEPO. A "successful completion of the phase 2 clinical trial" is defined as: six (6) months after the trial of the rHuEPO on the last patient in accordance with trial protocol, or on an earlier date if XTL notifies Yeda of XTL's desire to discontinue the trial. In August 2010, our Board of Directors approved the agreement as well as granting options to Prof. Mittelman to purchase a total of 640,000 ordinary shares at an exercise price of NIS 0.1 per share. These options shall vest over a twenty four-month period, on a monthly basis, commencing from August 27, 2010 as long as Prof. Mittelman's agreement with us is not terminated. Also, upon the commencement of a Phase 2 clinical trial (first-in-man), 50% of Prof. Mittelman's unvested options (until the date of the commencement of the trial) shall vest immediately. If Prof. Mittelman is terminated by XTL without cause, 25% of the unvested options (until the date of termination) shall vest immediately.

## Compensation

The aggregate compensation paid by us to all persons who served as directors or officers for the year 2011 (7 persons) was approximately \$0.5 million. This amount includes payments of approximately \$0.07 million made for social

security, pension, disability insurance and health insurance premiums, severance accruals, payments made in lieu of statutory severance, payments for continuing education plans, payments made for the redemption of accrued vacation, and amounts expended by us for automobiles made available to our officers. See “Item 5. Operating and Financial Review and Prospects – 2009 Restructuring”.

All members of our Board of Directors who are not our employees are reimbursed for their expenses for each meeting attended. Our directors are eligible to receive share options under our share option plans. Non-executive directors do not receive any remuneration from us other than their fees for services as members of the board, additional fees if they serve on committees of the board and expense reimbursement.

In March 2012, we granted to our external directors, Mr. Diament Jaron and Ms. Dafna Cohen, 150,000 options each, to purchase our ordinary shares of NIS 0.1 par value, pursuant to the shareholder meeting of March 19, 2012, exercisable at an exercise price of NIS 0.58633 (which is the average of the three-day closing price on TASE prior to the issuance). 33% of the said options are vested and 67% of said options shall vest and be exercisable on a monthly basis, commencing from the date of the mentioned shareholders meeting, for the duration of two years.

In March 2009, pursuant to a shareholders' meeting, the monetary compensation was set for each of Mr. Grossman, Mr. Shweiger, Mr. Allouche, Mr. Yonay, Mr. Diament and Ms. Cohen as follows: annual consideration of \$10,000 (to be paid in 4 equal quarterly payments), payments of \$375 for attendance at each board or committee meeting in person or held by teleconference, \$187.5 for unanimous board resolutions and reimbursement of reasonable out-of-pocket expenses. Mr. Grossman serves as the Company's Chief Executive Officer since February 11, 2009 and is entitled to a compensation package as detailed above in the Employment Agreements paragraph, and therefore is not entitled to Directors fee.

We granted to three of our directors, Mr. Yonay, Mr. Shweiger (former director) and Mr. Allouche, 150,000 options each, to purchase our ordinary shares of NIS 0.1 par value, pursuant to the shareholder meeting of March 2, 2010, exercisable at an exercise price of NIS 0.298 (which is the average of the three-day closing price on TASE prior to the issuance). 33% of the said options are vested and 67% of said options shall vest and be exercisable on a monthly basis, commencing from March 2, 2010, for the duration of two years. On November 22, 2010, Mr. Shweiger ceased his directorship in the Company and therefore 63,747 of the total options granted to him were forfeited in accordance. Upon his departure, Mr. Shweiger exercised the vested 86,253 options.

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

· first, our compensation committee reviews the proposal for compensation.

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

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

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

## **Board Practices**

### *Election of Directors and Terms of Office*

Our Board of Directors currently consists of five members, including our non-executive Chairman. Other than our two external directors, our directors are elected by an ordinary resolution at the annual general meeting of our shareholders. The nomination of our directors is proposed by a nomination committee of our Board of Directors, whose proposal is then approved by the board. The current members of the nomination committee are Amit Yonay (chairman of the nomination committee), Jaron Diament (chairman of the audit committee) and Dafna Cohen. Our board, following receipt of a proposal of the nomination committee, has the authority to add additional directors up to the maximum number of 12 directors allowed under our Articles. Such directors appointed by the board serve until the next annual general meeting of the shareholders. Unless they resign before the end of their term or are removed in accordance with our Articles, all of our directors, other than our external directors, will serve as directors until our next annual general meeting of shareholders. In July 2011, at an annual general meeting of our shareholders, Amit Yonay, Marc Allouche, and David Grossman were re-elected to serve as directors of our company. Dafna Cohen and Jaron Diament were elected to serve as external directors of our company at the March 2009 extraordinary general meeting. Dafna Cohen and Jaron Diament are serving as external directors pursuant to the provisions of the Israeli Companies Law for a three-year term ending in March 2012. On March 19, 2012 at an annual general meeting of our shareholders, Amit Yonay, Marc Allouche and David Grossman were re-elected to serve as directors of our company until the next shareholders meeting and our external directors, Dafna Cohen and Jaron Diament, were re-elected to serve as external directors of our company for an additional period of three years. After this date, the external directors term of service may be renewed for an additional last three-year term.

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

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

### *External and Independent Directors*

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

· an employment relationship;

· a business or professional relationship maintained on a regular basis;

· control; and

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

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

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

the majority of shares voted at the meeting, including at least one-third of the shares held by non-controlling shareholders voted at the meeting, vote in favor of election of the director, with abstaining votes not being counted in this vote; or

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

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

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

Dafna Cohen and Jaron Diament serve as external directors pursuant to the provisions of the Israeli Companies Law. They both serve on our audit committee, our nomination committee and our compensation committee.

#### *Audit Committee*

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

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



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

The Israeli Companies Law regulations require each public company to appoint a committee that examines the financial statements (the "Committee") which shall be compounded from at least Three (3) members, of which the majority among them shall be independent directors and the Committee's Chairman shall be an external director. The Committee's duties are, among others, to examine the Company's Financial Statements and to recommend and report to the board of directors of the Company regarding any problem or defect found in such Financial Statements.

In addition to the above-said, all of Committee's members must apply with the following requirements:

All members shall be members of the board of directors of the Company.

At least one of the Committee's members shall have a Financial and Accounting expertise and the rest of the Committee's members must have the ability to read and understand Financial Statements.

The Company is in full compliance with the above-said requirements.

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

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

Our compensation committee consists of three independent directors: Jaron Diament, Dafna Cohen and Marc Allouche. The responsibilities of the compensation committee are to set our overall policy on executive remuneration and to decide the specific remuneration, benefits and terms of employment for directors and the Chief Executive Officer.

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

**Internal Auditor**

Under the Israeli Companies Law, the board of directors must appoint an internal auditor, nominated by the audit committee. The role of the internal auditor is to examine, among other matters, whether the company's actions comply with the law and orderly business procedure. Under the Israeli Companies Law, the internal auditor cannot be an office holder, an interested party or a relative of an office holder or interested party, and he or she may not be the company's independent accountant or its representative. We comply with the requirement of the Israeli Companies Law relating to internal auditors. Our internal auditors examine whether our various activities comply with the law and orderly business procedure.

**Employees**

As of March 29, 2012, we had three full-time employees (one of whom is an officer, which is engaged with the Company as a service provider). We and our Israeli employees are subject, by an extension order of the Israeli Ministry of Welfare, to a certain provisions of collective bargaining agreements between the Histadrut, the General Federation of Labor Unions in Israel and the Coordination Bureau of Economic Organizations, including the Industrialists Associations. These provisions principally address cost of living increases, recreation pay, travel expenses, vacation pay and other conditions of employment. We provide our employees with benefits and working conditions equal to or above the required minimum. Other than those provisions, our employees are not represented by a labor union. See also "Item 5. Operating and Financial Review and Prospects - 2009 Restructuring" and "Item 6. Directors, Senior Management and Employees – Employment Agreements" above.

For the years ended December 31, 2011, 2010 and 2009, the number of our full-time employees engaged in the specified activities, by geographic location, are presented in the table below.

	Year ended December 31,		
	2011	2010	2009
Research and Development			
Israel	-	-	-
US	-	-	-
	-	-	-
Financial and general management			
Israel	3	3	2
US	-	-	-
	3	3	2
Total	3	3	2
Average number of full-time employees	3	3	3



## Share Ownership

The following table sets forth certain information as of February 29, 2012, regarding the beneficial ownership by our directors and executive officers. All numbers quoted in the table are inclusive of options to purchase shares that are exercisable within 60 days of February 29, 2012.

	Amount and nature of beneficial ownership					Percent of ordinary shares beneficially owned
	Options <sup>1</sup>	exercisable within 60 days of February 29, 2012	Total ordinary shares beneficially owned including options			
Amit Yonay <i>Chairman of the Board</i>	—	150,000 (2)	150,000			*
Marc Allouche <i>Director</i>	—	150,000 (2)	150,000			*
Dafna Cohen <i>External Director</i>	—	54,167 (3)	54,167			*
Jaron Diament <i>External Director</i>	—	54,167 (3)	54,167			*
David Grossman <i>Director and Chief Executive Officer</i>	—	1,610,000 (4)	1,610,000			*
Ronen Twito <i>Chief Financial Officer</i>	—	1,348,151 (5)	1,348,151			*
Moshe Mittelman <i>Medical Director</i>	5,590,896	533,320 (6)	6,124,216	2.7	%	
All directors and executive officers as a group (7 persons)	5,590,896	3,899,805	9,490,701	4.2	%	

- (1) Options to purchase ordinary shares
- (2) 150,000 options at an exercise price of NIS 0.298 per ordinary share of NIS 0.1 par value, exercisable until March 1, 2020.
- (3) 150,000 options at an exercise price of NIS 0.58633 per ordinary share of NIS 0.1 par value, exercisable until March 18, 2022.
- (4) 1,610,000 options at an exercise price of NIS 0.075 per ordinary share of NIS 0.1 par value, exercisable until January 17, 2020.
- (5) 1,348,161 options at an exercise price of NIS 0.075 per ordinary share of NIS 0.1 par value, exercisable until June 23, 2019.
- (6) 533,320 options at an exercise price of NIS 0.1 per ordinary share of NIS 0.1 par value, exercisable until August 26, 2020.

\* Represents Less than 1% of ordinary shares outstanding.

### ***Share Option Plans***

We maintain the following share option plans for our and our subsidiary's employees, directors and consultants. In addition to the discussion below, see Note 16b of our consolidated financial statements, included at "Item 18. Financial Statements."

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

As of December 31, 2011, we have granted to employees, directors and consultants options that are outstanding to purchase up to 4,269,000 ordinary shares of NIS 0.1 par value, pursuant to two share option plans and pursuant to certain grants apart from these plans also discussed below under Non-Plan Share Options.

#### *2001 Share Option Plan*

Under a share option plan established in 2001, referred to as the 2001 Plan, we granted options during 2001-2011, at an exercise price between \$ 0.0198 and \$4.655 per ordinary share of NIS 0.1 par value. Up to 2,200,000 option of NIS 0.1 par value were available to be granted under the 2001 Plan. On July 29, 2009, the option pool was increased by 5,000,000 unissued additional ordinary shares of NIS 0.1 par value, as well as forfeited and expired options that reverted to the pool due to departure of employees. As of December 31, 2011, 4,110,000 options are outstanding. Options granted to Israeli employees were in accordance with section 102 of the Tax Ordinance, under the capital gains option set out in section 102(b)(2) of the ordinance. The options are non-transferable.

The option term is for a period of ten years from the grant date. The options were granted for no consideration. The options vest over a three or two year period. As of December 31, 2011, 3,629,725 options of NIS 0.1 par value are fully vested. On May 2, 2011, the 2001 Share Option Plan has expired and no options may be granted under this plan.

#### *2011 Share Option Plan*

On August 29, 2011, the Company's Board approved the adoption of an employee stock option scheme for the grant of options exercisable into shares of the Company according to section 102 to the Israeli Tax Ordinance ("2011 Plan"), and to maintain up to 10 million shares in the framework of the 2011 Plan, for options allocation to employees, directors and Company consultants.

The 2011 Plan shall be subject to section 102 of the Israeli Tax Ordinance. According to the Capital Gain Track, which was adopted by the Company and the abovementioned section 102, the Company is not entitled to receive a tax deduction that relates to remuneration paid to its employees, including amounts recorded as salary benefit in the Company's accounts for options granted to employees in the framework of the 2011 Plan, except the yield benefit component, if available, that was determined on the grant date. The terms of the options which will be granted according to the 2011 Plan, including option period, exercise price, vesting period and exercise period, shall be determined by the Company's Board on the date of the actual allocation. As of March 29, 2012 we have granted 300,000 share options under the 2011 Plan.

*Non-Plan Share Options*

In addition to the options granted under our share option plans, there are 159,000 of NIS 0.1 par value outstanding and exercisable options, as of December 31, 2011, which were granted to consultants and a member of our Scientific Advisory Board, not under an option plan during 1997 and 2011. The options were granted at an exercise price of \$2.69 and \$0.15. As of December 31, 2011, 63,000 options of NIS 0.1 par value are fully vested. On January 29, 2012, 39,000 options were expired.



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

As of March 26, 2012, there were 15,869,582 ADRs outstanding, held by approximately 7 record holders, whose holdings represented approximately 14.40% of the total outstanding ordinary shares, of which 6 record holders were in the US.

The following table sets forth the number of our ordinary shares owned by any person known to us to be the beneficial owner of 5% or more of our ordinary shares as of March 29, 2012. The information in this table is based on 220,386,912 outstanding ordinary shares as of such date. The number of Ordinary Shares beneficially owned by a person includes Ordinary Shares subject to options held by that person that were currently exercisable. None of the holders of the Ordinary Shares listed in this table have voting rights different from other holders of the Ordinary Shares.

Name	Number of shares owned	Percent of ordinary shares	
Alexander Rabinovitch <sup>(1)(2)(3)</sup>	43,132,361	19.57	%
David Bassa <sup>(2)</sup>	21,705,987	9.85	%
Shalom Manova <sup>(2)</sup>	17,175,573	7.79	%

(1) 23,574,902 of our ordinary shares are held through Green Forest Ltd., which to the best of our knowledge held jointly by Alexander Rabinovitch and Sagit Rabinovitch.

(2) Alexander Rabinovitch, David Bassa and Shalom Manova hold our shares since August 3, 2010 as part of the completion of the Bio-Gal transaction.

In addition to his holding as stated in the table above, Mr. Alexander Rabinovitch, through Green Forest Ltd., holds 573,750 warrants (series 2). Each warrant (series 2) is exercisable into one ordinary share of NIS 0.1 par value (3) from the date of registration for trade on the Tel-Aviv stock exchange (March 9, 2011) to February 27, 2013, at an exercise price equal to NIS 1.0 per share, linked to the US dollar. On a fully diluted basis, assuming exercise of all outstanding warrants, the total holding shall represent 17.89% of the share capital of the Company,

**Related Party Transactions**

To our knowledge, there are no related party transactions existing as of March 29, 2012.

## **Item 8. Financial Information**

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

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

### **Legal Proceedings**

Neither we nor our subsidiaries are a party to, and our property is not the subject of, any material pending legal proceedings.

### **Dividend Distributions**

We have never declared or paid any cash dividends on our ordinary shares and do not anticipate paying any such cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors. Cash dividends may be paid by an Israeli company only out of retained earnings as calculated under Israeli law. We currently have no retained earnings and do not expect to have any retained earnings in the foreseeable future.

## Significant Changes

On January 29, 2012, 39,000 options which had been issued in 1997 to a former service provider expired.

On March 14, 2012, we entered into a strategic collaboration framework agreement with Clalit Health Services – Clalit Research Institute Ltd. (the “Institute”) and Mor Research Applications Ltd., the technology transfer office of Clalit Health Services (“Mor”). Pursuant to the agreement, the Institute will provide XTL the right to receive content based on data which originates from a database of the Institute in connection with technologies that stem from inventions and patents of Clalit Health Services’ physicians. The contents of the specific projects shall be agreed upon by XTL, the Institute and Mor in advance in writing. XTL, in consideration for the above, shall pay the Institute the cost of its activity in the collaboration framework of any project plus an additional 10% of the total royalties Mor is entitled pursuant to its agreements with the Company in connection with each technology where rights were granted to XTL. The agreement may be terminated by a one hundred and eighty (180) day written notice by each of the parties, subject to having completed all mutual active projects. Management estimates that access to data through this agreement will enable XTL to evaluate safety and efficacy data of technologies in development as well as technologies where development has not yet commenced.

As of the date of this report, XTL has the rights to two technologies that were in-licensed from Mor: rHuEPO for the treatment of multiple myeloma blood cancer, and SAM-101 for the treatment of psychotic patients.

On March 19, 2012, the annual meeting of shareholders approved to grant 300,000 share options to external directors at XTL to purchase 300,000 Ordinary shares of NIS 0.1 par value each at an exercise price equal to NIS 0.58633 per share. Pursuant to the guidance of IFRS 2, the fair value of all share options on the date of approval by the annual meeting, using the Black-Scholes model was approximately \$ 79 thousand. The option term is for a period of 10 years from the grant date. 33% of the options are exercisable immediately and the remaining share options are exercisable in 24 tranches every month over a two-year period. The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 153%, risk-free interest rate of 4.08% and expected life of 6 years.

On March 19, 2012 the company Annual General Meeting of shareholders (“AGM”) held in Ramat Gan, Israel. At the AGM, all of the proposals set forth in XTL’s proxy statement were approved by the required majority of shareholders.

## ITEM 9. THE OFFER AND LISTING

### Markets and Share Price History

Since July 12, 2005 our shares have been traded on Tel Aviv Stock Exchange (TASE) under the symbol “XTL”. As of April 17, 2009, when we were delisted from Nasdaq, then our primary trading market, our dual-listing provisions ceased and since then TASE has become our primary trading market for our securities, and our ADRs are quoted on the Pink Sheets under the symbol “XTLBY.PK”, with each ADR representing two NIS 0.1 par value ordinary shares.

On January 27, 2009, we received a Staff Determination Letter from The Nasdaq Stock Market notifying us that the staff of Nasdaq's Listing Qualifications Department determined, using its discretionary authority under Nasdaq Marketplace Rule 4300, that our ADRs would be delisted from Nasdaq. The letter further stated that Nasdaq would suspend trading on our ADRs at the opening of trading on February 5, 2009, unless we appealed Nasdaq's delisting determination. Nasdaq's determination to delist our ADRs was due to the fact we do not meet the stockholders' equity requirement, or any of its alternatives, and that we had failed to comply with Nasdaq's listing criteria. On February 3, 2009, we appealed the determination by the Nasdaq Listing Qualification Staff to delist our ADRs from the Nasdaq Capital Market. The Nasdaq Office of the General Counsel assigned a date of March 19, 2009, for an oral hearing before the Nasdaq Hearings Panel. Nasdaq's delisting action has been stayed, pending a final written determination by the Panel following the hearing. At the hearing, we presented our opposition to Nasdaq's arguments and our business plan that among others enabled compliance with all other applicable Nasdaq listing requirements. In April 2009, we received a letter from the NASDAQ Stock Market informing us of their final decision to delist our ADRs from NASDAQ Capital Markets as of April 17, 2009, which has become final and unappealable as of July 2009.

Following the delisting in April 2009, our ADRs are quoted on the Pink Sheets under the symbol XTLBY.PK). Since September 1, 2005 until April 2009 our primary trading market was NASDAQ Capital Markets. Our ADRs have been traded on the NASDAQ Stock Market under the symbol "XTLB," with each ADR representing ten NIS 0.02 par value ordinary shares (prior to the 1:5 share consolidation, which was resolved on March 18, 2009, and effected in June 2009).

In the past, our primary trading market was the London Stock Exchange, or LSE, where our shares were listed and traded under the symbol "XTL" since our initial public offering in September of 2000. On October 31, 2007, our ordinary shares were delisted from the LSE, pursuant to the October 2, 2007 vote at our extraordinary general meeting of shareholders.

### American Depositary Shares

The following table presents, for the periods indicated, the high and low market prices for our ADRs as reported on the NASDAQ Stock Market<sup>1</sup> since September 1, 2005 and on the Pink Sheets since April 17, 2009, the date on which our ADRs were initially quoted. Prior to the initial quotation of our ADRs on the NASDAQ Stock Market on September 1, 2005, our ADRs were not traded in any organized market and were not liquid.

	US Dollar	
	High	Low
<b>Last Six Calendar Months</b>		
March 2012 (until March 27)	0.73	0.42
February 2012	0.45	0.29
January 2012	0.41	0.27

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December 2011	0.44	0.15
November 2011	0.28	0.26
October 2011	0.33	0.23
September 2011	0.37	0.24
Financial Quarters During the Past Two Full Fiscal Years		
First Quarter of 2012 (until March 28)		
Fourth Quarter of 2011	0.44	0.15
Third Quarter of 2011	0.43	0.24
Second Quarter of 2011	0.38	0.22
First Quarter of 2011	0.54	0.23
Fourth Quarter of 2010	0.48	0.12
Third Quarter of 2010	0.28	0.07
Second Quarter of 2010	0.13	0.06
First Quarter of 2010	0.15	0.09
Full Five Financial Years		
2011	0.54	0.15
2010	0.48	0.06
2009	0.32	0.05
2008	4.96	0.04
2007	4.99	1.10

<sup>1</sup> Our ADRs are quoted on the Pink Sheets since April 17, 2009. Our ADRs were quoted on the NASDAQ Capital Market since December 3, 2007 until April 17, 2009 and prior to that were quoted on the NASDAQ Global Market.

The following table sets forth, for the periods indicated, the high and low sales prices of the NIS 0.1 par value ordinary shares (after the 1:5 share consolidation which was resolved on June 22, 2009) on the Tel Aviv Stock Exchange. For comparative purposes only, we have also provided such figures translated into US Dollars at an exchange rate of 3.715 New Israeli Shekel per US Dollar, as of March 27, 2012 according to the Bank of Israel.

	New Israeli Shekel		US Dollar	
	High	Low	High	Low
<b>Last Six Calendar Months</b>				
March 2012 (until March 27)	1.260	0.640	0.339	0.172
February 2012	0.790	0.555	0.213	0.149
January 2012	0.621	0.503	0.167	0.135
December 2011	0.580	0.429	0.156	0.115
November 2011	0.528	0.405	0.142	0.109
October 2011	0.530	0.482	0.143	0.130
September 2011	0.609	0.480	0.164	0.129
<b>Financial Quarters During the Past Two Full Fiscal Years</b>				
First Quarter of 2012	1.260	0.503	0.339	0.135
Fourth Quarter of 2011	0.580	0.405	0.156	0.109
Third Quarter of 2011	0.780	0.480	0.210	0.129
Second Quarter of 2011	0.679	0.451	0.183	0.121
First Quarter of 2011	0.987	0.400	0.266	0.108
Fourth Quarter of 2010	0.700	0.335	0.188	0.090
Third Quarter of 2010	0.415	0.225	0.112	0.061
Second Quarter of 2010	0.318	0.162	0.086	0.044
First Quarter of 2010	0.407	0.275	0.110	0.074
<b>Full Financial Years Since 2006</b>				
2011	0.987	0.400	0.266	0.108
2010	0.700	0.162	0.188	0.044
2009	1.285	0.095	0.346	0.026
2008	8.700	0.075	2.342	0.020
2007	10.20	2.275	2.746	0.612

<sup>2</sup> On June 22, 2009 a 1:5 share consolidation was resolved. All figures prior to the effective date were adjusted accordingly.

## ITEM 10. ADDITIONAL INFORMATION

### Memorandum and Articles of Association

***Objects and Purposes of the Company***

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

***Powers and Obligations of the Directors***

Pursuant to the Israeli Companies Law and our Articles of Association, a director is not permitted to vote on a proposal, arrangement or contract in which he or she has a personal interest. Also, the directors may not vote on compensation to themselves or any members of their body, as that term is defined under Israeli law, without the approval of our audit committee and our shareholders at a general meeting. The requirements for approval of certain transactions are set forth below in “Item 10. Additional Information – Memorandum and Articles of Association–Approval of Certain Transactions.” The power of our directors to enter into borrowing arrangements on our behalf is limited to the same extent as any other transaction by us.



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

*Indemnification of Directors and Officers; Limitations on Liability*

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

- a breach of the office holder's duty of care to the company or to another person;
- a breach of the office holder's fiduciary duty to the company, provided that he or she acted in good faith and had reasonable cause to believe that the act would not prejudice the company; and
- a financial liability imposed upon the office holder in favor of another person.

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

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

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

Our Articles of Association allow for insurance, exculpation and indemnification of office holders to the fullest extent permitted by law. We have entered into indemnification, insurance and exculpation agreements with our directors and

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

### *Approval of Certain Transactions*

The Israeli Companies Law codifies the fiduciary duties that office holders, including directors and executive officers, owe to a company. An office holder, as defined in the Israeli Companies Law, is a director, general manager, chief business manager, deputy general manager, vice general manager, executive vice president, vice president, other manager directly subordinate to the managing director or any other person assuming the responsibilities of any of the foregoing positions without regard to such person's title. An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of loyalty includes avoiding any conflict of interest between the office holder's position in the company and his personal affairs, avoiding any competition with the company, avoiding exploiting any business opportunity of the company in order to receive personal advantage for himself or others, and revealing to the company any information or documents relating to the company's affairs which the office holder has received due to his position as an office holder. Each person listed in the table under "Directors and Senior Management," which is displayed under "Item 6. Directors, Senior Management and Employees – Directors and Senior Management," holds such office in our Company. Under the Israeli Companies Law, all arrangements as to compensation of office holders who are not directors require approval of the Board of Directors, or a committee thereof. Arrangements regarding the compensation of directors also require audit committee and shareholders approval, with the exception of compensation to external directors in the amounts specified in the regulations discussed in "Item 6. Directors, Senior Management and Employees – Directors and Senior Management – Compensation."

The Israeli Companies Law requires that an office holder promptly discloses any personal interest that he or she may have, and all related material information known to him or her, in connection with any existing or proposed transaction by the company. The disclosure must be made to our Board of Directors or shareholders without delay and prior to the meeting at which the transaction is to be discussed. In addition, if the transaction is an extraordinary transaction, as defined under the Israeli Companies Law, the office holder must also disclose any personal interest held by the office holder's spouse, siblings, parents, grandparents, descendants, spouse's descendants and the spouses of any of the foregoing, or by any corporation in which the office holder is a 5% or greater shareholder, or holder of 5% or more of the voting power, director or general manager or in which he or she has the right to appoint at least one director or the general manager. An extraordinary transaction is defined as a transaction not in the ordinary course of business, not on market terms, or that is likely to have a material impact on the company's profitability, assets or liabilities.

In the case of a transaction which is not an extraordinary transaction (other than transactions relating to a director's conditions of service), after the office holder complies with the above disclosure requirement, only board approval is required unless the Articles of Association of the company provides otherwise. The transaction must not be adverse to the company's interest. If the transaction is an extraordinary transaction, then, in addition to any approval required by the Articles of Association, the transaction must also be approved by the audit committee and by the Board of Directors, and under specified circumstances, by a meeting of the shareholders. An office holder who has a personal interest in a matter that is considered at a meeting of the Board of Directors or the audit committee may not be present at this meeting or vote on this matter.

The Israeli Companies Law applies the same disclosure requirements to a controlling shareholder of a public company, which is defined as a shareholder who has the ability to direct the activities of a company, other than in circumstances where this power derives solely from the shareholder's position on the Board or any other position with the company, and includes a shareholder that holds 25% or more of the voting rights if no other shareholder owns more than 50% of the voting rights in the company. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, and the terms of compensation of a controlling shareholder who is an office holder, require the approval of the audit committee, the Board of Directors and the shareholders of the company. The shareholders' approval must either include at least the majority of the disinterested shareholders who are present, in person or by proxy, at the meeting, or, alternatively, the total shareholdings of the disinterested shareholders who vote against the transaction must not represent more than two percent of the voting rights in the company.

In addition, a private placement of securities that will increase the relative holdings of a shareholder that holds 5% or more of the company's outstanding share capital, assuming the exercise by such person of all of the convertible securities into shares held by that person, or that will cause any person to become a holder of more than 5% of the company's outstanding share capital, requires approval by the Board of Directors and the shareholders of the company. However, subject to certain exceptions under regulations adopted under the Israeli Companies Law, shareholder approval will not be required if the aggregate number of shares issued pursuant to such private placement, assuming the exercise of all of the convertible securities into shares being sold in such a private placement, comprises less than 20% of the voting rights in a company prior to the consummation of the private placement.

Under the Israeli Companies Law, a shareholder has a duty to act in good faith towards the company and other shareholders and refrain from abusing his power in the company, including, among other things, voting in the general meeting of shareholders on the following matters:

any amendment to the Articles of Association;

an increase of the company's authorized share capital;

a merger; and

approval of interested party transactions that require shareholders approval.

In addition, any controlling shareholder, any shareholder who knows it can determine the outcome of a shareholders vote and any shareholder who, under a company's Articles of Association, can appoint or prevent the appointment of an office holder, is under a duty to act with fairness towards the company. The Israeli Companies Law does not describe the substance of this duty. The Israeli Companies Law requires that specified types of transactions, actions and arrangements be approved as provided for in a company's articles of association and in some circumstances by the audit committee, by the Board of Directors and by the shareholders. In general, the vote required by the audit committee and the Board of Directors for approval of these matters, in each case, is a majority of the disinterested directors participating in a duly convened meeting.

### ***Rights Attached to Ordinary Shares***

Through March 18, 2009, our authorized share capital was NIS 10,000,000 consisting of 500,000,000 ordinary shares, par value NIS 0.02 per share. On March 18, 2009, pursuant to a shareholder's meeting, the share capital of our company was consolidated and re-divided so that each five (5) shares of NIS 0.02 nominal value was consolidated into one (1) share of NIS 0.1 nominal value so that following such consolidation and re-division, our authorized share

capital consisted of 100,000,000 ordinary shares, par value NIS 0.10 per share. In addition, the authorized share capital of our company was increased from NIS 10,000,000 to NIS 70,000,000 divided into 700,000,000 ordinary shares, NIS 0.10 nominal value. The share consolidation was effected in June 22, 2009.

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

### ***Transfer of Shares***

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

### ***Dividend and Liquidation Rights***

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

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

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

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

### ***Voting Rights***

Our ordinary shares do not have cumulative voting rights in the election of directors. As a result, the holders of ordinary shares that represent more than 50% of the voting power represented at a shareholders meeting in which a quorum is present have the power to elect all of our directors, except the external directors whose election requires a special majority as described under the section entitled "Item 6. Directors, Senior Management and Employees – Board Practices – External and Independent Directors."

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

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

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

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



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

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

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

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

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

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

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

provide that these tender offer requirements do not apply to companies whose shares are listed for trading external of Israel if, according to the law in the country in which the shares are traded, including the rules and regulations of the stock exchange or which the shares are traded, either:

- there is a limitation on acquisition of any level of control of the company; or
  
- the acquisition of any level of control requires the purchaser to do so by means of a tender offer to the public.

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

### ***Rights of Shareholders***

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

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

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

### ***Enforceability of Civil Liabilities***

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

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

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

- adequate service of process was effected and the defendant had a reasonable opportunity to be heard;
- the judgment is not contrary to the law, public policy, security or sovereignty of the State of Israel and its enforcement is not contrary to the laws governing enforcement of judgments;

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

the judgment is no longer appealable; and

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

We have irrevocably appointed XTL Biopharmaceuticals, Inc., our US subsidiary, as our agent to receive service of process in any action against us in any US federal court or the courts of the State of New York.

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

## **Material Contracts**

### ***VivoQuest Inc.***

In August 2005, we entered into an asset purchase agreement with VivoQuest, a privately held biotechnology company based in the US, pursuant to which we agreed to purchase from VivoQuest certain assets, including VivoQuest's laboratory equipment, and to assume VivoQuest's lease of its laboratory space. In consideration, we paid \$450,000 to VivoQuest, which payment was satisfied by the issuance of ordinary shares having a fair market value in the same amount as of the closing date. The asset purchase was completed in September 2005. In addition, we entered into a license agreement with VivoQuest pursuant to which we acquired exclusive worldwide, perpetual, irrevocable and non-terminable rights to VivoQuest's patents, intellectual property and technology. The license covers a proprietary compound library, including VivoQuest's lead HCV compounds, that was developed through the use of Diversity Oriented Synthesis, or DOS, technology. The terms of the license agreement include an initial upfront license fee of approximately \$941,000 that was paid in our ordinary shares. The license agreement also provides for additional milestone payments triggered by certain regulatory and sales targets. The milestone payments amount to an aggregate of \$34 million, \$25 million of which will be due upon or following regulatory approval or actual product

sales, and are payable in cash or ordinary shares at our election. In addition, the license agreement requires that we make royalty payments in the range of 2% to 8%, depending on net product sales. Commercialization of the DOS program has been out-licensed to Presidio Pharmaceuticals, Inc. (see “Presidio Pharmaceuticals, Inc.” below).

***Presidio Pharmaceuticals, Inc.***

In March 2008, and as revised August 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 was granted a license for patent rights and technology relating to the DOS program, and became 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 are eligible to receive up to an additional aggregate amount of \$59 million upon reaching certain development and commercialization milestones. In addition, we will receive a royalty payment in the range of 1% to 10% 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. Presidio is responsible for all further development and commercialization activities relating to the DOS program and, to our knowledge based upon the most current reports we have received from Presidio, no commercial sales have begun. The license remains in effect until the expiration of all of Presidio's payment obligations, including milestone and royalty payments. Presidio's royalty obligations continue until a certain number of years from the first commercial sale in such country or until the expiration date of the last to expire of the licensed patents (currently, 2023), whichever is later. Upon expiration of the agreement, on a licensed product-by-product and country-by-country basis, the license granted to Presidio shall convert to a non-exclusive, perpetual, fully paid-up, non-royalty-bearing license. Presidio may terminate the license agreement at any time upon ninety days written notice to us, after which Presidio must return the licensed intellectual property to us and cease development and commercialization for a period of ten years.

***Bio-Gal Ltd.***

On March 18, 2009, we announced that we had entered into an asset purchase agreement with Bio-Gal Ltd. ("Bio-Gal"), a Gibraltar private company, for the rights to a use patent on Recombinant Erythropoietin ("rHuEPO") for the prolongation of multiple myeloma patients' survival and improvement of their quality of life. On December 31, 2009, we amended the asset purchase agreement with Bio-Gal, so that XTL could acquire XTEPO Ltd., a special purpose company that was established by Bio-Gal's shareholders who received from Bio-Gal all of Bio-Gal's rights on rHuEPO and raised approximately \$1.5 million. We intend to develop rHuEPO for the prolongation of MM patients' survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. In accordance with the terms of the amended asset purchase agreement, we issued to XTEPO's shareholders ordinary shares representing approximately 69.44% of our then issued and outstanding ordinary share capital. In addition, the parties agreed to cancel a \$10 million cash milestone payment to Bio-Gal upon the successful completion of a Phase 2 clinical trial, which was under the original asset purchase agreement. We are obligated to pay 1% royalties on net sales of the product, as well as a fixed royalty payment in the total amount of \$350,000 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 at any time after the completion of the 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 prerequisites had been met, including, among other things, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption

granted to the share swap transaction pursuant to article 104 and 103 to the Israeli tax ordinance (Revised), 1961. (See notes 1b and 9a to the consolidated financial statements: General, Intangible Asset).

*MinoGuard Ltd.*

On March 24, 2011, the Company entered into a term sheet to acquire the assets of MinoGuard by an exclusive license to use MinoGuard's entire technology in return for royalties on sales and milestone payments throughout the clinical development process, without any other payments. MinoGuard was founded in 2007 in order to commercialize combination therapies for treating psychotic diseases, focusing on schizophrenia. The transaction was subject, among others, to completion of due diligence studies, examination of the regulatory track for the continued development of the drug and the approval of the Company's Board. On November 30, 2011, the agreement with MinoGuard was completed after all prerequisites abovementioned had fully met. In accordance with the terms of the license agreement we shall pay MinoGuard accumulated clinical development and marketing approvals milestone-based payments of approximately \$2.5 million. In addition, we will pay MinoGuard royalty-based payments on products that are based on the Technology, equal to 3.5% of 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. The agreement states that 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.



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

The license may be terminated in by either XTL without cause upon 30 days notice, or by the licensor for no commercial progress in the event that by the date of June 30th, 2013 neither commencement of phase II Clinical Trial with respect to the licensed product has occurred, nor XTL has entered into a Sublicense Agreement with a substantial third party.

### ***Bicifadine License***

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 in 2008. In January 2007, XTL Development had signed an agreement with DOV to in-license the worldwide rights for Bicifadine. XTL Development was developing Bicifadine for the treatment of diabetic neuropathic pain. In accordance with the terms of the license agreement, XTL Development paid an initial up-front license fee of \$7.5 million in cash in 2007. In addition, XTL Development would have been required to make milestone payments of up to \$126.5 million over the life of the license. These milestone payments would have been made in either cash and/or our ordinary shares, at our election, with the exception of \$5 million in cash, due upon or after regulatory approval of the product. XTL Development was also obligated to pay royalties to DOV on net sales of Bicifadine. Following our announcement of the failure of the phase 2b clinical trial, we ceased development of Bicifadine for diabetic neuropathic pain in 2008 and all rights under the agreement reverted to DOV. Since the failure of the Bicifadine phase 2b clinical trial, both XTL Development and DOV ceased the prosecution and maintenance of those patents relating to Bicifadine. In March 2010, the agreement was formally terminated.

In addition, XTL Development was committed to pay a transaction advisory fee to certain third party intermediaries in connection with the in-license of Bicifadine from DOV. Once the Bicifadine license agreement was terminated, the commitment to pay a further transaction advisory fee ceased. In March 2010, we formally terminated the license agreement and therefore all unvested SARs have automatically expired. See “Item 5 – Operating and Financial Review and Prospects – Obligations and Commitments.”

### **Exchange Controls**

Under Israeli Law, Israeli non-residents who purchase ordinary shares with certain non-Israeli currencies (including dollars) may freely repatriate in such non-Israeli currencies all amounts received in Israeli currency in respect of the ordinary shares, whether as a dividend, as a liquidating distribution, or as proceeds from any sale in Israel of the ordinary shares, provided in each case that any applicable Israeli income tax is paid or withheld on such amounts. The

conversion into the non-Israeli currency must be made at the rate of exchange prevailing at the time of conversion.

## **Taxation**

We issued XTEPO's shareholders ordinary shares representing approximately 69.44% of our then issued and outstanding ordinary share capital as part of the Bio-Gal transaction (see also Israeli Tax Considerations below). As a result of the shifts of ownership, the Company's US carry back losses are subject to significant certain limitations and/or reductions. See "Item 3- Key Information – Risk Related to our Financial Condition."

The following discussion of Israeli and US tax consequences material to our shareholders is not intended and should not be construed as legal or professional tax advice and does not exhaust all possible tax considerations. To the extent that the discussion is based on new tax legislation, which has not been subject to judicial or administrative interpretation, the views expressed in the discussion might not be accepted by the tax authorities in question. This summary does not purport to be a complete analysis of all potential tax consequences of owning ordinary shares or ADRs. In particular, this discussion does not take into account the specific circumstances of any particular shareholder (such as tax-exempt entities, certain financial companies, broker-dealers, shareholders subject to Alternative Minimum Tax, shareholders that actually or constructively own 10% or more of our voting securities, shareholders that hold ordinary shares or ADRs as part of straddle or hedging or conversion transaction, traders in securities that elect mark to market, banks and other financial institutions or shareholders whose functional currency is not the US dollar), some of which may be subject to special rules.

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

### ***Israeli Tax Considerations***

The following discussion refers to the current tax law applicable to companies in Israel, with special reference to its effect on us. This discussion also includes specified Israeli tax consequences to holders of our ordinary shares and Israeli Government programs benefiting us.

### **Corporate Tax Rate**

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%.

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

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

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

### **Israeli Estate and Gift Taxes**

Generally, Israel does not currently impose taxes on inheritance or bona fide gifts. For transfer of assets by inheritance or gift that would normally be subject to capital gains tax or land appreciation tax, the recipient's tax cost basis and date of purchase are generally deemed to be the same as those for the transferor of the property.

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

Israeli law generally imposes a capital gains tax on the sale of capital assets located in Israel, including shares in Israeli resident companies, by both residents and non-residents of Israel, unless a specific exemption is available or unless a treaty between Israel and the country of the non-resident provides otherwise. The law distinguishes between the inflationary surplus and the real gain. The inflationary surplus is the portion of the total capital gain, which is equivalent to the increase of the relevant asset's purchase price attributable to the increase in the Israeli consumer price index from the date of purchase to the date of sale. The real gain is the excess of the total capital gain over the inflationary surplus. A non resident that invests in taxable assets with foreign currency may elect to calculate the inflationary amount by using such foreign currency.

Non-Israeli residents will be exempt from Israeli capital gains tax on any gains derived from the sale of shares publicly traded on a stock exchange recognized by the Israeli Ministry of Finance (including the Tel-Aviv Stock Exchange and NASDAQ), provided such shareholders did not acquire their shares prior to an initial public offering and that such capital gains are not derived by a permanent establishment of the foreign resident in Israel. Notwithstanding the foregoing, dealers in securities in Israel are taxed at the regular tax rates applicable to business income. However, Non-Israeli corporations will not be entitled to such exemption if an Israeli resident (1) has a controlling interest of 25% or more in such non-Israeli corporation, or (2) is the beneficiary of, or is entitled to, 25% or more of the revenue or profits of such non-Israeli corporation, whether directly or indirectly. In any event, the provisions of the tax reform shall not affect the exemption from capital gains tax for gains accrued before January 1, 2003, as described in the previous paragraph.

The capital gains tax imposed on Israeli tax resident individuals on the sale of securities was 20%. With respect to an Israeli tax resident individual who is a "substantial shareholder" on the date of sale of the securities or at any time during the 12 months preceding such sale, the capital gains tax rate was increased to 25%. In December 2011, following the enactment of the Tax Burden Distribution Law, the tax rates mentioned above were increased to 25% and 30%, respectively, from 2012 and thereafter. A "substantial shareholder" is defined as someone who alone, or together with another person, holds, directly or indirectly, at least 10% in one or all of any of the means of control in the corporation. With respect to Israeli tax resident corporate investors, capital gains tax at the regular corporate rate will be imposed on such taxpayers on the sale of traded shares.

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

## **Taxation of Dividends**

Non-residents of Israel are subject to income tax on income accrued or derived from sources in Israel.

The tax rate imposed on dividends distributed by an Israeli company to Israeli tax resident individuals or to non-Israeli residents was set at a rate of 20%. With respect to “substantial shareholders,” as defined above, the applicable tax rate was 25%. In December 2011, following the enactment of the Tax Burden Distribution Law, the tax rates mentioned above were increased to 25% and 30%, respectively, from 2012 and thereafter. The taxation of dividends distributed by an Israeli company to another Israeli corporate tax resident is generally exempt from tax.

In any case, dividends distributed from the taxable income attributable to an Approved Enterprise, to both Israeli tax residents and non-Israeli residents remains subject to a 15% tax rate.

Notwithstanding, dividends distributed by an Israeli company to Israeli tax resident individuals or to non-Israeli residents was subject to a 20% withholding tax, which was increased to 25% from 2012 and thereafter, following the enactment of the Tax Burden Distribution Law (15% in the case of dividends distributed from the taxable income attributable to an Approved Enterprise), unless a lower rate is provided in a treaty between Israel and the shareholder’s country of residence. Dividends distributed by an Israeli company to another Israeli tax resident company are generally exempt, unless such dividends are distributed from taxable income attributable to an Approved Enterprise, in which case such dividends are taxed at a rate of 15%, or unless such dividends are distributed from income that was not sourced in Israel, in which case such dividends are taxed at a rate of 25%.

Under the US-Israel Tax Treaty, the maximum Israeli tax and withholding tax on dividends paid to a holder of ordinary shares who is a resident of the US is generally 25%, but is reduced to 12.5% if the dividends are paid to a corporation that holds in excess of 10% of the voting rights of company during the company’s taxable year preceding the distribution of the Dividend and the portion of the company’s taxable year in which the dividend was distributed. Dividends of an Israeli company derived from the income of an Approved Enterprise will still be subject to a 15% dividend withholding tax; if the dividend is attributable partly to income derived from an Approved Enterprise, and partly to other sources of income, the withholding rate will be a blended rate reflecting the relative portions of the two types of income. A non-resident of Israel who has dividend income derived from or accrued in Israel, from which tax was withheld at the source, is generally exempt from the duty to file tax returns in Israel in respect of such income, provided such income was not derived from a business conducted in Israel by the taxpayer.

## ***US Federal Income Tax Considerations***

The following discusses the material US federal income tax consequences to a holder of our ordinary shares, who qualifies as a US holder, which is defined as:

- a citizen or resident of the US;
- a corporation created or organized under the laws of the US, the District of Columbia, or any state; or
- a trust or estate, treated, for US federal income tax purposes, as a domestic trust or estate.

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



- have elected mark-to-market accounting;
- hold our ordinary shares as part of a straddle, hedge or conversion transaction with other investments;
- own directly, indirectly or by attribution at least 10% of our voting power;
- are tax exempt entities;
- are persons who acquire shares in connection with employment or other performance of services; and
- have a functional currency that is not the US dollar.

Additionally, this discussion does not consider the tax treatment of partnerships or persons who hold ordinary shares through a partnership or other pass-through entity or the possible application of US federal gift or estate taxes. Material aspects of US federal income tax relevant to a holder other than a US holder are also described below.

Each shareholder should consult its tax advisor regarding the particular tax consequences to such holder of ownership and disposition of our shares, as well as any tax consequences that may arise under the laws of any other relevant foreign, state, local, or other taxing jurisdiction.

### **Taxation of Dividends Paid on Ordinary Shares**

Subject to the description of the passive foreign investment company rules below, a US holder will be required to include in gross income as ordinary income the amount of any distribution paid on ordinary shares, including any Israeli taxes withheld from the amount paid, to the extent the distribution is paid out of our current or accumulated earnings and profits as determined for US federal income tax purposes. Distributions in excess of these earnings and profits will be applied against and will reduce the US holder's basis in the ordinary shares and, to the extent in excess of this basis, will be treated as gain from the sale or exchange of ordinary shares.

Certain dividend income may be eligible for a reduced rate of taxation. Dividend income will be taxed to a non-corporate holder at the applicable long-term capital gains rate if the dividend is received from a "qualified foreign corporation," and the shareholder of such foreign corporation holds such stock for more than 60 days during the 121 day period that begins on the date that is 60 days before the ex-dividend date for the stock. The holding period is tolled for any days on which the shareholder has reduced his risk of loss. A "qualified foreign corporation" is either a

corporation that is eligible for the benefits of a comprehensive income tax treaty with the US or a corporation whose stock, the shares of which are with respect to any dividend paid by such corporation, is readily tradable on an established securities market in the United States. However, a foreign corporation will not be treated as qualified if it is a passive foreign investment company (as discussed below) for the year in which the dividend was paid or the preceding year. Distributions of current or accumulated earnings and profits paid in foreign currency to a US holder will be includible in the income of a US holder in a US dollar amount calculated by reference to the exchange rate on the day the distribution is received. A US holder that receives a foreign currency distribution and converts the foreign currency into US dollars subsequent to receipt will have foreign exchange gain or loss based on any appreciation or depreciation in the value of the foreign currency against the US dollar, which will generally be US source ordinary income or loss.

As described above, we will generally be required to withhold Israeli income tax from any dividends paid to holders who are not resident in Israel. See “- Israeli Tax Considerations—Taxation of Dividends” above. If a US holder receives a dividend from us that is subject to Israeli withholding, the following would apply:

You must include the gross amount of the dividend, not reduced by the amount of Israeli tax withheld, in your US taxable income.

You may be able to claim the Israeli tax withheld as a foreign tax credit against your US income tax liability. However, to the extent that 25% or more of our gross income from all sources was effectively connected with the conduct of a trade or business in the US (or treated as effectively connected, with limited exceptions) for a three-year period ending with the close of the taxable year preceding the year in which the dividends are declared, a portion of this dividend will be treated as US source income, possibly reducing the allowable foreign tax.

The foreign tax credit is subject to significant and complex limitations. Generally, the credit can offset only the part of your US tax attributable to your net foreign source passive income. Additionally, if we pay dividends at a time when 50% or more of our stock is owned by US persons, you may be required to treat the part of the dividend attributable to US source earnings and profits as US source income, possibly reducing the allowable credit.

A US holder will be denied a foreign tax credit with respect to Israeli income tax withheld from dividends received on the ordinary shares to the extent the US holder has not held the ordinary shares for at least 16 days of the 31-day period beginning on the date which is 15 days before the ex-dividend date or, alternatively, to the extent the US holder is under an obligation to make related payments with respect to substantially similar or related property. Any days during which a US holder has substantially diminished its risk of loss on the ordinary shares are not counted toward meeting the 16-day holding period required by the statute.

If you do not elect to claim foreign taxes as a credit, you will be entitled to deduct the Israeli income tax withheld from your XTL dividends in determining your taxable income.

Individuals who do not claim itemized deductions, but instead utilize the standard deduction, may not claim a deduction for the amount of the Israeli income taxes withheld.

If you are a US corporation holding our stock, the general rule is that you cannot claim the dividends-received deduction with respect to our dividends. There is an exception to this rule if you own at least 10% of our ordinary shares (by vote) and certain conditions are met.

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

**Taxation of the Disposition of Ordinary Shares**

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

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

### **Tax Consequences If We Are A Passive Foreign Investment Company**

Special tax rules apply to the timing and character of income received by a US holder of a PFIC. We will be a PFIC if either 75% or more of our gross income in a tax year is passive income or the average percentage of our assets (by value) that produce or are held for the production of passive income in a tax year is at least 50%. The IRS has indicated that cash balances, even if held as working capital, are considered to be assets that produce passive income. Therefore, any determination of PFIC status will depend upon the sources of our income, and the relative values of passive and non-passive assets, including goodwill. Furthermore, because the goodwill of a publicly-traded corporation such as us is largely a function of the trading price of its shares, the valuation of that goodwill is subject to significant change throughout each year. A determination as to a corporation's status as a PFIC must be made annually. We believe that we were likely not a PFIC for the taxable years ended December 31, 2010, 2009 and 2008. 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 classified as a PFIC for the taxable year ended December 31, 2011 and we may be a PFIC in subsequent years. In addition, even though we may not be a PFIC in any one particular year, the PFIC taint remains, and the special PFIC tax regime will continue to apply.

If we are classified as a PFIC, a special tax regime would apply to both (a) any "excess distribution" by us (generally, the US holder's ratable share of distributions in any year that are greater than 125% of the average annual distributions received by such US holder in the three preceding years or its holding period, if shorter) and (b) any gain recognized on the sale or other disposition of your ordinary shares. Under this special regime, any excess distribution and recognized gain would be treated as ordinary income and the federal income tax on such ordinary income is determined under the following steps: (i) the amount of the excess distribution or gain is allocated ratably over the US holder's holding period for our ordinary shares; (ii) tax is determined for amounts allocated to the first year in the holding period in which we were classified as a PFIC and all subsequent years (except the year in which the excess distribution was received or the sale occurred) by applying the highest applicable tax rate in effect in the year to which the income was allocated; (iii) an interest charge is added to this tax calculated by applying the underpayment interest rate to the tax for each year determined under the preceding sentence from the due date of the income tax return for such year to the due date of the return for the year in which the excess distribution or sale occurs; and (iv) amounts allocated to a year prior to the first year in the US holder's holding period in which we were classified as a PFIC or to the year in which the excess distribution or the disposition occurred are taxed as ordinary income and no interest charge applies.



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

A QEF Election is made on a shareholder-by-shareholder basis. A US holder must make a QEF Election by completing Form 8621, Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, and attaching it to the holder’s timely filed US federal income tax return. We have complied with the record-keeping and reporting requirements that are a prerequisite for US holders to make a QEF Election for the 2007 and 2006 tax years. While we plan to continue to comply with such requirements, if, in the future, meeting those record-keeping and reporting requirements becomes onerous, we may decide, in our sole discretion, that such compliance is impractical and will so notify US holders.

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

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

The mark-to-market election is made on a shareholder-by-shareholder basis. The mark-to-market election is made by completing Form 8621, Return by a Shareholder of a Passive Foreign Investment Company or Qualified Electing Fund, and attaching it to the holder’s timely filed US federal income tax return for the year of election. Such election is

effective for the taxable year for which made and all subsequent years until either (a) the ordinary shares cease to be marketable stock or (b) the election is revoked with the consent of the IRS.

A US holder who did not make an election either to (i) treat us as a “qualified electing fund,” or (ii) mark our ordinary shares to market, will be subject to the following:

gain recognized by the US holder upon the disposition of, as well as income recognized upon receiving certain excess distributions on the ordinary shares would be taxable as ordinary income;

the US holder would be required to allocate the excess distribution and/or disposition gain ratably over such US holder's entire holding period for such ordinary shares;



the amount allocated to each year other than the year of the excess distribution or disposition and pre-PFIC years would be subject to tax at the highest applicable tax rate, and an interest charge would be imposed with respect to the resulting tax liability;

the US holder would be required to file an annual return on IRS Form 8621 for the years in which distributions were received on and gain was recognized on dispositions of, our ordinary shares; and

any US holder who acquired the ordinary shares upon the death of the shareholder would not receive a step-up to market value of his income tax basis for such ordinary shares. Instead such US holder beneficiary would have a tax basis equal to the decedent's basis, if lower.

*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.*

#### **US Federal Income Tax Consequences for Non-US holders of Ordinary Shares**

Except as described in “Information Reporting and Back-up Withholding” below, a Non-US holder of ordinary shares will not be subject to US federal income or withholding tax on the payment of dividends on, and the proceeds from the disposition of, ordinary shares, unless:

the item is effectively connected with the conduct by the Non-US holder of a trade or business in the US and, in the case of a resident of a country which has a tax treaty with the US, the item is attributable to a permanent establishment in the US;

the Non-US holder is subject to tax under the provisions of US tax law applicable to US expatriates; or

the individual non-US holder is present in the US for 183 days or more in the taxable year of the disposition and certain other conditions are met.

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

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

information reporting and back-up withholding on proceeds paid from the disposition of ordinary shares unless the US holder provides IRS Form W-9 or otherwise establishes an exemption.

Non-US holders generally are not subject to information reporting or back-up withholding with respect to dividends paid on, or upon the disposition of, ordinary shares, provided that the non-US holder provides a taxpayer identification number, certifies to its foreign status, or otherwise establishes an exemption to the US financial institution holding the ordinary shares.

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

### **US Federal Income Tax Consequences for XTL**

As of April 7, 2009, we did not have a “permanent establishment” in the US. Our board of directors consists of a majority of Israeli residents and our CEO is domiciled in Israel. However, for the period we did have a “permanent establishment” in the US, any income attributable to such US permanent establishment would be subject to US corporate income tax in the same manner as if we were a US corporation. The maximum US corporate income tax rate (not including applicable state and local tax rates) is currently at 35%. In addition, if we had income attributable to the permanent establishment in the US, we may be subject to an additional branch profits tax of 30% on our US effectively connected earnings and profits, subject to adjustment, for that taxable year if certain conditions occur, unless we qualified for the reduced 12.5% US branch profits tax rate pursuant to the United States-Israel tax treaty. We would be potentially able to credit any foreign taxes that may become due in the future against its US tax liability in connection with income attributable to its US permanent establishment and subject to both US and foreign income tax.

As of December 31, 2011, we did not earn any taxable income for US federal tax purposes and we do not have a permanent establishment. If we eventually earn taxable income attributable to our US permanent establishment, we would be able to utilize accumulated loss carryforwards to offset such income only to the extent these carryforwards were attributable to our US permanent establishment. As of December 31, 2011, the net operating tax losses (“NOL”) of the US subsidiaries amounted to approximately \$23 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 that result 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. Pursuant to a US tax rule.

*The above comments are intended as a general guide to the current position. Any person who is in any doubt as to his or her taxation position, and who requires more detailed information than the general outline above or who is subject to tax in a jurisdiction other than the United States should consult professional advisers.*

### **Documents on Display**

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

You may review and obtain copies of our filings with the SEC, including any exhibits and schedules, at the SEC's public reference facilities in Room 1580, 100 F. Street, N.E., Washington, D.C. 20549. You may call the SEC at 1-800-SEC-0330 for further information on the public reference rooms. Our periodic filings will also be available on the SEC's website at [www.sec.gov](http://www.sec.gov). These SEC filings are also available to the public from commercial document retrieval services. Any statement in this annual report about any of our contracts or other documents is not necessarily complete. If the contract or document is filed as an exhibit to this annual report, the contract or document is deemed to modify the description contained in this annual report. We urge you to review the exhibits themselves for a complete description of the contract or document.

## Item 11. Quantitative and Qualitative Disclosures About Market Risk

*Interest Rate Risk.* The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in bank deposits in accordance with our investment policy. As of December 31, 2011, our portfolio of financial instruments consists of cash and cash equivalents, short-term bank deposits with multiple institutions. The average duration of all of our investments held as of December 31, 2011, was less than one year. Due to the short-term nature of these investments, we believe we have no material exposure to interest rate risk arising from our investments.

*Foreign Currency and Inflation Risk.* We have generated all of our revenues and hold most of our cash, cash equivalents and bank deposits in US dollars. Until 2008, most of our operating expenses were in US dollars. Commencing from 2009 the Company's head office moved back to Israel and thus the portion of our expenses in New Israeli Shekels ("NIS") and our cash held in NIS has increased, mainly due to payment to Israeli employees and suppliers. Additionally, our future activities could lead us to perform a clinical trial in Israel, which may lead us to reassess the use of the US dollar as our functional currency. As a result, we are 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.

## Item 12. Description of Securities Other than Equity Securities

### American Depositary Shares

*Fees Payable By ADS Holders.* A copy of our Form of Deposit Agreement with The Bank of New York Mellon (the "Depository") (including the Form of American Depositary Receipt or "ADR") was filed with the SEC as an exhibit to our Form F-6 filed on November 28, 2007 (the "Deposit Agreement"). Pursuant to the Deposit Agreement, holders of our ADSs may have to pay to the Depository, either directly or indirectly, fees or charges up to the amounts set forth in the table below.

Item	Associated Fee	Depository Action
------	----------------	-------------------

1.	Taxes and other governmental charges	As applicable
----	--------------------------------------	---------------

2. Registration fees in effect for the registration of transfers of shares generally on the share register of XTL or foreign registrar and applicable to transfers of shares to or from the name of the Depositary or its nominee or the custodian or its nominee on the making of deposits or withdrawals As applicable
- Cable, telex and facsimile transmission (where expressly provided for in the Deposit Agreement)
3. Expenses incurred by the Depositary
- Foreign currency conversion into US dollars

- |  |   |
|--|---|
| 4. \$5.00 or less per 100 ADSs (or portion thereof)  | <p>Execution and delivery of ADRs for distributions and dividends in shares and rights to subscribe for additional shares or rights of any other nature and surrender of ADRs for the purposes of withdrawal, including the termination of the Deposit Agreement</p> <p>Any cash distribution made pursuant to the Deposit Agreement, including, among other things:</p> <ul style="list-style-type: none"> <li>• cash distributions or dividends,</li> </ul> |
| 5. \$0.02 or less per ADS (or portion thereof)   | <ul style="list-style-type: none"> <li>• distributions other than cash, shares or rights,</li> <li>• distributions in shares, and</li> <li>• rights of any other nature, including rights to subscribe for additional shares.</li> </ul>  |
| 6. A fee for the distribution of securities equal to the fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities  | Distributions of securities other than cash, shares or rights   |
| 7. A fee of \$.02 or less per ADS (or portion thereof) for depositary services, which will accrue on the last day of each calendar year, <u>provided</u> , however, that no fee will be assessed to the extent a fee of \$.02 was charged pursuant to Item 5 above during that calendar year | As applicable   |
| 8. Any other charge payable by the Depositary, any of the Depositary's agents, including its custodian, or the agents of the Depositary's agents in connection with the servicing of shares or other deposited securities  | As applicable   |

*Fees Paid to XTL by the Depositary.* As of January 1, 2011 through March 28, 2012, the Company has not received any fees, direct payments or indirect payments from The Bank of New York Mellon.

PART II

**Item 13. Defaults, Dividend Arrearages and Delinquencies**

Not applicable.

**Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds**

Not applicable.



## Item 15. Controls and Procedures

(a) *Disclosure controls and procedures.* Our management is responsible for establishing and maintaining effective disclosure controls and procedures, as defined under Rules 13a-15 and 15d-15 of the Securities Exchange Act of 1934. As of December 31, 2011, an evaluation was performed under the supervision and with the participation of our management of the effectiveness of the design and operation of our disclosure controls and procedures. Based on that evaluation, management, including the Chief Executive Officer and Chief Financial Officer, concluded that our disclosure controls and procedures as of December 31, 2011 were effective.

(b) *Internal controls over financial reporting.* Our management is responsible for establishing and maintaining adequate control over financial reporting, as such term is defined in Rule 13a-15(f) of the exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2011. In making this assessment, our management used the criteria established in *Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO)*. Also, our evaluation was conducted pursuant to section 9b(c) to the Israeli Securities regulations (Periodic and Immediate Reports), 1970, which came into effect on the reporting for December 31, 2010 for the first time (as we are traded on the TASE). Based on that evaluation, our management believes our internal control over financial reporting was effective as of December 31, 2011.

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

Kesselman & Kesselman, a member of PricewaterhouseCoopers International Limited, the independent registered public accounting firm that audited the financial statements included in this annual report, has issued an audit report as of December 31, 2011, and dated March 29, 2012 relating to the financial statements which appear in this annual report on Form 20-F for the year ended December 31, 2011. See “Item 18. Financial Statements.”

(c) *Internal controls.* There have been no significant changes in our internal control over financial reporting that occurred during the fiscal year ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## Item 16. Reserved

Not applicable.

**Item 16A. Audit Committee Financial Expert**

Our Board of Directors has determined that Jaron Diament, chairperson of our audit committee, is an audit committee financial expert, as defined by applicable SEC regulations, and is independent in accordance with applicable SEC regulations.

**Item 16B. Code of Ethics**

We have adopted a Code of Conduct applicable that applies to all employees, directors and officers of our company, including our principal executive officer, principal financial officer, principal accounting officer or controller and other individuals performing similar functions. A copy of our Code of Conduct can be found on our website ([www.xtlbio.com](http://www.xtlbio.com)) and may also be obtained, without charge, upon a written request addressed to our investor relations department, XTL Biopharmaceuticals Ltd., PO Box 4033, Herzliya 46140, Israel.

**Item 16C. Principal Accountant Fees and Services****Policy on Pre-Approval of Audit and Non-Audit Services of Independent Auditors**

Our audit committee is responsible for the oversight of the independent auditors' work. The audit committee's policy is to pre-approve all audit and non-audit services provided by our independent auditors, Kesselman & Kesselman, a member of PricewaterhouseCoopers International Ltd. ("PWC"). These services may include audit services, audit-related services and tax services, as further described below.

**Principal Accountant Fees and Services**

We were billed the following fees for professional services rendered by PWC, for the years ended December 31, 2011 and 2010.

	2011	2010
	(in thousands US\$)	
Audit fees	51	60
Audit-related fees	-	-
Tax fees	-	-
All Other fees	4	12
Total	55	72

The audit fees for the years ended December 31, 2011 and 2010, respectively, were for professional services rendered for the audit of our annual consolidated financial statements, review of interim consolidated financial statements and statutory audits, including Israeli tax reports. Other fees for the year ended December 31, 2010 were for professional services rendered for the review of our Israeli prospectus.

For the fiscal year ended December 31, 2011 and 2010, all of our audit-related fees, tax fees and other fees were pre-approved by our audit committee.

**Item 16D. Exemptions from the Listing Standards for Audit Committees**

Not applicable.

**Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

Not applicable.

**ITEM 16F. cHANGE IN REGISTRANT’S REGISTERED ACCOUNTANT**

Not applicable.

**ITEM 16G. CORPORATE GOVERNANCE**

Not applicable. Our securities are not traded on a national securities exchange. Our ADRs are traded 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.”

PART III

**Item 17. Financial Statements**

We have elected to furnish financial statements and related information specified in Item 18.

**Item 18. Financial Statements**

See pages F-1 to F-60 of this Annual Report.

**Item 19. Exhibits**

The following exhibits are filed as part of this annual report:

Exhibit

Number Description

- 3.1 Articles of Association †
- 4.1 Form of Share Certificate (including both Hebrew and English translations). \*
- 4.2 Form of American Depositary Receipt (included in Exhibit 4.3). †  
Deposit Agreement, dated as of August 31, 2005, by and between XTL Biopharmaceuticals Ltd., The Bank of New York, as Depositary, and each holder and beneficial owner of American Depositary Receipts issued thereunder. †
- 4.3 of New York, as Depositary, and each holder and beneficial owner of American Depositary Receipts issued thereunder. †
- 4.5 Form of Director and Senior Management Lock-up Letter.
- 10.16 2001 Share Option Plan dated February 28, 2001. †
- 10.17 Letter of Understanding, dated August 5, 2005, relating to the License Agreement dated June 2, 2004 between Cubist Pharmaceuticals, Inc. and XTL Biopharmaceuticals Ltd. †
- 10.26 License Agreement Between XTL Biopharmaceuticals Ltd. and VivoQuest, Inc., dated August 17, 2005 †
- 10.27 Asset Purchase Agreement Between XTL Biopharmaceuticals Ltd. and VivoQuest, Inc., dated August 17, 2005 †
- 10.28 Securities Purchase Agreement, dated March 17, 2006, by and among XTL Biopharmaceuticals Ltd., and the purchasers named therein. #
- 10.29 Registration Rights Agreement, dated March 22, 2006, by and among XTL Biopharmaceuticals Ltd. and the purchasers named therein. #

- 10.30 Form of Ordinary Share Purchase Warrants, dated March 22, 2006, issued to the purchasers under the Securities Purchase Agreement. ^
- 10.32 License Agreement between XTL Development, Inc. and DOV Pharmaceutical, Inc., dated January 15, 2007. \*
- 10.34 Securities Purchase Agreement, dated October 25, 2007, by and among XTL Biopharmaceuticals Ltd., and the purchasers named therein. #
- 10.35 Registration Rights Agreement, dated October 25, 2007, by and among XTL Biopharmaceuticals Ltd. and the purchasers named therein. #
- 10.36 License Agreement By and Between XTL Biopharmaceuticals Ltd. and Presidio Pharmaceuticals, Inc. dated March 19, 2008. #
- 10.37 Amended and Restated License Agreement By and Between XTL Biopharmaceuticals Ltd. and Presidio Pharmaceuticals, Inc. dated August 4, 2008. &>
- 10.38 Services Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., Quoque Bioventures LLC and Antecip Bioventures LLC. +

- 10.39 Stock Appreciation Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Quoque Bioventures LLC. +
- 10.40 Registration Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Quoque Bioventures LLC. +
- 10.41 Stock Appreciation Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Antecip Bioventures LLC. +
- 10.42 Registration Rights Agreement, dated as of October 15, 2008, by and among XTL Biopharmaceuticals Ltd., XTL Development Inc., and Quoque Bioventures LLC. +
- 10.43 Asset Purchase Agreement, dated as of March 18, 2009 between XTL Biopharmaceuticals Ltd. and Bio-Gal Ltd. &, >
- 10.44 Research and License Agreement Between Yeda Research and Development Company Ltd., Mor Research Applications Ltd., Biogal Ltd. (under its previous name Haverfield Ltd.) and Biogal Advanced Biotechnology Ltd. dated January 7, 2002. &, >
- 10.45 Amendment to Research and License Agreement Between Yeda Research and Development Company Ltd., Mor Research Applications Ltd., Haverfield Ltd. and Biogal Advanced Biotechnology Ltd. effective as of April 1, 2008. &, >
- 10.46 Amended Bio-Gal Agreement, entered into December 31, 2009. @
- 10.47 Share Transfer Agreement, entered into December 31, 2009. @
- 10.48 Termination to Bicifadine License, dated March 2010. @
- 10.49 Employment Agreement, dated as of January 18, 2010, between XTL Biopharmaceuticals Ltd. and David Grossman. @
- 10.50 Employment Agreement, dated as of July 29, 2009, between XTL Biopharmaceuticals Ltd. and Ronen Twito. @
- 10.51 Consulting Agreement, dated as of August 27, 2010, between XTL Biopharmaceuticals Ltd. and Moshe Mittelman. ~
- 10.52 Option to License Agreement, dated as of September 1, 2010, between XTL Biopharmaceuticals Ltd. and Yeda Research and Development Company Limited. ~
- 10.53 License Agreement, dated as of November 30, 2011, between XTL Biopharmaceuticals Ltd. and MinoGuard Ltd. >
- 21.1 List of Subsidiaries
- 23.1 Consent of Kesselman & Kesselman, a member of PricewaterhouseCoopers International Ltd, dated March 29, 2012.
- 23.2 Consent of BDO Ziv Haft Consulting and Management Ltd, dated March 29, 2012.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 29, 2012.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 29, 2012.
- 32.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 29, 2012

† Incorporated by reference from the registration statement on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on July 14, 2005, as it may be amended or restated.

^ Incorporated by reference from the registration statement on Form F-1 filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on April 20, 2006, as it may be amended or restated.

\* Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007.

# Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 27, 2008.

+ Incorporated by reference from the current annual report on Form 6-K filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on October 24, 2008.

& Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on April 6, 2009.

@ Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on June 30, 2010.

~ Incorporated by reference from the annual report on Form 20-F filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on May 30, 2011.

> Confidential treatment has been requested with respect to the omitted portions of this exhibit.



**SIGNATURES**

The registrant hereby certifies that it meets all the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this registration statement on its behalf.

XTL BIOPHARMACEUTICALS  
LTD.  
*(Registrant)*

Signature: /s/ David Grossman  
David Grossman  
Chief Executive Officer

Date: March 29, 2012

**XTL BIOPHARMACEUTICALS LTD.**

**CONSOLIDATED FINANCIAL STATEMENTS**

**AS OF DECEMBER 31, 2011**

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**AUDITORS' REPORT TO SHAREHOLDERS OF XTL BIOPHARMACEUTICALS LTD.  
ON AUDITING COMPONENTS OF INTERNAL CONTROL OVER FINANCIAL REPORTING**

**Pursuant to Section 9b(c) to the Israel Securities Regulations**

**(Periodic and Immediate Reports), 1970**

We have audited components of internal control over financial reporting of XTL Biopharmaceuticals Ltd. (hereinafter - the Company), and its subsidiary as of December 31, 2011. These components of internal control were set as explained in the next paragraph. The Company's Board of Directors and Management are responsible for maintaining effective internal control over financial reporting and for assessing the effectiveness of components of internal control over financial reporting included in the accompanying interim financial information for the above date. Our responsibility is to express an opinion on the components of internal control over financial reporting based on our audit.

Components of internal control over financial reporting were audited by us according to Audit Standard no. 104 of the Institute of Certified Public Accountants in Israel "Audit of the Internal Control Components over Financial Reporting" (hereafter - "Audit Standard 104"). These components are: (1) entity level controls, including controls over the preparation process and closing of the financial reporting and general controls over information systems, (2) controls over the Equity and share based payment process (3) controls over the Intangible asset valuation and impairment process (all of which hereinafter "Audited control components").

We conducted our audits in accordance with Audit Standard 104. This standard requires that we plan and perform the audit to identify the audited control components and to obtain reasonable assurance whether these control components have been maintained effectively in all material respects. The audit includes obtaining an understanding of the internal control over financial reporting, identifying the audited control components, assessing the risk that a material weakness exists in the audited control components, as well as review and assessment of effective planning and maintaining of these audited control components based on the estimated risk. Our audit, relating to those audited control components, also included performing such other procedures as we considered necessary under the circumstances. Our audit referred only to the audited control components, unlike internal control of all material processes over financial reporting, and therefore our opinion refers only to the audited control components. In addition, our audit did not take into account the mutual influences between the audited control components and those which are not audited, and therefore our opinion does not take into account such possible effects. We believe that our audit provides a reasonable basis for our opinion in the context described above.

Due to inherent limitations, internal control over financial reporting in general and components of internal controls in particular, may not prevent or detect a misstatement. Also, making projections on the basis of any evaluation of effectiveness is subject to the risk that controls may become inadequate because of changes in circumstances, or that the degree of compliance with the policies or procedures may be adversely affected.

In our opinion, the Company effectively maintained, in all material respects, the audited control components as of December 31, 2011.

We also audited the Company's consolidated financial statements as of December 31, 2011 and 2010 and for each of the three years in the period ended December 31, 2011, in accordance with auditing standards generally accepted in Israel, and our report, dated March 29, 2012 included an unqualified opinion on those financial statements.

Tel-Aviv, Israel Kesselman & Kesselman

March 29, 2012 Certified Public Accountants (Isr.)

A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 68125, Israel, P.O Box 452 Tel-Aviv 61003  
Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.co.il

## **REPORT OF THE AUDITORS**

To the shareholders of

### **XTL BIOPHARMACEUTICALS LTD.**

We have audited the consolidated Statements of Financial Position of XTL Biopharmaceuticals Ltd. (hereafter - the "Company") and its subsidiaries as of December 31, 2011 and 2010, and the related consolidated statements of Comprehensive Income (Loss), changes in equity and cash flows for each of the three years ended December 31, 2011. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in Israel, including those prescribed by the Israeli Auditors Regulations (Mode of Performance), 1973, and in accordance with the standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by the Company's Board of Directors and management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, based upon our audits, the consolidated financial statements referred to above ,present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of December 31, 2011 and 2010, and the consolidated comprehensive income (loss), changes in equity and cash flows for each of the three years ended December 31, 2011, in conformity with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB") and Israeli Securities Regulations (Preparation of Annual Financial Statements), 2010.

We have audited, according to Audit Standard No. 104 "Audit of components of internal control over financial reporting" published by the Israeli Institute of Certified Public Accountants, components of the internal controls over financial reporting of the Company as of December 31, 2011 and our report dated March 29, 2012 included an unqualified opinion on the effective existence of those components.

Tel-Aviv, Israel Kesselman & Kesselman

March 29, 2012 Certified Public Accountants (Isr.)

A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 68125, Israel, P.O Box 452 Tel-Aviv 61003  
Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.co.il

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## CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

		December 31,	
		2011	2010
	Note	U.S. dollars in thousands	
<b>ASSETS</b>			
<b>CURRENT ASSETS:</b>			
Cash and cash equivalents	5	123	1,066
Short-term deposits	6	1,372	-
Accounts receivable	7	68	110
Restricted deposits		21	46
		1,584	1,222
<b>NON-CURRENT ASSETS:</b>			
Property, plant and equipment	9	32	35
Intangible assets	10	2,457	2,540
		2,489	2,575
<u>Total</u> assets		4,073	3,797
<b>LIABILITIES AND EQUITY</b>			
<b>CURRENT LIABILITIES:</b>			
Trade payables	11	88	203
Other accounts payable	12	541	760
		629	963
<b>EQUITY ATTRIBUTABLE TO EQUITY HOLDERS OF THE COMPANY:</b>			
Ordinary share capital	16	5,335	4,993
Share premium and options		141,385	139,983
Accumulated deficit		(143,276 )	(142,142 )
<u>Total</u> equity		3,444	2,834
<u>Total</u> liabilities and equity		4,073	3,797

The accompanying notes are an integral part of the consolidated financial statements.

Amit Yonay                      David Grossman    Ronen Twito  
Chairman of the Board    Director and CEO    CFO

Date of approval of the financial statements by the Company's Board: March 29, 2012

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## CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

	Note	Year ended December 31, 2011    2010    2009 U.S. dollars in thousands (except per share data)		
Research and development expenses	17	158	64	-
General and administrative expenses	18	1,078	1,222	*) (2,429)
Other gains, net	19	12	30	139
Operating income (loss)		(1,224)	(1,256)	2,568
Finance income	20	24	6	6
Finance expenses	20	7	7	10
Finance income (expenses), net		17	(1)	(4)
Income (loss) before taxes on income		(1,207)	(1,257)	2,564
Tax benefit	21	-	-	23
Net income (loss) and comprehensive income (loss) for the year attributable to equity holders of the Company		(1,207)	(1,257)	2,587
Basic and diluted earnings (loss) per share (in U.S. dollars)	22	(0.006)	(0.011)	0.044

\*) Include reduced expenses which result from forfeiture of share options that were contingent on the performance of the former chairman and former CEO, see also Note 16b.

The accompanying notes are an integral part of the consolidated financial statements.

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

	Year ended December 31, 2011				
	Capital attributable to the shareholders of the parent company				
		Share			
	Note	Share capital	premium and options	Accumulated deficit	Total
	U.S. dollars in thousands				
Balance at January 1, 2011		4,993	139,983	(142,142 )	2,834
Comprehensive loss for the year		-	-	(1,207 )	(1,207 )
Issue of shares and warrants	16	342	1,399	-	1,741
Share-based payment to employees and others	16	-	-	73	73
Exercise of warrants	16	*) -	3	-	3
Balance at December 31, 2011		5,335	141,385	(143,276 )	3,444

	Year ended December 31, 2010				
	Capital attributable to the shareholders of the parent company				
		Share			
	Note	Share Capital	premium and options	Accumulated deficit	Total
	U.S. dollars in thousands				
Balance at January 1, 2010		1,445	139,786	(141,224 )	7
Comprehensive loss for the year		-	-	(1,257 )	(1,257 )
Issue of shares	16	3,545	193	-	3,738
Share-based payment to employees and others	16	-	-	339	339
Exercise of share options	16	3	4	-	7
Balance at December 31, 2010		4,993	139,983	(142,142 )	2,834

\*) Represents less than \$ 1 thousand.

The accompanying notes are an integral part of the consolidated financial statements.

**CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY**

	Year ended December 31, 2009				
	Capital attributable to the shareholders of the parent company				
		Share	Share	Accumulated	Total
		Capital	premium and options	deficit	
	Note	U.S. dollars in thousands			
Balance at January 1, 2009		1,445	139,786	(139,757 )	1,474
Comprehensive income for the year	16	-	-	2,587	2,587
Share-based payment to employees and others		-	-	(4,180 )	(4,180 )
Transfer to equity for liability for share appreciation rights	14	-	-	126	126
Balance at December 31, 2009		1,445	139,786	(141,224 )	7

The accompanying notes are an integral part of the consolidated financial statements.

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## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2011	2010	2009
	Note U.S. dollars in thousands		
Cash flows from operating activities:			
Net income (loss) for the year	(1,207)	(1,257)	2,587
Adjustments to reconcile net income (loss) to net cash used in operating activities (a)	(105 )	522	(5,075)
Net cash used in operating activities	(1,312)	(735 )	(2,488)
Cash flows from investing activities:			
Decrease (increase) in restricted deposit	25	(6 )	31
Increase in short-term bank deposits	(1,377)	-	-
Purchase of property, plant and equipment	9 (12 )	(16 )	-
Other investments	(8 )	(81 )	(55 )
Net cash used in investing activities	(1,372)	(103 )	(24 )
Cash flows from financing activities:			
Issue of shares in Bio-Gal transaction	1a -	1,473	-
Proceeds from issue of shares and warrants	16 1,741	-	-
Exercise of share options	16 3	7	-
Net cash provided by financing activities	1,744	1,480	-
Increase (decrease) in cash and cash equivalents	(940 )	642	(2,512)
Gains (losses) from exchange differences on cash and cash equivalents	(3 )	12	-
Cash and cash equivalents at beginning of year	1,066	412	2,924
Cash and cash equivalents at end of year	123	1,066	412

The accompanying notes are an integral part of the consolidated financial statements.

## CONSOLIDATED STATEMENT OF CASH FLOWS

		Year ended December 31,		
		2011	2010	2009
(a)	Note	U.S. dollars in thousands		
Adjustments to reconcile net income (loss) to net cash used in operating activities:				
Income and expenses not involving cash flows:				
Depreciation and amortization	9, 10	94	42	13
Loss from disposal of property, plant and equipment	19	3	-	5
Share-based payment transactions to employees and others	16	73	219	(4,180 )
Finance expenses on short-term deposits		5	-	-
Gains from exchange differences on operating activities		3	(12 )	-
Change in retirement benefit obligation, net		-	-	(435 )
Change in liability for share appreciation rights	14	-	-	119
		178	249	(4,478 )
Changes in operating asset and liability items:				
Decrease (increase) in accounts receivable and income taxes receivable	7	42	(5 )	249
Increase (decrease) in trade payables	11	(109 )	5	(304 )
Increase (decrease) in other accounts payable	12	(216 )	273	(542 )
		(283 )	273	(597 )
		(105 )	522	(5,075 )

The accompanying notes are an integral part of the consolidated financial statements.

## CONSOLIDATED STATEMENT OF CASH FLOWS

	Year ended December 31,		
	2011	2010	2009
	U.S. dollars in thousands		
(b) Additional information on cash flows from operating activities:			
Interest received	11	2	3
Interest paid	-	-	-
Refund of taxes on income	-	72	-
Payment of taxes on income	-	-	-
(c) Non-cash transactions:			
Deferred charges in connection with the Bio-Gal transaction which were recorded in "intangible assets" and "other investments"	-	40	80
Purchase of an intangible asset as consideration for the issuance of the Company's shares under the Bio-Gal transaction	-	2,265	-
Purchase of an exclusive right to examine a medical technology for a 15-month period against equity	-	120	-
Purchase of property, plant and equipment on suppliers' credit	-	6	-

The accompanying notes are an integral part of the consolidated financial statements.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

NOTE 1:- GENERAL

- a. A general description of the Company and its activity:

XTL Biopharmaceuticals Ltd. ("the Company") is engaged in the development of therapeutics, among others, for the treatment of unmet medical needs, improvement of existing medical treatment and business development in the medical realm. The Company was incorporated under the Israeli Companies Law on March 9, 1993. The registered office of the Company is located at Medinat Hayehudim 85 Street, Herzliya 46766. The Company owns 100% of Xtepo Ltd. ("Xtepo") and owns 100% of a U.S. company, XTL Biopharmaceuticals Inc. ("XTL Inc."), which was incorporated in 1999 under the laws of the State of Delaware.

As of the reporting date, the Company is in the planning and preparation stages for implementing a Phase 2 clinical trial of rHuEPO drug designed to treat multiple myeloma cancer patients (for additional details regarding the rHuEPO drug, see Note 10a below). As part of these 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 of rHuEPO drug. The Company's management and its advisors estimate that receipt of an approval to its commence is expected by the end of 2012.

On April 20, 2011, the Company has applied to the U.S. Food and Drug Administration (FDA), a sub-unit of the Health and Human Services (HHS) for orphan drug designation for its rHuEPO drug for the treatment of multiple myeloma blood cancer for which it owns a patent through 2019.

An "orphan drug" is defined as a drug for treating diseases that affect a small number of people. In U.S. an "orphan drug" is defined as a disease affecting fewer than 200,000 people a year. To encourage the development of drugs for these diseases, the different regulatory authorities grant benefits and incentives to developers. The main standard benefit of orphan drugs in the U.S. is receiving seven years marketing exclusivity from the date of approval by the FDA, as far as the FDA gives such approval. Other benefits are local U.S. tax breaks on research and development expenses and exemption from paying commissions to the FDA.

On May 29, 2011, the Company announced that it was granted an orphan drug designation from the FDA for its rHuEPO drug for the treatment of multiple myeloma blood cancer.

On March 24, 2011, the Company has entered into a term sheet to acquire the activity of MinoGuard Ltd. ("MinoGuard"), which was founded by Mor Research Applications Ltd. ("Mor"), by an exclusive license to use MinoGuard's entire technology, including the SAM-101 drug, MinoGuard's lead drug, which is based on a combination of existing anti-psychotic drugs and a recognized medicinal compound (minocycline), in return for royalties on sales and milestone payments throughout the clinical development process, without making any other payment.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

NOTE 1:- GENERAL (Cont.)

On November 30, 2011, after all the closing conditions had been met, MinoGuard transaction was completed (for additional details regarding the MinoGuard agreements, see Note 15a below).

On August 3, 2010, the Company completed a share exchange transaction with Bio-Gal shareholders ("the Bio-Gal transaction") under which the Company acquired 100% of the shares of Xtepo Ltd. which, for the purpose of the transaction, held a license for the exclusive use of the patent for rHuEPO drug for multiple myeloma and had an amount of approximately \$ 1.5 million in its account on the date of closing and this in return for the allocation of 133,063,688 Ordinary shares of the Company of NIS 0.1 par value each representing about 69.44% of the Company's issued and outstanding share capital after closing (for additional details regarding the Bio-Gal transaction, see Note 15a below).

Further, the Company has certain milestone rights in the development of treatment for hepatitis C ("DOS") from Presidio Pharmaceuticals Inc. ("Presidio "). Presidio is a U.S. biotechnology company (see Note 15a below).

The following are the Company's subsidiaries:

Xtepo - an Israeli privately-held company incorporated in November 2009 by the shareholders of Bio-Gal Ltd. for the execution of the Bio-Gal transaction and which holds a license for the exclusive use of the patent for rHuEPO drug for multiple myeloma.

XTL Inc. was engaged in development of therapeutics and business development in the medical realm. XTL Inc. has a wholly-owned subsidiary, XTL Development Inc. ("XTL Development"), which was incorporated in 2007 under the laws of the State of Delaware and was engaged in development of therapeutics for the treatment of diabetic neuropathic pain ("Bicifadine") until November 18, 2008, when the Company announced that the Phase 2b clinical trial of Bicifadine failed to meet its endpoints and, as a result, the development of the drug was ceased. In March 2010, the Company terminated the agreement with DOV Pharmaceutical Inc. ("DOV"), the owner of the Bicifadine patent, and all rights under the agreement were reverted to DOV in coordination with it.

As of the date of the approval of the financial statements, the companies XTL Inc. and XTL Development are inactive.

The Company and its subsidiaries ("the Group") operate in one business segment.

The Company is a public company traded on the Tel-Aviv Stock Exchange and its American Depository Receipts (ADRs) are quoted on the Pink Sheets.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

NOTE 1:- GENERAL (Cont.)

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 given the Company's current business plan, the cash and short term deposits together with the proceeds from the private placement and the exercise of warrants in March 2012, totaling approximately \$3.8 million (see note 24 below), 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 the Company to consume capital significantly faster than the management currently anticipation and the Company may need to spend more money than currently expected because of circumstances beyond its 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, in order to complete the clinical trials to bring a product to market 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.

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES

a. Basis of presentation of the financial statements:

The financial statements of the Group as of December 31, 2011 and 2010 and for each of the three years in the period ended December 31, 2011 have been prepared in accordance with International Financial Reporting Standards which are standards and interpretations issued by the International Accounting Standards Board ("IFRS") and include the additional disclosure required in accordance with the Israeli Securities Regulations (Annual Financial Statements), 2010.

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

The consolidated financial statements have been prepared under the historical cost convention.

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

2. The Group's operating cycle is 12 months.

3. The Group analyses the expenses recognized in the statement of comprehensive income by classification based on the function of expense.

b. Consolidated financial statements:

The consolidated financial statements comprise the financial statements of companies that are controlled by the Company (subsidiaries). The Company wholly owns all subsidiaries. Control exists when the Company has the power, directly or indirectly, to govern the financial and operating policies of an entity. The consolidation of the financial statements commences on the date on which control is obtained and ends when such control ceases.

Significant intragroup balances and transactions and gains or losses resulting from transactions between the Company and the subsidiaries are eliminated in full in the consolidated financial statements.

c. Foreign currency translation of transactions and balances:

1. Functional currency and presentation currency:

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ("the functional currency"). The consolidated financial statements are presented in U.S. dollars, which is the functional currency of each of the Group's entities and the Company's presentation currency.

Below are the changes in the reporting periods in the exchange rate of the U.S. dollar ("the dollar") in relation to the NIS:

Year ended	Change in the exchange rate of U.S. \$ 1 %
December 31, 2011	7.66
December 31, 2010	(5.99 )
December 31, 2009	(0.71 )

As of	Exchange rate of U.S. \$ 1 NIS
December 31, 2011	3.821
December 31, 2010	3.549

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)

2. Transactions and balances:

Transactions in a currency other than the functional currency ("foreign currency") are translated into the functional currency using the exchange rates at the dates of the transactions. After initial recognition, monetary assets and liabilities denominated in foreign currency are translated at the end of each reporting period into the functional currency at the exchange rate at that date. Exchange differences are recognized in the statement of comprehensive income in the line item finance income (expenses). Non-monetary assets and liabilities denominated in foreign currency and measured at cost are translated at the exchange rate at the date of the transaction.

d. Property, plant and equipment:

Items of property, plant and equipment are measured at cost with the addition of direct acquisition costs, less accumulated depreciation, less accumulated impairment losses and excluding day-to-day servicing expenses.

Depreciation of property, plant and equipment is calculated on a straight-line basis to reduce their cost to their residual value over their useful life as follows:

	%
Computers	33
Office furniture and equipment	6 - 15

Leasehold improvements are depreciated on a straight-line basis over the shorter of the lease term and the expected life of the improvement.

The useful life, depreciation method and residual value of an asset are reviewed at least each year-end and any changes are accounted for prospectively as a change in accounting estimate.

Depreciation of an asset ceases at the earlier of the date that the asset is classified as held for sale and the date that the asset is derecognized. An asset is derecognized on disposal or when no further economic benefits are expected from its use. The gain or loss arising from the derecognition of the asset (determined as the difference between the net disposal proceeds and the carrying amount in the financial statements) is included when the asset is derecognized in "other gains, net" in the consolidated statements of comprehensive income (loss).

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount (see f below).

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

e. Intangible assets:

*Research and development* - research expenditure is recognized as an expense when incurred. Costs arising from a development project are recognized as intangible assets when the following criteria are met:

- it is technically feasible to complete the intangible asset so that it will be available for use;
- management intends to complete the intangible asset and use or sell it;
- there is an ability to use or sell the intangible asset;
- it can be demonstrated how the intangible asset will generate probable future economic benefits;
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available; and
- the expenditure attributable to the intangible asset during its development can be reliably measured.

Other development expenditures that do not meet these criteria are recognized as an expense when incurred. During the reported period, the Group did not capitalize development costs to intangible assets.

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

*Amortized intangible assets* - an exclusive right to examine an acquired technology in the field of the immune system with a finite life of 15 months starting September 1, 2010 that was amortized on a straight-line basis over the useful life of this right. On November 30, 2011, the amortization of this right ceased.

f. Impairment of non-financial assets:

Depreciable assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less

costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets that suffered an impairment are reviewed for possible reversal of the impairment at each date of the statement of financial position.

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

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

g. Financial assets:

1. Classification:

The Group classifies its financial assets in the following categories: financial assets at fair value through profit or loss, loans and receivables, available-for-sale financial assets and held-to-maturity investments. The classification depends on the purpose for which the financial assets were acquired. The Group's management determines the classification of its financial assets at initial recognition.

a) Financial assets at fair value through profit or loss:

This category contains two sub-categories: financial assets held for trading purposes and financial assets at fair value through profit or loss. A financial asset is classified in this category if acquired principally for the purpose of selling in the short-term or if designated to this category by management. Derivative financial assets are also classified as held for trading unless they are designated as financial guarantee contracts or designated and effective hedges. Assets in this category are classified as current assets if it is probable that they will be disposed of within one year after the date of the statement of financial position. In the reporting periods, the Group did not hold financial assets at fair value through profit or loss.

b) Loans and receivables:

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for maturities greater than 12 months after the date of the statement of financial position. These maturities are classified as non-current assets. The Group's loans and receivables are included in the line items: "accounts receivable", "cash and cash equivalents", "short-term deposits" and "restricted deposits" on the face of the statement of financial position.

c) Available-for-sale financial assets:

Available-for-sale financial assets are non-derivatives that are either designated in this category or not classified in any of the other categories. They are included in non-current assets unless management intends to dispose the investment therein within 12 months after the date of the statement of financial position. In the reporting periods, the Group did not hold available-for-sale financial assets.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

d)Held-to-maturity investments:

Held-to-maturity investments are non-derivatives financial assets with fixed or determinable payments and fixed maturity that the Group's management has the positive intention and ability to hold to maturity. If the Group was to sell other than an insignificant amount of held-to-maturity financial assets, the whole category would be "tainted" and reclassified as available-for-sale. In the reporting periods, the Group did not hold investments that were classified to this category.

2. Recognition and measurement:

Regular purchases and sales of financial assets are recognized in the books of the Group companies on the trade-date which is the date on which the asset is transferred to the Group or transferred by the Group. Investments are initially recognized at fair value plus transaction costs for all financial assets not carried at fair value through profit or loss. Financial assets carried at fair value through profit or loss are initially recognized at fair value, and transaction costs are expensed in the statement of comprehensive income (loss). Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Group has transferred substantially all risks and rewards of ownership. Available-for-sale financial assets and financial assets at fair value through profit or loss are subsequently carried at fair value. Loans and receivables and held-to-maturity investments are subsequently carried at amortized cost using the effective interest method.

3. Offsetting financial instruments:

Financial assets and liabilities are offset and the net amount reported in the statement of financial position when there is a legally enforceable right to offset the recognized amounts and there is an intention to settle the financial assets and liabilities on a net basis or realize the asset and settle the liability simultaneously.

4. Impairment of financial assets:

*Financial assets carried at amortized cost:*

The Group assesses at the date of each statement of financial position whether there is objective evidence that a financial asset or group of financial assets is impaired. A financial asset or a group of financial assets is impaired and impairment losses are incurred only if there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset ("a loss event") and that loss event (or events) has an impact on the estimated future cash flows of the financial asset or group of financial assets that can be reliably estimated.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

h. Cash and cash equivalents:

Cash and cash equivalents include cash in hand, short-term bank deposits with original maturities of three months or less.

i. Share capital:

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

j. Trade payables:

Trade payables are the Group's obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if payment is due within one year or less. If not, they are presented as non-current liabilities.

Trade payables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

k. Taxes on income:

Taxes on income in the statement of comprehensive income (loss) comprise current and deferred taxes.

l. Current taxes:

The current tax liability is measured using the tax rates and tax laws that have been enacted or substantively enacted by the reporting date as well as adjustments required in connection with the tax liability in respect of prior years.

2. Deferred taxes:

Deferred taxes are computed in respect of temporary differences between the carrying amounts in the financial statements and the amounts attributed for tax purposes.

Deferred tax balances are measured at the tax rate that is expected to apply when the taxes are taken to the statement of comprehensive income (loss), to other comprehensive income or equity based on tax laws that have been enacted or substantively enacted by the reporting date. The amount for deferred taxes in the statement of comprehensive income (loss) represents the changes in said balances during the reported period, except for items attributable to other comprehensive income or equity.



**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

Deferred tax assets are reviewed at the end of each reporting period and reduced to the extent that it is not probable that they will be utilized. Also, temporary differences (such as carryforward losses) for which deferred tax assets have not been recognized are reassessed and deferred tax assets are recognized to the extent that their utilization has become probable. Any resulting reduction or recognition is recognized in the line item "taxes on income".

Taxes that would apply in the event of the sale of investments in investees have not been taken into account in computing the deferred taxes, as long as the sale of the investments in investees is not expected in the foreseeable future. Also, deferred taxes that would apply in the event of distribution of earnings by investees as dividend have not been taken into account in computing the deferred taxes, since the distribution of dividend does not involve an additional tax liability or since it is the Company's policy not to initiate distribution of dividend that triggers an additional tax liability.

Deferred tax assets and deferred tax liabilities are offset if there is a legally enforceable right to set off a current tax asset against a current tax liability and the deferred taxes relate to the same taxpayer and the same taxation authority.

Deferred tax asset has not been recognized in the Group's accounts because the availability of taxable income in the future is not probable.

1. Employee benefits:

1. Employment benefits for retirement compensation/pension:

Defined contribution plan is a post-employment employee benefit plan under which the Company pays fixed contributions into a separate and independent entity so that the Company has no legal or constructive obligation to pay

further contributions if the fund does not hold sufficient assets to pay all employees the benefits relating to employee service in the current and prior periods. A defined benefit plan is a post-employment employee benefit plan that is not a defined contribution plan.

The Company operates various pension plans. The plans are generally funded through payments to insurance companies or trustee-administered funds. Said pension plans qualify for the criteria of defined contribution plan, as above, based on their terms.

According to the labor laws and employment agreements in Israel and according to the Company's practice, the Company is obligated to pay compensation to employees who are dismissed and, under certain circumstances, to employees who retire. The Company's liability to pay compensation is accounted for as a defined contribution plan.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

As abovementioned, the Company buys insurance policies and makes payments to pension and compensation funds to fund its obligation under defined contribution plan. The Company has no further payment obligations once the contributions have been paid. The contributions are recognized as employee benefit expense and, correspondingly, the service which entails the contribution is rendered by the employees. Prepaid contributions are recognized as an asset to the extent that a cash refund or reduction in the future payments is available.

2. Paid annual leave and sick leave:

According to the Law, an employee is entitled to paid annual leave and sick leave on an annual basis. The entitlement is based on the number of years of service. The Company recognizes an obligation and expense for paid annual leave and sick leave based on the benefit accumulated for each employee.

m. Share-based payment:

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

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

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

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

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

Share-based payments for share appreciation rights with settlement alternative which were granted to the Group's service provider were accounted in the past as a cash-settled grant. The Company remeasured the value of the liability at each reporting date. On September 30, 2009, in accordance with IFRS 2 and after the Company's management examined the settlement issue, in furtherance to the Company's financial condition, the classification of the transaction was modified to an equity-settled transaction. The Company is not obligated to settle the transaction in cash.

Share-based payment transactions in which the Company acquired assets as consideration for the Company's equity instruments are measured at the value of the assets acquired (see Note 10b).

n. Leases:

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the statement of comprehensive income (loss) on a straight-line basis over the period of the lease.

o. Earnings (loss) per share:

Basic earning (loss) per share is calculated by dividing income or loss attributable to equity holders of the Company by the weighted average number of Ordinary shares outstanding during the period.

For the purpose of calculating diluted earnings or loss per share, the number of Ordinary shares shall be the average Ordinary shares calculated in basic earnings per share plus the weighted average number of shares that would be issued on the conversion of all the dilutive potential shares into shares. Potential Ordinary shares are taken into account as above only when their conversion is dilutive (decreases the earnings or increases the loss per share).

q. New and amended IFRS standards and IFRIC interpretations:

1. Standards and amendments to existing standards that have been issued and are effective for reporting periods after January 1, 2011:

Amendment to IFRS 7, "Financial Instruments: Disclosures". This amendment represents part of the improvements to IFRSs published in May 2010. This amendment changes part of the quantitative and qualitative disclosures required for the nature and extent of risks associated with financial assets and clarifies the interaction between these quantitative and qualitative disclosures. This amendment is applied for annual reporting periods beginning on or after January 1, 2011. The Group adopted this amendment on January 1, 2011 and its initial adoption had no material impact on the Group's financial statements.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

2. Standards and amendments and interpretations to existing standards that are not yet effective and have not been early adopted by the Group:

IFRS 9, "Financial Instruments" ("IFRS 9"). The first part of IFRS 9 which deals with classification and measurement of financial assets was published in November 2009 and the second part of IFRS 9 which includes guidance on financial liabilities and derecognition of financial instruments was published in October 2010. IFRS 9 replaces the parts of IAS 39, "Financial Instruments: Recognition and Measurement" ("IAS 39") that relate to the classification and measurement of financial instruments. IFRS 9 requires financial assets to be classified into one of the two following categories: financial assets measured after initial recognition at fair value and financial assets measured after initial recognition at amortized cost. The decision to which category a financial asset should be a)classified is made on initial recognition. This classification is driven by the model the entity manages its financial instruments (its business model) and the contractual characteristics of the cash flows from the instrument. For financial liabilities, IFRS 9 retains most of the IAS 39 requirements. The main change is that, in cases where an entity has a financial liability that is designated at fair value through profit or loss, the part of a change in fair value due to changes in the liability's credit risk (an entity's own credit risk) is recorded directly in other comprehensive income rather than the statement of income, unless this creates an accounting mismatch. There is not subsequent recycling of the amounts in other comprehensive income to profit or loss. But, accumulated gains or losses may be transferred within equity.

In December 2011, an amendment to IFRS 9 and to IFRS 7, "Financial Instruments: Disclosures" ("the amendment") was published. The amendment deferred the mandatory effective date of IFRS 9 and the transitional provisions upon implementation and added certain transition disclosure requirements ("the additional disclosures").

According to IFRS 9, after its amendment, as above, both parts of IFRS 9 will apply for annual periods beginning on or after January 1, 2015. Entities may elect to apply IFRS 9 early but it is not possible to apply the second part of IFRS 9 early without applying at the same time the first part of IFRS 9. However, the first part of IFRS may be applied earlier without being required to apply at the same time the second part of IFRS 9.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

Entities that adopt IFRS 9 for reporting periods:

1. Beginning before January 1, 2012 - are not required to restate prior periods upon or provide the additional disclosures upon initial adoption.
2. Beginning on or after January 1, 2012 and before January 1, 2013 - may elect to either restate its prior periods or provide the additional disclosures.
3. Beginning on or after January 1, 2013 - are not required to restate prior periods but are required to provide the additional disclosures.

The Group is assessing the possible impact of IFRS 9 on its financial statements and the timing of its implementation.

b) IFRS 10, "Consolidated Financial Statements" ("IFRS 10"). IFRS 10 replaces all the guidance on control and consolidation of financial statements in IAS 27, "Consolidated and Separate Financial Statements" ("IAS 27") and SIC-12, "Consolidation - Special Purpose Entities". IFRS 10 redefines "control". The new definition focuses on the requirement that control and variable returns should exist in order for control to exist. "Power" is the current ability to direct the activities which significantly affect the returns. IFRS 10 contains, inter-alia, guidance relating to differentiating between participating rights and protective rights as well as guidance relating to cases where an investor is acting on behalf of another party or on behalf of a group of parties (agent/principal relationships). The core principle that a consolidated entity presents a parent company and its subsidiaries as if they are a single entity remained unchanged as well as the mechanics of consolidation. IFRS 10 will be applied for annual periods beginning on or after January 1, 2013. Earlier application is permitted. If an entity elects to apply earlier, it shall disclose this fact and early apply IFRS 11, "Joint Arrangements" ("IFRS 11"), IFRS 12, "Disclosures of Interests in Other Entities" ("IFRS 12"), IAS 27 (Revised), "Separate Financial Statements" ("IAS 27R"), IAS 28 (Revised), "Associates and Joint Ventures" ("IAS 28R") simultaneously. The initial adoption of this amendment is not



expected to have a material impact on the Group's financial statements.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

IAS 28R - IAS 28R replaces IAS 28, "Investments in Associates" ("IAS 28") and the key changes contained therein compared to IAS 28 relate to adding explicit references to the application of the equity method when accounting for investments in joint ventures as a result of the new guidance prescribed by IFRS 11. IAS 28R will be applied for annual periods beginning on or after January 1, 2013. Earlier application is permitted. If an entity elects to apply earlier, it shall disclose this fact and early apply IFRS 10, IFRS 11, IFRS 12 and IAS 27R simultaneously. The Group is assessing the possible impact of IAS 28R on its financial statements and the timing of its implementation.

IFRS 13, "Fair Value Measurements" ("IFRS 13") - focuses on improving consistency and reducing complexity of fair value measurement by providing a precise definition of "fair value" and a single source of fair value measurement and disclosure requirements for use across IFRSs. The requirements of IFRS 13 do not extend the use of fair value accounting but provide guidance on how it should be applied where its use is already required or permitted by other standards within IFRSs. IFRS 13 will be applied for annual periods beginning on or after January 1, 2013. Earlier application is permitted while disclosing this fact. IFRS will be applied prospectively as of the beginning of the annual period in which it is initially applied. The disclosure requirements of IFRS 13 do not need to be applied in comparative information for periods before initial application of IFRS 13. The Group is assessing the possible impact of IFRS 12 on its financial statements and the timing of its implementation.

The amendment to IAS 32, "Offsetting Financial Assets and Financial Liabilities" ("the amendment to IAS 32") and the amendment to IFRS 7, "Disclosures: Offsetting Financial Assets and Financial Liabilities" ("the amendment to IFRS 7") were published in December 2011. The amendment to IAS 32 does not modify the existing model in IAS 32, "Financial Instruments: Presentation" regarding offsetting financial assets and financial liabilities ("offsetting") but clarifies that in order for the criteria of offsetting to exist in the financial statements it is required, inter alia, that the right of set-off must be available today namely, it should not be contingent on a future event and, in addition, it is required that the right of set-off will be legally enforceable in all of the following circumstances: in the normal course of business and in the event of default, insolvency or bankruptcy of the entity and all counterparties. The amendment to IAS 32 also clarifies the circumstances in which the right of set-off through gross settlement mechanism will meet the criteria of right to set-off by net settlement.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 2:- SIGNIFICANT ACCOUNTING POLICIES (Cont.)**

The amendment to IFRS 7 adds new disclosure requirements that focus on quantitative information about recognized financial instruments that are offset in the statement of financial position as well as recognized financial instruments that are subject to certain netting arrangements (irrespective of whether they are offset in the statement of financial position). The amendment to IAS 32 will be retrospectively applied for annual periods beginning on or after January 1, 2014. Earlier application is permitted. The amendment to IFRS 7 will be retrospectively applied for annual and interim periods beginning on or after January 1, 2013. The Group is assessing the possible impact of IFRS 12 on its financial statements and the timing of its implementation

**NOTE 3:- CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

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

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

a. Intangible assets - in determining the fair value of assets acquired in share-based payment transactions and in testing impairment of these research and development assets, the Company's management is to estimate, among others, the probable endpoints of trials conducted by the Company, the commercial technical feasibility of the development and the resulting economic benefits. Actual results and estimates to be made in the future may significantly differ from current estimates.

b. Share-based payments as well as share appreciation rights (see Note 2m) - in evaluating the fair value and the recognition method of share-based payment, the Company's management is to estimate, among others, different parameters included in the computation of the fair value of the options and the Company's results and the number of

options that will vest. Actual results and estimates to be made in the future may significantly differ from current estimates.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 4:- FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT**

a. Financial risk management:

1. Financial risk factors:

The Group's activities expose it to a variety of financial risks: market risks (including currency risk, fair value interest rate risk, cash flow interest rate risk and price risk), credit risk and liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance.

Risk management is carried out by the Group's management under policies approved by the Board. The Group's treasury identifies, evaluates and defines financial risks. The Board provides written principles for overall risk management, as well as written policies covering specific areas, such as foreign exchange risk, interest rate risk and investment of excess liquidity.

a) Market risk:

*Foreign exchange risk:*

The Group operates internationally and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to the NIS. Foreign exchange risk arises from assets and liabilities denominated in currency that is other than the functional currency.

The Group's management has set up a policy to require Group companies to manage their foreign exchange risk against their functional currency. The Group companies are required to hedge their entire foreign exchange risk exposure. To manage their foreign exchange risk arising from future commercial transactions and recognized assets and liabilities, the Group uses short-term deposits denominated in foreign currency. Foreign exchange risk arises when future commercial transactions or recognized assets or liabilities are measured and denominated in a currency that is not the entity's functional currency.

The Company treasury's risk management policy is to hold NIS-denominated cash and cash equivalents and short-term deposits in the amount of the anticipated NIS-denominated liabilities for nine to twelve consecutive months, from time to time, in line with the directives of the Company's Board.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 4:- FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (Cont.)**

As of December 31, 2011, if the Group's functional currency had weakened by 10% against the NIS with all other variables held constant, post-tax loss for the year would have been \$ 30 thousand lower (2010 - post-tax loss \$ 11 thousand higher and 2009 - post-tax income \$ 8 thousand lower), mainly as a result of exchange rate changes on translation of accounts receivable net and exchange rate changes on NIS-denominated cash and cash equivalents. Loss is more sensitive to movement in the exchange rate in relation to the NIS in 2011 than in 2010 mainly because of the increased amount of the NIS-denominated balances in the items cash, receivables and payables of the Group.

b) Credit risk:

Credit risk is managed on group basis. Credit risk arises from cash and cash equivalents, restricted bank deposits as well as outstanding receivables. For banks and financial institutions, only independently rated parties with a minimum rating of 'A' are accepted.

See Note 4b(2) for further disclosure on credit risk.

c) Liquidity risk:

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

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

As of December 31, 2011 and 2010, the maturity of the Group's financial liabilities is less than one year from each of the reporting dates.



**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 4:- FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (Cont.)**

2. Capital management:

The Group's objectives when managing capital are to endure the Group's ability to continue as a going concern in order to provide returns on investments for shareholders and benefits for other interested parties and to maintain an optimal capital structure to reduce the cost of capital.

In order to maintain or adjust the capital structure, the Group may take variety of measures such as issue new shares or sell assets to reduce liabilities (see also Note 1b).

b. Financial instruments:

1. Financial instruments by category:

As of December 31, 2011 and 2010, all financial assets were classified in the category loans and receivables. Likewise, all financial liabilities as of such dates were classified in the category other financial liabilities at amortized cost.

2. Credit quality of financial assets:

The credit quality of financial assets that are not impaired can be assessed by reference to external credit ratings (if available) or to historical information about counterparty default rates:

	December 31,	
	2011	2010
	U.S. dollars in thousands	
Cash at banks, short-term deposits and restricted deposits:		
AA+	275	354
AA	1,237	754
AA-	3	3
	1,515	1,111
Cash not in banks	1	1
	1,516	1,112

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 5:- CASH AND CASH EQUIVALENTS**

	December 31, 2011 2010 U.S. dollars in thousands	
Cash at bank and on hand	51	313
Bank deposits for periods of three months or less	72	753
	123	1,066

The currencies in which the cash and cash equivalents are denominated or linked to are:

	December 31, 2011 2010 U.S. dollars in thousands	
U.S. dollar	8	853
NIS (not linked to the Israeli CPI)	114	210
Other currencies	1	3
	123	1,066

The carrying amount of cash and cash equivalents is a reasonable approximation of the fair value because the effect of discounting is immaterial.

**NOTE 6:- SHORT-TERM DEPOSITS**

a. The currencies in which the short-term deposits are denominated:

	December 31,	
	2011	2010
	U.S. dollars	
	in thousands	
U.S. dollars	1,000	-
NIS (not linked to the Israeli CPI)	372	-
	1,372	-

b. The dollar-denominated deposits earn interest at the average annual rate of 1.25%. The NIS-denominated deposits earn annual interest at the average rate of 2.59%.

The carrying amount of short-term deposits is a reasonable approximation of the fair value because the effect of discounting is immaterial.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 7:- ACCOUNTS RECEIVABLE**

a. Composition:

	December 31, 2011 2010 U.S. dollars in thousands	
Government authorities	17	51
Prepaid expenses	43	57
Other receivables	8	2
	68	110

b. The carrying amount of accounts receivable which represent monetary items is denominated in NIS and amounts to \$ 25 thousand and \$ 53 thousand as of December 31, 2011 and 2010, respectively.

The carrying amount of accounts receivable is a reasonable approximation of the fair value because the effect of discounting is immaterial.

**NOTE 8:- ADDITIONAL INFORMATION ABOUT INVESTMENT IN SUBSIDIARIES**

Name and country of incorporation	Date	Equity interests and voting rights	Scope of investments (in \$ 000)	Dividends received or receivable
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Xtepo Ltd., incorporated in Israel	31.12.11	100	% \$ 3,867	-
	31.12.10	-	\$ 3,918	-
XTL Biopharmaceuticals Inc., incorporated in Delaware	31.12.11	100	% \$ (161 )	-
	31.12.10	100	% \$ (218 )	-

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 9:- PROPERTY, PLANT AND EQUIPMENT**

a. Composition of property, plant and equipment and accumulated depreciation, by major classes, and the movement therein in 2011 are:

	Cost				Accumulated depreciation				Depreciated cost	
	Opening	Additions	Disposals	Closing	Opening	Additions	Disposals	Closing	December 31, 2011	2010
	book	during	during	book	Book	during	during	book		
	amount	the	the	amount	amount	the	the	amount		
		year	year			year	year			
	U.S. dollars in thousands									
Office furniture and equipment	62	5	(18 )	49	33	4	(15 )	22	27	29
Computers	98	1	(18 )	81	92	2	(18 )	76	5	6
	160	6	(36 )	130	125	6	(33 )	98	32	35

Composition of property, plant and equipment and accumulated depreciation, by major classes, and the movement therein in 2010 are:

	Cost				Accumulated depreciation				Depreciated cost	
	Opening	Additions	Disposals	Closing	Opening	Additions	Disposals	Closing	December 31, 2010	2009
	book	during	during	book	Book	during	during	book		
	amount	the	the	amount	amount	the	the	amount		
		year	year			year	year			
	U.S. dollars in thousands									
Office furniture and equipment	46	16	-	62	30	3	-	33	29	16
Computers	92	6	-	98	85	7	-	92	6	7

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 9:- PROPERTY, PLANT AND EQUIPMENT (Cont.)**

Composition of property, plant and equipment and accumulated depreciation, by major classes, and the movement therein in 2009 are:

	Cost			Accumulated depreciation				Depreciated cost		
	Opening book amount	Additions during the year	Disposals during the year	Closing book amount	Opening book amount	Additions during the year	Disposals during the year	Closing book amount	December 31, 2009	2008
Office furniture and equipment	61	-	(15 )	46	38	3	(11 )	30	16	23
Computers	101	-	(9 )	92	83	10	(8 )	85	7	18
Leasehold improvements	141	-	(141 )	-	141	-	(141 )	-	-	-
	303	-	(165 )	138	262	13	(160 )	115	23	41

## b. Additional information:

In 2011, 2010 and 2009, depreciation of property, plant and equipment has been charged to general and administrative expenses.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 10:- INTANGIBLE ASSETS**

- a. As stated in Note 1a above, on August 3, 2010, the Bio-Gal transaction was completed.

Following the closing of the transaction, the Company recognized in its accounts an intangible asset representing the license for the exclusive use of the patent for rHuEPO drug for multiple myeloma as well as all the research data and accumulated know-how underlying the patent in a total of approximately \$ 2,265 thousand (excluding transaction costs of approximately \$ 187 thousand), based on its fair value as of the date of closing of the transaction according to an independent external valuation.

According to the guidance of IAS 38, this asset is not systematically amortized and the Company reviews the asset for impairment once a year or more frequently if indicators show that the asset may be impaired.

In December 2011, the Company tested for impairment with the assistance of an external valuer (BDO Ziv Haft Consulting and Management Ltd.) in accordance with the guidance of IAS 36. According to the valuation performed, there is no need to reduce the value of the asset in relation to its book value. Since there is no reference to similar transactions in which the fair value of the patent can be determined, the value of the patent was determined by the value in use on the basis of the discounted future cash flow method for the years 2012 to 2025. The discount period was determined on the basis of the schedules to perform the clinical trials in order to approve the drug for marketing and under the limitation of the years of patent and the orphan drug designation as above.

The key assumptions used in the valuation in measuring value in use as of December 31, 2011 are: life of Phase 2 and 3 clinical trials of 2.5 and 3.5 years, respectively, expected penetration levels of 10% in 2019 to 55% in 2025 out of an estimate of 45,000 new cases of multiple myeloma diagnosis each year, royalties at the rate of 12.5% and (pre-tax) discount rate of 25%.

- b. On September 1, 2010, the Company and Yeda Research and Development Co. Ltd. ("Yeda") entered into a license agreement of an exclusive right to examine a medical technology in the field of the immune system,

comprising 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, the Chron's disease, psoriasis and etc. Under the agreement, the Company purchased this exclusive right to examine the medical technology for a 15-month period ("the right") in consideration of \$ 120 thousand ("the option fee") payable by the Company in the following manner and at the earlier of (i) In the event of raising by a prospectus to the public more than \$ 2 million, the Company is obligated to settle the payment to Yeda 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 election and after obtaining Yeda's approval to the timing, in cash or by issuance of options with equivalent value.

The Company's option to purchase said technology expired on November 30, 2011 and the Company elected not to exercise the option.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 10:- INTANGIBLE ASSETS (Cont.)**

In the years ended December 31, 2011 and 2010, the Company recognized in its accounts amortization expenses of \$ 88 thousand and \$ 32 thousand, respectively relating to the right to examine a medical technology over the option period. These expenses were recorded in research and development expenses item.

c. On November 18, 2008, the Company received the results of Phase 2b clinical trial of Bicifadine for diabetic neuropathic pain which did not meet its endpoints and, therefore, the development activity of this drug was ceased.

In March 2010, the Company terminated the agreement with DOV from which the Bicifadine compound had been acquired, and all the rights under the agreement were reverted to DOV in coordination with it.

**NOTE 11:- TRADE PAYABLES**

a. Composition:

	December 31, 2011 2010 U.S. dollars in thousands	
Open accounts	83	183
Checks payable	5	20
	88	203

The carrying amount of trade payables is a reasonable approximation of their fair value because the effect of discounting is immaterial.

b. The carrying amount of trade payables is denominated in the following currencies:

	December 31, 2011 2010	
	U.S. dollars in thousands	
U.S. dollar	75	161
NIS (not linked to the Israeli CPI)	12	39
Others	1	3
	88	203

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 12:- OTHER ACCOUNTS PAYABLE**

a. Composition:

	December 31, 2011 2010 U.S. dollars in thousands	
Employees and payroll accruals	206	199
Accrued expenses	329	555
Other	6	6
	541	760

The carrying amount of other accounts payable is a reasonable approximation of their fair value because the effect of discounting is immaterial.

b. The carrying amount of other accounts payable is denominated in the following currencies:

	December 31, 2011 2010 U.S. dollars in thousands	
U.S. dollar	325	407
NIS (not linked to the Israeli CPI)	216	353

541 760

**NOTE 13:- RETIREMENT BENEFIT OBLIGATION**

a. According to the effective labor laws and employment agreements in Israel and overseas, the Company and the subsidiaries are obligated to pay compensation and/or pension to employees who are dismissed and, under certain circumstances, to employees who retire.

b. The Company's obligation for pension payment in Israel and the Company's obligation for compensation payments to employees in Israel for whom the applicable obligation is pursuant to section 14 to the Severance Pay Law, are covered by fixed contributions into defined contribution plans. The amounts contributed as above are not reflected in the statements of financial position. In 2011, section 14 to the Severance Pay Law applied to all of the Company's employees.

The amount recognized as an expense for defined contribution plans in 2011, 2010 and 2009 was \$ 22 thousand, \$ 22 thousand and \$ 23 thousand, respectively.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 13:- RETIREMENT BENEFIT OBLIGATION (Cont.)**

Since that as of December 31, 2011, section 14 to the Severance Pay Law applies to the Company's employees, as above, pursuant to which they are covered by fixed contributions into defined contribution plans, no contributions in defined benefit plans are expected for the year ending December 31, 2012.

**NOTE 14:- LIABILITY FOR SHARE APPRECIATION RIGHTS**

In January 2007, a subsidiary had committed to pay advisory fee to a third party in connection with the DOV transaction. In October 2008, in furtherance to the above commitment, the Company and the subsidiary entered into an agreement with the third party according to which advisory fee is structured in the form of stock appreciation rights in the amount equivalent to as follows:

- (i) 3% of the Company's fully diluted shares at the close of the transaction, representing 1,659,945 shares after the capital consolidation of June 2009 (see Note 16a(2)) exercisable one year after the close of the transaction;
- (ii) 7% of the Company's fully diluted shares at the close of the transaction, representing 3,873,204 shares after the capital consolidation of June 2009 vesting on the "date of milestone event."

Payment of the share appreciation rights can be satisfied, at the Company's election, in cash or by issuance of the Company's shares. Upon the exercise of share appreciation rights, the amount paid will be an amount equal to the amount by which the market value (the greater of the share price on the exercise date or the preceding five day average share price) exceeds the \$ 1.7. The share appreciation rights expire on January 15, 2017.

The share appreciation rights in the amount equivalent to 3% are vesting, as stated in 1 above, and presented in equity in accordance with IFRS 2; the share appreciation rights in the amount equivalent to 7%, as stated in 2 above, expired



in March 2010 with the termination of the Company's license agreement with DOV for the Bicifadine compound.

As stated in Note 2m, since September 30, 2009 the share appreciation right instrument is carried to equity.

The Company used a Black & Scholes model as the fair value pricing model for the share appreciation rights in all reporting periods through September 30, 2009. The following assumptions were used for the economic valuation of the share appreciation rights on September 30, 2009: standard deviation of: 124%; discount coefficient of 3.3%; expected dividend of 0% and expected remaining contractual life of 7.3 years.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 15:- COMMITMENTS AND CONTINGENT LIABILITIES**

a. Royalty and contingent milestone payments:

1. As stated in Note 1a above, on November 30, 2011, the Company completed the MinoGuard transaction according to which an exclusive license to the SAM-101 drug (combination drug to treat mental disorders focusing on schizophrenia) has been transferred to the Company. According to the terms of the agreement with MinoGuard, the Company will act to conduct clinical trials, develop, register, market, distribute and sell the drug candidates that will emerge from the technology, with no limitations to a specific disorder.

In return for the receipt of the license, as above, the Company will pay MinoGuard milestone payments throughout the research and development and the approval of the drug of an aggregate of approximately \$ 2.5 million. In addition, the Company will make royalty payments to MinoGuard of 3.5% on sales net of products derived from the license and/or a percentage of the Company's net income of any third-party sublicense in the range of 7.5% to 20% depending on the clinical phase of the drug at the time of the above out-license transaction.

In addition to the above payments, if the Company does not commence a Phase 2 clinical trial by June 30, 2013 (the agreement sets that receipt of an approval to commence such trial or continuance of the clinical trials that were conducted/will be conducted by MinoGuard and/or its researchers, shall be deemed commencement of Phase 2 clinical trial for this matter), the Company will then pay MinoGuard an annual license fee of \$ 45 thousand for the first payment and its cost will increase in \$ 90 thousand per year (should the trial not commence) up to \$ 675 thousand for the eighth year of license

The Company can pay any of the above amounts in cash or by issuance of shares to MinoGuard, at its sole discretion.

The licensed technology transferred to the Company is protected by a registered patent through 2027. If the Company does not commence a Phase 2 clinical trial (as described above) during 9.5 years from the date of the license agreement, the license will expire.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 15:- COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)**

2. On November 2, 2011, the Company entered into a term sheet by which it will acquire a technology ("NiCure" - "the technology") from Mor Research Applications Ltd., the Technology Transfer Office of Clalit Health Services, by obtaining an exclusive license to use the entire technology 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 technology and the approval of the Company's Board.

The technology mentioned above is based on the local administration of renin-angiotensin inhibitors (a known drug for the treatment of hypertension, "Enalaprilat") and is a novel treatment for the symptoms of cartilage-related diseases (such as Osteoarthritis). The therapy focuses on increasing or replenishing the level of glycoaminoglycans (GAGs) in the synovial fluid and cartilage, thereby relieving or even reversing symptoms of such diseases. Moreover, the same technology can be used to treat skin wrinkles.

According to estimates of the scientists who have invented this technology, the technology may enter a phase 2 clinical trial for the continuance of the clinical development based on this technology, as the drug mentioned above was approved for the treatment of reducing hypertension and is being provided to patients for already approximately 20 years.

As of the date of the approval of the financial statements, the transaction was not closed.

3. As stated in Note 1a above, on August 3, 2010, the Company closed the Bio-Gal transaction. According to this agreement, the Company is obligated to pay 1% royalties on net sales of the product and \$ 350 thousand upon the successful completion of a Phase 2 clinical trial. The payment conditions for the above amount are at the earlier of occurrence of the following events:

- (i) Raising at least \$ 2 million by the Company or Xtepo after a successful completion of a Phase 2 clinical trial;

(ii) Six months after the successful completion of a Phase 2 clinical trial.

4. In accordance with the terms of the license agreement with DOV, the subsidiary was obligated to pay milestone payments of up to \$ 126.5 million, in cash or its shares (at its election) over the life of the license, of which up to \$ 115 million will be due upon regulatory approval for the marketing of the Bicifadine compound. The subsidiary was also obligated to pay royalties to DOV on sales of Bicifadine.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 15:- COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)**

In November 2008, the Company announced that the Phase 2b clinical trial Bicifadine failed to meet its endpoints and, as a result, the Company ceased to develop the drug.

In March 2010, the Company terminated the agreement with DOV, in the issue of the Bicifadine candidate, and all rights under the agreement were reverted to DOV in coordination with it.

5. The subsidiary is committed to pay an advisory fee (in cash or by issuance of shares) to a third party in connection with the DOV transaction (see Note 14 above).

6. During September 2005, the Company acquired from VivoQuest patent rights and other assets (DOS program), covering a proprietary compound library, which includes hepatitis C compounds, laboratory equipment and employment agreements with research and development employees in consideration of approximately \$ 1,939 thousand (including transaction costs of \$ 148 thousand), of which an amount of \$ 1,391 thousand was paid by issuance of Ordinary shares of the Company. According to the agreement with VivoQuest, the Company is obligated to contingent milestone payments triggered by certain regulatory and sales targets, totaling as of the reporting date \$ 34 million, of which \$ 25 million due upon regulatory approval or actual product sales, and payable in cash or issuance of shares at the Company's election. No contingent consideration has been paid pursuant to the license agreement as of December 31, 2011 because none of the milestones have been achieved. The Company is also obligated to make royalty payments to VivoQuest on future product sales.

In March 2008 (and as revised in August 2008), the Company signed an agreement to out-license the DOS program to the U.S. Presidio in consideration of \$ 5.94 million payment in cash. Under this agreement, Presidio becomes responsible for all further development and commercialization activities relating to the DOS program. Presidio is also obligated to pay the Company up to \$ 59 million upon reaching certain milestones and royalty payments in the range of 1% to 10% on Presidio product sales. Presidio is also obligated to pay the Company for any milestone consideration owed to VivoQuest pursuant to the VivoQuest license agreement.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 15:- COMMITMENTS AND CONTINGENT LIABILITIES (Cont.)**

b. Operating lease commitments:

As of December 31, 2011, the Company leases three vehicles under an operating lease. The lease agreements expire in 2013-2014. Vehicle lease expense for the years ended December 31, 2011, 2010 and 2009 were \$ 32 thousand, 1. \$ 26 thousand and \$ 25 thousand, respectively. The lease fees are stated in NIS and are linked to the Israeli CPI. Expected lease fees for the years 2012, 2013 and 2014 under the lease fees as of December 31, 2011 are approximately \$ 32 thousand, \$ 30 thousand and \$ 7 thousand, respectively.

The Company entered into an operating lease agreement on the offices it uses. The agreement is in effect until August 2013 with a renewal option of additional 24 months. The lease fees are stated in NIS and are linked to the 2. Israeli CPI. To secure the lease, the Company provided a bank guarantee which is secured by a restricted NIS deposit of approximately \$ 21 thousand.

The expected lease fees and management fees for subsequent years under the prevailing lease fees as of December 31, 2011 are as follows:

	U.S. dollars in thousands
2012	90
2013 (through August 2013)	56

The Company entered into a sub-lease agreement on space in its offices for approximately \$ 35 thousand a year. The agreements are in effect until August-December 2012 with a renewal option of additional 12 months.



**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 16:- SHARE CAPITAL, RESERVES AND RETAINED EARNINGS**

a. Share capital:

1. Composition:

	Number of shares		Issued and outstanding		Amount		Issued and outstanding	
	Authorized		December 31,	December 31,	Authorized		December 31,	December 31,
	December 31,	2010	2011	2010	December 31,	2010	2011	2010
	Thousand				NIS in thousand			
Ordinary shares of NIS 0.1 *)	700,000	700,000	204,032	191,711	70,000	70,000	20,403	19,171

\*) Traded on the Tel-Aviv Stock Exchange. The share price was NIS 0.535 as of December 31, 2011.

2. Ordinary shares confer upon their holders voting rights and right to participate in the shareholders' meeting, right to receive earnings and the right to participate in the excess of assets upon liquidation of the Company.

On March 18, 2009, the extraordinary shareholders' meeting approved the following:

a) that the share capital of the Company be consolidated so that each 5 shares of NIS 0.02 par value shall be consolidated into one (1) share of NIS 0.1 par value.

b) that the authorized share capital of the Company be increased from NIS 10,000,000 par value divided into 100,000,000 Ordinary shares of NIS 0.1 par value to NIS 70,000,000 divided into 700,000,000 Ordinary shares of NIS 0.1 par value.

c)

that the ADR ratio be amended from one (1) ADR representing two (2) Ordinary shares of NIS 0.1 par value to one (1) ADR representing twenty (20) Ordinary shares of NIS 0.1 par value.

d) The consolidation of the Company's share capital triggered a change in the number of options granted before the capital consolidation and a corresponding change in exercise price.

On June 22, 2009, the share capital was consolidated and the authorized share capital of the Company was increased, as stated above. The change in the conversion ratio of ADR was not effected because the Board accepted a decision that such change is not required. On July 10, 2009, the SEC informed that the Company's ADRs were delisted from NASDAQ. The Company's ADRs continue to be quoted on the Pink Sheets.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 16:- SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

On August 3, 2010, upon the closing of the Bio-Gal transaction, 133,063,688 Ordinary shares of NIS 0.1 par value each were allocated to Xtepo's shareholders in return for 100% of the shares of Xtepo whom, before closing, held a license for the exclusive use of the patent for rHuEPO drug for multiple myeloma and approximately \$ 1.5 million in its account.

On March 7, 2011, the Company 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 a net immediate amount of approximately NIS 6.3 million (approximately \$ 1.75 million) net of issuance expenses of approximately \$ 68 thousand.

Warrants (series 1) are exercisable into one Ordinary share of NIS 0.1 par value from the date of registration for trade on the Stock Exchange (March 9, 2011) to November 27, 2011 an exercise price equal to NIS 0.7 per share, linked to the U.S. dollar. On July 21, 2011, a Company's warrant holder exercised 15,544 warrants (series 1) into 15,544 Ordinary share of NIS 0.1 par value each for the total exercise price of approximately \$ 3 thousand. The remaining warrants (series 1) expired on November 27, 2011.

Warrants (series 2) are exercisable into one Ordinary share of NIS 0.1 par value from the date of registration for trade on the Stock Exchange (March 9, 2011) to February 27, 2013 at an exercise price equal to NIS 1 per share, linked to the U.S. dollar (as of December 31, 2011, the exercise price was equal to approximately NIS 1.06 per share). As for the exercise of warrants (series 2) after the reporting period, see Note 24 below.

On March 22, 2011, 4,666,667 warrants (unregistered) which had been issued in 2006 under a private placement to American investors, expired.

After the reporting date, in March 2012, the Company issued through a private placement 11,560,362 Ordinary shares of the Company of NIS 0.1 par value each, 3,853,454 warrants (series A) and 1,926,727 warrants (series B). Further details on the private placement are given in Note 24 below.

b.

Share-based payment:

On August 29, 2011, the Company's Board approved the adoption of an employee share option plan for the grant of options exercisable into shares of the Company in accordance with section 102 to the Israeli Tax Ordinance ("2011 Plan") in lieu of the option plan established in 2011 ("2001 Plan") which has ended after 10 years and to maintain up to 10 million shares in the framework of the 2011 Plan, for options allocation to employees, directors and Company consultants.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 16:- SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

The 2011 Plan shall be subject to the directives determined for this purpose in section 102 to the Income Tax Ordinance. Under the capital track which was adopted by the Company and the abovementioned directives, the Company is not entitled to receive a tax deduction that relates to remuneration paid to employees, including amounts recorded as salary benefit in the Company's accounts for options granted to employees in the framework of the plan, except the yield benefit component, if available, that was determined on the grant date.

The terms of the options which will be granted according to the 2011 Plan, including option period, exercise price, vesting period and exercise period shall be determined by the Company's Board on the date of the actual allocation.

As of December 31, 2011, no share options were granted under the 2011 Plan. For details regarding grants after the reporting period, see Note 24 below.

Below is information about share-based payments granted to the Group's directors, employees and service providers during the reported years in accordance with section 102 to the Income Tax Ordinance based on the Company's plan from 2001 which was reconfirmed in 2003 and options granted without a plan in accordance with section 3i to the Income Tax Ordinance (all data presented herein reflect the capital consolidation of June 22 (see a above)):

In July 2009, the Company's Board approved to grant 1,400,000 share options (unlisted) to the Company's CFO to purchase 1,400,000 Ordinary shares of NIS 0.1 par value each at an exercise price equal to NIS 0.075 per share. The fair value of all share options using the Black-Scholes model on the date the Board accepted the decision was 1. approximately \$ 148 thousand. The option term is for a period of 120 months from the grant date, such that 33.33% of the share options are exercisable immediately and the remaining 66.67% share options are exercisable on a straight-line basis every month of the grant date over a three-year period.

The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 175%, risk-free interest rate of 3.85% and expected life of five years. The volatility is based on the historical volatility of the Company's share for comparative periods that commensurate with the expected term of the option.

Also, the Company has committed to supplement the difference between the par value of the share and the exercise price in this plan on the actual exercise date by allocating amounts from share premium to share capital.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 16:- SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

On January 18, 2010, the Company's Board approved to grant 450,000 share options to directors in the Company to purchase 450,000 Ordinary shares of NIS 0.1 par value each at an exercise price equal to NIS 0.298 per share. On March 2, 2010, the annual meeting of shareholders approved to grant options to the directors. Pursuant to the guidance of IFRS 2, the fair value of all share options on the date of approval by the annual meeting, using the Black-Scholes model was approximately \$ 36 thousand. The option term is for a period of 10 years from the grant date. 33% of the options are exercisable immediately and the remaining share options are exercisable in 24 tranches every month over a two-year period. On November 22, 2010, one of the optionees discontinued serving as a director and, accordingly, the 63,747 options granted to him have been forfeited.

The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 175%, risk-free interest rate of 3.9%-4.3% and expected life of five to six years.

On January 18, 2010, the Company's Board approved to grant 1,610,000 share options to the Company's CEO to purchase 1,610,000 Ordinary shares of NIS 0.1 par value each at an exercise price equal to NIS 0.075 per share. On March 2, 2010, the annual meeting of shareholders approved to grant options to the Company's CEO with approval of his employment terms, subject to the closing of Bio-Gal transaction (whose closing occurred on August 3, 2010). Pursuant to the guidance of IFRS 2, the fair value of all share options on the date of approval by the annual meeting, using the Black-Scholes model was approximately \$ 133 thousand. The option term is for a period of 10 years from the grant date. 33% of the options are exercisable immediately and the remaining options are exercisable in 24 tranches every month over a two-year period.

The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 175%, risk-free interest rate of 3.87%-4.11% and expected life of five to six years.

Also, the Company has committed to supplement the difference between the par value of the share and the exercise price in this plan on the actual exercise date by allocating amounts from share premium to share capital.

4. On January 26, 2010, the Company's Board approved to grant 100,000 share options to an employee in the Company to purchase 100,000 Ordinary shares of NIS 0.1 par value each at an exercise price equal to NIS 0.1 per

share. Pursuant to the guidance of IFRS 2, the fair value of all share options on the date the Board accepted the decision using the Black-Scholes model was approximately \$ 10 thousand. The option term is for a period of 10 years from the grant date. The options are exercisable in equal quarterly tranches over a three-year period.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 16:- SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 175%, risk-free interest rate of 4.3% and expected life of five to six years.

5. On August 27, 2010, the Company's Board approved the employment agreement of Professor Moshe Mittelman as an executive officer - Medical Director of the development plan of the rHuEPO drug designed to treat multiple myeloma. It also approved the allocation of 640,000 share options (unlisted) to purchase 640,000 Ordinary shares of NIS 0.1 par value each at an exercise price equal to NIS 0.1 per share. The fair value of all share options on the date the Board accepted the decision using the Black-Scholes model was approximately \$ 50 thousand. The option term is for a period of 10 years from the grant date. The options are exercisable in equal monthly tranches over a 24-month period.

Also, upon the commencement of a Phase 2 clinical trial (first-in-man), 50% of the unvested options (until the date of the commencement of the said trial) of Prof. Mittelman shall vest immediately. In addition, upon the termination by the Company (with no cause) of the Prof. Mittelman's employment agreement, 25% of Prof. Mittelman's unvested options (until the date of the said termination) shall vest immediately.

The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 160%, risk-free interest rate of 3.54%-3.68% and expected life of five to six years.

On June 1, 2011, the Company's Board approved to allocate to the Company's external consultant options that are exercisable into 120,000 Ordinary shares of the Company of NIS 0.1 par value each at an exercise price equal to 6.NIS 0.572 per share. According to the provisions of IFRS 2, the fair value of all options on the grant date using the Black-Scholes model was approximately \$ 19 thousand. The option term is for a period of 10 years from the grant date. The options are exercisable on a straight-line basis every month of the grant date over a 30-month period.

The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 155%, risk-free interest rate of 4.83% and expected life of 6.25 years.

Ordinary shares issued upon the exercise of options of all grants will have identical rights to Ordinary shares of the Company immediately after their allocation.

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 16:- SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

On March 18, 2009, at an extraordinary shareholders' meeting, new Board members were elected to the Company and the former Board members resigned. As a result of the above, 306,443 unvested options that were granted to the former directors in 2008 were forfeited. The remaining 659,224 vested options expired. Similarly, with the resignation of the Chairman on March 18, 2009, 616,667 options (with performance-related conditions) that were granted to him in December 2007 at an exercise price equal to \$ 1.8 per share expired. The remaining 1,233,333 unvested options (with performance-related conditions) granted to him in December 2007 at an exercise price equal to \$ 1.8 per share were forfeited. The effect of the forfeiture of these options for the year ended December 31, 2009 totaled approximately \$ 2.65 million and it was included as a deduction of general and administrative expenses in the statement of comprehensive income (loss).

In addition, 933,333 options (with performance-related conditions) of the Company's former CEO who resigned in April 2009 were forfeited. The effect of the forfeiture of these options totaled approximately \$ 1.45 million and it was included as a deduction of general and administrative expenses in the statement of comprehensive income (loss). Further, 466,667 options that were granted to him in March 2006 at an exercise price equal to \$ 3.85 per share expired.

Movements in the number of share options and their related weighted average exercise prices (in dollars) are as follows:

	Year ended December 31,				2009	
	2011	Weighted	2010	Weighted	2009	Weighted
	Number of	average	Number of	average	Number of	average
	options	exercise	options	exercise	options	exercise
		price		price		price
Outstanding at beginning of year	4,149,000	0.07	2,140,714	1.70	6,165,036	2.63
Granted	120,000	0.15	2,800,000	0.03	1,400,000	0.02
Exercised *)	-	-	(86,253 )	0.08	-	-
Expired	-	-	(641,714 )	5.32	(2,607,217)	2.18
Forfeited	-	-	(63,747 )	0.08	(2,817,105)	2.44

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Outstanding at end of year	4,269,000	0.07	4,149,000	0.07	2,140,714	1.70
Exercisable at end of year	3,692,725	0.08	2,352,611	0.10	1,338,121	2.65

\*) Total proceeds received from these exercises aggregated \$ 7 thousand in 2010.

The weighted average share price at the time of exercise was \$ 0.14 per share in 2010.

No shares were exercised in 2011 and 2009.

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 16:- SHARE CAPITAL, RESERVES AND RETAINED EARNINGS (Cont.)**

Options exercised in 2010 resulted in 86,253 shares being issued at \$ 0.08 for each option.

In May 2011, after 10 years, the above 2001 Plan has ended and, accordingly, since that date no new options can be granted under this plan. In August 2011, the 2011 Plan has been approved (see details above). As of December 31, 2011, the remaining number of options available for grant under the 2011 Plan is 10 million options (as for new grants under the 2011 Plan, see note on events after the reporting period).

Below is information about the exercise price (in dollars) and the remaining contractual life (in years) for options outstanding at end of year:

December 31, 2011			December 31, 2010		
Options outstanding at end of year	Range of exercise prices	Weighted average remaining contractual life	Options outstanding at end of year	Range of exercise prices	Weighted average remaining contractual life
4,170,000	0 - 0.500	8.0	4,050,000	0 - 0.500	9.0
-	0.500 - 1.499	-	-	0.500 - 1.499	-
60,000	1.500 - 2.499	6.0	60,000	1.500 - 2.499	7.0
39,000	2.500 - 3.495	0.1	39,000	2.500 - 3.495	1.1
4,269,000		7.9	4,149,000		8.9

Net expenses (income) recognized for grant of options to employees were \$ 73 thousand, \$ 219 thousand and \$ (4,180) thousand in the statements of comprehensive income (loss) for the years ended December 31, 2011, 2010 and 2009, respectively.

These plans are administered in accordance with the principles set forth in this issue in section 102 to the Income Tax Ordinance.

According to the track which was adopted by the Company (capital track) and these principles, the Company is not entitled to receive a tax deduction that relates to remuneration paid to its employees, including amounts recorded as salary benefit in the Company's accounts for options granted to employees in the framework of the plan, except the yield benefit component, if available, that was determined on the grant date.

As for share-based payment under the Yeda transaction, see Note 10b above.

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 17:- RESEARCH AND DEVELOPMENT EXPENSES**

	Year ended December 31, 2011 2010 2009 U.S. dollars in thousands		
Salaries and expenses relating to employees and service providers	26	4	-
Expenses relating to options to employees and service providers	20	19	-
Professional consulting	9	-	-
Depreciation and amortization	88	32	-
Other	15	9	-
	158	64	-

**NOTE 18:- GENERAL AND ADMINISTRATIVE EXPENSES**

	Year ended December 31, 2011 2010 2009 U.S. dollars in thousands		
Salaries and expenses relating to employees and service providers	421	355	428
Expenses relating to options to employees and service providers	53	200	*) (4,180 )
Patents and fees	25	50	14
Expenses relating to share appreciation rights	-	-	119
Directors' fees	63	85	98
Foreign services, public relation and travel	2	2	13
Rent and office maintenance	115	39	355
Vehicle maintenance	44	41	25
Insurance	57	84	198
Professional services	233	287	378
Depreciation and amortization	6	10	13
Other	59	69	110
	1,078	1,222	(2,429 )

\*) Include reduced expenses which result from forfeiture of shares that were contingent on the performance of the former chairman and CEO, see also Note 16b.

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 19:- OTHER GAINS, NET**

	Year ended December 31, 2011 2010 2009 U.S. dollars in thousands		
Loss from disposal of property, plant and equipment	(3 )	-	(5 )
Other	15	30	144
	12	30	139

**NOTE 20:- FINANCE EXPENSES (INCOME), NET**

	Year ended December 31, 2011 2010 2009 U.S. dollars in thousands		
Finance expenses:			
Interest charge	-	-	2
Management fees and commissions	7	7	8
Total finance expenses	7	7	10
Finance income:			
Interest income on bank deposits	24	2	3
Exchange differences	-	4	3
Total finance income	24	6	6
Finance income (expenses), net	17	(1 )	(4 )

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 21:- TAXES ON INCOME**

a. Taxation in Israel:

Since the 2008 tax year, the results for tax purposes of the Company and its Israeli subsidiary are measured in nominal values. Until the end of the 2007 tax year, the results for tax purposes of the Company were adjusted for the changes in the Israeli CPI pursuant to the Income Tax (Inflationary Adjustments) Law, 1985 ("the inflationary adjustments law"). According to the transition provisions of the scope of the inflationary adjustments law, it is determined that adjustments to the Israeli CPI relating to carryforward tax losses, deduction for depreciation and real loss from sale of a depreciable asset or security continue to apply until the end of the 2007 tax year and starting that date they will no longer apply.

2. Tax rates:

The income of the Company and its Israeli subsidiary is subject to corporate tax at the regular rate; the guidance of the amendment to the Income Tax Ordinance, 2005 from August 2005 prescribes a gradual reduction in the corporate tax rates and the resulting corporate tax rates starting 2009 are as follows: 2009 - 26%, 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 ("the 2009 amendment"), 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 Law for Tax Burden Reform (Legislative Amendments), 2011 was published in the records ("the 2011 amendment"), which prescribes a halt in the scheduled reduction in the corporate tax rate as in the 2009 amendment, as above, and an increase in the corporate tax rate to 25% in 2012 and thereafter.

Capital gains in the hands of the Company are taxable according to the corporate tax rate applicable in the tax year. However, tax at the rate of 26% in 2009, 25% in 2010 and 24% in 2011 applies on capital gains arising before January 1, 2003. Starting 2012, the tax rate applicable to all capital gains in the hands of the Company will be 25%.

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**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 21:- TAXES ON INCOME (Cont.)**

b. Foreign subsidiaries:

The subsidiaries whose place of incorporation is the U.S. are taxed according to the tax laws in their countries of residence. The principal tax rates applicable to subsidiaries, including the Federal tax in the country of registration, is 42%.

As a rule, intragroup transactions between the Company and the foreign subsidiaries are subject to the guidance and reporting of the Income Tax Regulations (Determination of Market Conditions), 2006.

c. Carryforward tax losses and real loss on sale of marketable securities:

Deferred tax assets for carryforward tax losses are recognized to the extent that the realization of the related tax benefit through future taxable income is probable.

As stated in Note 1a above, on August 3, 2010, the Bio-Gal transaction was completed after all the closing conditions had been met including, inter alia, the signing of an agreement with the Israeli Tax Authority regarding the tax exemption granted to the share exchange transaction pursuant to sections 104 and 103 to the Income tax Ordinance (New Version), 1961.

Below is the summary of principal conditions of the agreement signed with the Israeli Tax Authority:

The balance of the Company's business losses and capital losses for tax purposes was reduced to approximately NIS 80 million (approximately \$ 22 million) and approximately NIS 0.7 million (approximately \$ 0.19 million),<sup>1</sup> respectively. This item is not to derogate from the Tax Assessing Officer's authority to establish that the balance of losses is lower than the abovementioned amounts.

Any losses incurred to the Company prior to the share exchange, after their reduction as discussed in 1 above, will  
2. not be offset against any income originating from Xtepo (the transferred company) or against a capital gain from the sale of shares of Xtepo.

3. Xtepo shareholders will not be allowed to sell their shares in the Company for a period of two years from the end of the year of completion of the transaction ("the lock-up period"), subject to any changes in legislation.

4. The Company and Xtepo undertake to maintain their main economic activity as it was prior to the transaction during the lock-up period.

5. The Company will not be permitted to sell its holdings in Xtepo for the duration of the lock-up period.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 21:- TAXES ON INCOME (Cont.)**

It is indicated that the guidance to sections 104 and 103 to the Israeli Income Tax Ordinance which deal with restructuring and mergers impose statutory limitations and various conditions on the entities participating in the change in structure/merger during the lock-up period, inter alia, restrictions on dilution of holdings from raising by a prospectus or by private placements. The summary of the principal restrictions detailed above does not constitute a substitute to the overall articles.

On February 1, 2012, the Israeli Tax Authority published a position circular regarding the limitations in sections 103 and 104 according to which a relief is granted in the issue of the various limitations under the sections mentioned above during the lock-up period, inter alia, in instances of allocation of rights to "new" shareholders by private placements.

The Company's carryforward Israeli tax losses as of December 31, 2011 and 2010, after giving effect to the agreement with the Israeli Tax Authority in connection with the Bio-Gal transaction, as above, totaled approximately \$ 24 million for each of the years. The carryforward tax losses of the U.S. subsidiaries as of December 31, 2011 totaled approximately \$ 20 million (approximately \$ 15 million as of December 31, 2010). These losses of the U.S. subsidiaries are limited in use and they may be even significantly reduced due to state tax laws that deal in cases of "change of control" which is, among other, the outcome of the carrying out the Bio-Gal transaction as above. The Company does not recognize deferred taxes for tax losses because their utilization in the foreseeable future is not probable.

Carryforward capital losses on securities which were not offset (including carryforward losses on securities that were reversed after January 1, 2006) and other carryforward capital losses total approximately \$ 0.18 million as of December 31, 2011 after giving effect to the agreement with the Tax Authority in connection with the Bio-Gal transaction, as above. These losses may be used only against capital gains (including, since 2006, against gains on marketable securities).

A real loss for tax purposes from sale of securities through December 31, 2005 which was not offset by December 31, 2011 total approximately \$ 13 thousand. This loss is deductible in the coming years only against real gain on marketable securities, if available in these years.

The Company did not recognize deferred taxes for carryforward losses, as well as capital losses and real losses, because their utilization in the foreseeable future is not probable.

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 21:- TAXES ON INCOME (Cont.)**

d. Taxes on income included in the statements of comprehensive income (loss) for the years presented:

1. The Company did not record tax expenses or benefits in the years 2011 and 2010. In 2009, the Group recorded a tax benefit of \$ 23 thousand in respect of prior years.

2. Below is a reconciliation between the "theoretical" tax expense, assuming that all the income were taxed at the regular tax rate applicable to companies in Israel (see a(2) above) and the taxes recorded in the statement of comprehensive income in the reported year:

	Year ended December 31,		
	2011	2010	2009
	U.S. dollars in thousands		
Income (loss) before taxes on income, as reported in the statements of comprehensive income (loss)	(1,207)	(1,257)	2,564
Theoretical tax (tax saving) on this income (loss)	(290 )	(314 )	667
Increase (decrease) in taxes resulting from different tax rates for foreign subsidiaries	(3 )	(2 )	85
Expenses not deductible for tax purposes	18	55	2
Adjustments under the agreement with the Tax Authority in connection with the Bio-Gal transaction	-	35	-
Tax exempt income	-	-	(1,087)
Increase in taxes resulting mainly from taxable losses in the reported year for which no deferred taxes were recognized	275	226	333
Taxes in respect of prior year	-	-	(23 )
Tax benefit	-	-	(23 )

3. Since the balance of carryforward tax losses exceeds other temporary differences (net), and considering that the Company can not assess with certainty that it will have sufficient income in the future to allow the losses to be used in the foreseeable future due to the nature of the Company as a research and development company, in 2011, the Company did not record deferred taxes on these losses.



**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 21:- TAXES ON INCOME (Cont.)**

e. The effect of the adoption of IFRS in Israel on the tax liability:

Since January 1, 2009, the Company prepares its financial statements in accordance with IFRS.

IFRS differ from generally accepted accounting principles in Israel and, accordingly, the preparation of financial statements in accordance with IFRS could reflect a financial position, operating results and cash flows that differ significantly from those presented in accordance with Israeli GAAP.

According to the Amendment to the Income Tax Ordinance (No. 174 and Temporary Provision for the Tax Years 2007, 2008 and 2009), 2010 which was passed by the Knesset on January 25, 2010 and published in the records on February 4, 2010 and the Law for the Amendment to the Income Tax Ordinance (No. 188), 2012 which was passed by the Knesset on January 9, 2012 and published in the records on January 12, 2012 (both will be referred to as "temporary order"), Accounting Standard No. 29 of the Israel Accounting Standards Board does not apply to taxable income for the tax years 2007 to 2011 even if it was adopted in the financial statements for those years. The implication of the temporary order is that, practically, IFRS do not apply to the computation of income reported for tax purposes for the above tax years.

On October 31, 2011, a bill of the Law for the Amendment to the Income Tax Ordinance ("the bill") which derives from the adoption of IFRS in the financial statements was published. The bill, in general, adopts IFRS. However, the bill proposes several amendments to the Income Tax Ordinance which will clarify and determine the method for measuring taxable income in unclear cases where IFRSs does not comply with the principles of the Israeli tax method. Simultaneously, the bill adopts, as a rule, IFRS. Since the temporary order applies to the tax years 2007 to 2011, as above, the Company's management estimates that, currently, the new legislation will not take effect to tax years before 2012.

The Company's management computed its taxable income for the tax years 2009 to 2011 based on Israeli GAAP that existed before IFRS was adopted in Israel, subject to certain adjustments and, accordingly, the temporary order had no impact on the measurement of the current and deferred taxes in the financial statements.

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**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 21:- TAXES ON INCOME (Cont.)**

## f. Tax assessments:

The Company filed self assessments that are deemed final through tax year 2007. The subsidiary, Xtepo, has not received tax assessments since its incorporation in November 2009. The U.S. subsidiaries filed self assessments that are deemed final through tax year 2007. However, the IRS may examine the tax reports for the years in which the U.S. subsidiaries claimed tax refunds for operating losses offset against taxes paid in the past for tax years 2003 to 2005. This examination is limited to the amount of tax refunds that the Company received (\$ 72 thousand in 2003-2004 and \$ 77 thousand in 2005).

**NOTE 22:- EARNINGS PER SHARE**

## a. Basic:

Basic earnings (loss) per share is calculated by dividing income attributable to equity holders of the parent by the weighted average number of issued Ordinary shares including the retroactive consolidation of shares effected on June 22, 2009 (see also Note 16a above).

	Year ended December 31,		
	2011	2010	2009
Income (loss) attributable to equity holders of the parent (U.S. dollars in thousands)	(1,207 )	(1,257 )	2,587
Weighted average number of issued Ordinary shares	201,825,645	113,397,846	58,561,065
Basic earnings (loss) per share (in U.S. dollars)	(0.006 )	(0.011 )	0.044

**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 22:- EARNINGS PER SHARE (Cont.)**

## b. Diluted:

Diluted earnings per share is calculated by adjusting the weighted average number of Ordinary shares outstanding to assume conversion of all dilutive potential Ordinary shares. For the share options, a calculation is done to determine the number of shares that could have been acquired at fair value (determined as the average annual market price of the Company's shares) based on the monetary value of the terms attached to outstanding options. The number of shares calculated as above is compared with the number of shares that would have been issued assuming the exercise of the options.

	Year ended December 31,		
	2011	2010	2009
	U.S. dollars in thousands		
Total income (loss) for the year attributable to equity holders of the parent according to the statements of comprehensive income (loss) used to determine basic and diluted earnings (loss) per share	(1,207)	(1,257)	2,587

	Year ended December 31,		
	2011	2010	2009
	Number of shares		
Weighted average number of shares used to determine basic earnings (loss) per share	201,825,645	113,397,846	58,561,065
Adjustment for incremental shares due to exercise of share options	-	-	209,102
Weighted average number of shares used to determine diluted earnings (loss) per share	201,825,645	113,397,846	58,770,167
Diluted earnings (loss) per share (in U.S. dollars)	(0.006 )	(0.011 )	0.044

**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 23:- TRANSACTIONS AND BALANCES WITH RELATED PARTIES**

"Interested party" - as the term is defined in the Israeli Securities Regulations (Annual Financial Statements), 2010.

"Related party" - as the term is defined in IAS 24, "Related Party Disclosures" ("IAS 24").

The Company's key management personnel who are included, along with other factors, in the definition of related party, as above in IAS 24, includes directors and executive officers.

a. Compensation to interested parties:

	Year ended December 31, 2011 2010 2009 U.S. dollars in thousands		
Wages and salaries to interested parties employed by the Group *)	226	287	(1,219)
Number of individuals to whom the benefit relates	1	1	2
Compensation to directors not employed by the Group **)	66	112	(2,569)
Number of individuals to whom the benefit relates	4	5	12

\*) In 2009 includes expenses reduced by approximately \$ 1.45 million which result from forfeiture of share options that were contingent on the performance of the former CEO.

\*\*\*) In 2009 includes expenses reduced by approximately \$ 2.65 million which result from forfeiture of share options that were contingent on the performance of the former chairman.





**XTL BIOPHARMACEUTICALS LTD.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011****NOTE 23:- TRANSACTIONS AND BALANCES WITH RELATED PARTIES (Cont.)**

## b. Compensation to key management personnel:

The compensation to key management personnel for employee services provided to the Group is shown below:

	Year ended December 31, 2011 2010 2009 U.S. dollars in thousands		
Salaries, management and consulting fees and other short-term benefits	493	425	424
Post-employment benefits	-	-	76
Share-based payments	59	208	*(4,059)
	552	633	(3,559)

\*) Include reduced expenses which result from forfeiture of share options that were contingent on the performance of the former chairman and former CEO. See also Note 16b.

It should be noted that following completion of the private placement and exercise of warrants by shareholders after the date of the statement of financial position (see Note 24 Sections C and D), executive officers are eligible for grants totaling approximately \$80 thousand. These amounts will be recorded as an expense in 2012.

As of December 31, 2011 and 2010, balances with related parties total approximately \$ 246 thousand (of which \$ 159 thousand are linked to the NIS) and \$ 359 thousand (of which \$ 228 thousand are linked to the NIS), respectively.

**NOTE 24: EVENTS AFTER THE REPORTING PERIOD**

- a. On January 29, 2012, 39,000 options which had been issued in 1997 to a former service provider expired.

On March 14, 2012, the Company signed a strategic collaboration framework agreement with Clalit Health Services - Clalit Research Institute Ltd. ("the Institute") and Mor Research Applications Ltd. according to which the Institute provides the Company with the right to receive data which are based on the Institute's database in connection with technologies that stem from inventions and patents of Clalit Health Services' physicians, in projects whose content shall be agreed upon by the Company, the Institute and Mor in advance and in writing.

In consideration for the above, the Company shall pay the Institute the cost basis related to the Institute's activity in the framework of any project plus an additional 10% of the total royalties Mor is entitled pursuant to its agreements with the Company in connection with each technology where rights were granted to the Company.

**XTL BIOPHARMACEUTICALS LTD.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS AS OF DECEMBER 31, 2011**

**NOTE 24: EVENTS AFTER THE REPORTING PERIOD (Cont.)**

This agreement may be terminated by giving a written and advance notice of 180 days by any of the parties on condition that all joint active projects have reached their end.

As of the date of the approval of the financial statements, the Company has the rights to two technologies that were in-licensed from Mor, rHuEPO drug for the treatment of multiple myeloma cancer and SAM-101 drug for the treatment of psychotic patients.

In March 2012, a warrant holders of the Company exercised 4,795,000 warrants (series 2) into 4,795,000 Ordinary c. share of NIS 0.1 par value each at an exercise price equal to NIS 1.05 per share for the total of approximately \$ 1.35 million (approximately NIS 5.0 million).

d. On March 18, 2012, the Company's Board approved a private placement to institutional and private investors (foreign as well as Israeli) for the total of approximately \$ 2.4 million (approximately NIS 9.1 million). According to the private placement, the Company allocated 11,560,362 Ordinary shares of the Company of NIS 0.1 par value each, 3,853,454 warrants (series A) and 1,926,727 warrants (series B).

Warrants (series A) are exercisable into one Ordinary share of NIS 0.1 par value from the date of allocation (March 18, 2012) to September 17, 2013 at an exercise price equal to NIS 1.046 per share, linked to the U.S. dollar.

Warrants (series B) are exercisable into one Ordinary share of NIS 0.1 par value from the date of allocation (March 18, 2012) to March 17, 2015 at an exercise price equal to NIS 1.124 per share, linked to the U.S. dollar.

e. On March 19, 2012, the annual meeting of shareholders approved to grant 300,000 share options to external directors in the Company to purchase 300,000 Ordinary shares of NIS 0.1 par value each at an exercise price equal to NIS 0.58633 per share. Pursuant to the guidance of IFRS 2, the fair value of all share options on the date of approval by the annual meeting, using the Black-Scholes model was approximately \$ 79 thousand. The option term is for a period of 10 years from the grant date. 33% of the options are exercisable immediately and the remaining

share options are exercisable in 24 tranches every month over a two-year period.

The value of each option is based on the following inputs: expected dividend of 0%, expected standard deviation of 153%, risk-free interest rate of 4.08% and expected life of 6 years.

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**Strictly private and confidential**

XTL Biopharmaceuticals Ltd.

Impairment Study - As Of December 31, 2011

March, 2012

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BDO Ziv Haft

Amot Bituach House Building B, 48

Menachem Begin Road, Tel Aviv

66180

Israel

Dear Madams/Sirs,

We were requested by XTL Biopharmaceuticals Ltd. (Hereinafter: "**XTL**" or the "**Company**") to perform an Impairment Examination Study (Hereinafter: "**the Study**") of its Intangible asset (Hereinafter: the "**Intangible Asset**" or the "**IP**") as of December 31, 2011 (Hereinafter: the "**Valuation Date**") under the requirements of Statement of International Accounting standards 38 (IAS 38) and Statement of International Accounting standards 36 (IAS 36). To the best of our knowledge there is no prevention, legal or other, to perform the Study enclosed herein.

The Study was prepared for XTL and its management (Hereinafter: the "**Management**") for the purpose of reporting its financial statements as of December 31, 2011 and may be provided to their external auditors. Unless required by applicable law (for instance, reference to a performance of an impairment test and its implications in the financial statements), it is not to be used or quoted in a prospectus and/or any other document without receiving our prior written consent.

The principal sources of information used in performing our Study include:

- The Company's audited financial statements for the fiscal years ended, 2009 and 2010;
- The Company's unaudited financial statements for the period ended September 30, 2011;
- The Company's budget for 2012;
- The Company's Phase II budget, which was approved by the board of directors;
- Discussions with Management;

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- Additional data, which was delivered to us by Management; and

- Publicly available information (articles, websites).

In forming our opinion we have relied on sources, which appeared to us as reliable, and nothing came to our attention, which is likely to indicate the lack of reasonability of the data we used. We did not examine the data in an independent manner and, therefore, our work does not constitute verification of the correctness, completeness or accuracy of the data.

We performed number of analysis of the data that we had received from the Company, as described below:

- An analysis of the Company's potential revenues from the Intangible Asset;

- An analysis of the predicted expenses of the Company due to its Intangible Asset;

This report summarizes the findings of our Study. The accompanying report provides a detailed explanation of our analysis.

The valuation of companies and businesses is not a precise science and the conclusions arrived at in many cases will of necessity be subjective and dependent on the exercise of individual judgment. There is therefore no indisputable single value and we normally express our opinion on the value as falling within a likely range. However, as purpose requires the expression of a single value, we have adopted a value at the mid-point of our valuation range. Whilst we consider our value/range of values to be both reasonable and defensible based on the information available to us, others may place a different value on the business.



It is emphasized that we do not have any personal interest in the Company and our fee is not conditioned on the results of the opinion.

According to the assumptions detailed in this report, we have arrived to the conclusion that the Recoverable amount of the Intangible Asset is greater than its Carrying amount, as of valuation Date. Therefore, the Intangible Asset is not deemed to be impaired.

**Details regarding the valuation specialist**

BDO Consulting and Management Ltd. were founded by the partners of BDO Certified Public Accountants.

BDO Consulting and Management is part of the international BDO network, provides a full range of business services required for national and international businesses in any sector. Our company has vast experience in the following fields: business valuations, financial and tax due diligence, goodwill and intangible assets valuations, financial analyses, business plans, project finance PFI/PPP advisory, M&A, investment banking and more.

**Respectfully submitted,**

**BDO Ziv Haft**

**Consulting & Management Ltd.**

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Section 1

Company Overview

Section 1: Company Overview |XTL Biopharmaceuticals Ltd. |

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## Company Overview<sup>1</sup>

### General

XTL was incorporated in Israel on 9 March, 1993 as a private company in accordance with the Israeli Companies Law 1999 (Hereinafter: the "**Companies Law**"), under the name Xenograft Technologies Ltd. On 3 July 1995, the company has changed its name to its current name, with its defined objectives being the practice of any legal activity. As of today, the Company is engaged in the development, acquisition, sale, sub-license and business ventures in the medical realm and in therapeutics for the treatment of unmet medical needs as well as improvement of existing medical treatment.

In September 2000, the Company shares were listed on the main stock exchange London and the Company raised approximately \$ 50.9 million in a public offering. In August 2004, the Company raised \$ 17.8 million in another offering in the London Stock Exchange. Between that date and October 2007, the Company shares were listed on the main stock exchange in London. In October 2007, the Company was de-listed from the main stock exchange in London and its shares were no longer traded there.

In July 2005, the Company performed a dual listing of its shares on the Tel-Aviv Stock Exchange Ltd. (Hereinafter: "**TASE**"). Since that date and to the date of this report, the Company shares are listed on the TASE. Accordingly, since its' listing date on the TASE and until July 2009, the company reported in compliance with the provisions of the foreign law (by virtue of Chapter E3 of the Law).

<sup>1</sup> XTL BioPharmaceuticals Ltd.'s annual report for the fiscal year 2010 and for the period ended September 30, 2011 and the Company's reports which were published in the Tel-Aviv stock exchange's website on November 30, 2011 and August 29, 2011.

Section 1: Company Overview |XTL Biopharmaceuticals Ltd. |

## Company Overview<sup>1</sup>

### General

On September 1, 2005, the Company filed with the Securities & Exchange Commission in the United States (Hereinafter: the "SEC") an application to list the Company's American Depositary Receipts (Hereinafter: "ADR") on Nasdaq under the list known as Nasdaq Global Market. Beginning on that date and until 17 April 2009, the Company's ADRs were traded on Nasdaq.

In 2005, the Company acquired from VivoQuest Inc. (Hereinafter: "**VivoQuest**"), the exclusive worldwide and perpetual rights to VivoQuest's intangible assets, covering a compound library including certain compounds (Hereinafter: "**DOS**") for the treatment of hepatitis C and other assets. In the course of 2008, the Company out-licensed the use of the DOS technology to Presidio Pharmaceuticals Inc.

In July 2009, the Company shares were de-listed from Nasdaq due to a claim of the Nasdaq Audit Committee that the Company has failed to comply with some of the listing criteria. Shortly after, the Company's ADR began being quoted over the counter (OTC) on the Pink Sheets, and accordingly, from this date on, the Company reports in accordance with Chapter F of the Securities Law and simultaneously reports in compliance with the obligation to report in accordance with the U.S. Securities Exchange Act of 1934 regarding a foreign private issuer whose securities are held by the public. Since the de-listing of the company's ADR from Nasdaq, the company is no longer subject to Nasdaq.

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## Company Overview

### General

The Company holds 100% of the issued and paid-up share capital of the U.S company XTL Biopharmaceuticals Inc. (Hereinafter: "**XTL Inc.**"), which was founded in 1999 in accordance with the laws of the state of Delaware in the United States as well as 100% of XTEPO Ltd. (Hereinafter: "**XTEPO**"), which was founded in Israel in November 2009 as a part of the Bio Gal transaction.

Until the start of 2008, the Company was involved in the development of drugs primarily used to treat Hepatitis C and B. At the end of 2007, the Company ceased the research and development plans of these drugs (with the exception of development of DOS technology) and an agreement was signed with Yeda Research and Development Ltd. (the technology-transfer entity of the Weizmann Institute of Science) (Hereinafter: "**Yeda**") to revert all the rights to the company's original technologies.

XTL Inc. was involved in the development of activities and business pertaining pharmaceutical development. XTL Inc. has a fully owned company, XTL Development Inc.. (Hereinafter: "**XTL Development**"), which was founded in 2007 in accordance with the laws of the State of Delaware in the US, was involved in business development, pharmaceutical development and primarily in clinical trial management of Bicifadine, a drug for diabetic neuropathic pain. As of the date of this report, XTL Inc. and XTL Development have no business activity.

In 2007, the Company signed an agreement with DOV Pharmaceutical Inc. (Hereinafter: "**DOV**") to obtain an international license for the Bicifadine.

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## Company Overview

### General

On 18 November, 2008 the Company announced that phase 2b of the trial that was conducted on Bicifadine for treating diabetic neuropathic pain did not meet the clinical endpoints that had been established in advance and as such, the trial had failed. As a result of the failure to meet the clinical endpoints of the said trial, the Company halted the development of Bicifadine for treating diabetic neuropathic pain, terminated the employment of most of its employees and stopped all maintenance of patents related to Bicifadine in coordination with DOV.

In addition, in December 2008, the Company underwent reorganization in order to develop the Company's business (Hereinafter: the "**Plan**"). The plan included, inter alia, the layoff of most company employees (who were employed in the Bicifadine development project), investment activities, cooperation and acquisition of holdings particularly in companies involved in applicable life science research and in pharmaceutical research and development (biotechnology and pharmaceuticals).

On 8 March, 2010 XTL Development ended the formal contractual arrangement with DOV with regards to Bicifadine, in which all intellectual property rights to Bicifadine were reverted to DOV. As of today, the Company has certain rights based on milestones in the development plans of drugs for treating Hepatitis C based on DOS technology acquired in 2005 from VivoQuest and that were sold in sub-license to Presidio in 2008 for a cash payment, development milestone payments totaled \$59 million by Presidio and royalties from sales.

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## Company Overview

### General

On 19 March, 2009 the Company entered an asset purchase agreement with Bio Gal Ltd. (Hereinafter: "**Bio Gal**") to purchase assets, rights to the patent to use Recombinant Erythropoietin to extend the lives of terminal Multiple Myeloma patients as well as improve the quality of their lives. The parties signed several extensions for the completion date of the transaction, with the last one being valid until 31 August 2010, in order to enable completion of the transaction.

On 31 December, 2009 the Company's board of directors approved the Company's asset purchase agreement to acquire 100% of the shares of XTEPO, a private Israeli company founded by the shareholders of the Bio Gal in order to carry out the aforementioned transaction, which will receive a license for exclusive use of a patent on the Recombinant EPO drug from Bio Gal, while simultaneously investing in XTEPO \$1.5 million from private investors (based on exercise of the options they were given).

In order to execute said acquisition, the Company issued approximately 133 million ordinary shares to XTEPO shareholders against 100% of their holdings in XTEPO and by issuing the Company's ordinary shares at an exceptional private offering in accordance with the Securities Regulations (Private Offering of Securities in a Listed Company) to XTEPO shareholders (Hereinafter: "**Exchange of Shares Agreement**") that was approved by an extraordinary shareholders meeting on 2 March 2010 so that upon completion of said Exchange of Share Agreement, XTEPO shareholders held (along with their holdings of company share on the eve prior to the exchange of shares) approximately 70.64% of the issued and paid-up share capital of the company and the balance, of 29.36%, were held by company shareholders on the eve of implementation of the Exchange of Shares Agreement.

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## Company Overview

### General

On March 24, 2011 the Company has entered into a term sheet to acquire the activity of MinoGuard Ltd. (Hereinafter: "**MinoGuard**") by an exclusive license to use MinoGuard's entire technology in return for royalties on sales and milestone payments throughout the clinical development process, without making any other payments in cash.

On November 30, 2011 the Company signed on the exclusive license with MinoGuard, according to which the Company will develop and commercialize the technology to treat patients who suffer from mental illnesses focusing on the schizophrenia illness. According to the terms of the agreement, the Company will perform clinical trials, develop, sign, market and sale the technology out coming drugs with no restriction on specific illness (Hereinafter: the "**License**").

On May 29, 2011, the Company announced that it was granted an orphan drug designation from the FDA for its EPO drug for the treatment of multiple myeloma blood cancer (which is in the planning and preparation towards Phase II clinical trial). The main standard benefit of orphan drugs in the U.S. is receiving seven years marketing exclusivity from the date of approval by the FDA, as far as the FDA gives such approval. Other benefits are local U.S. tax breaks on research and development expenses and exemption from paying commissions to the FDA.

On August 29, 2011 the Company decided to perform a research, which includes preliminary data collection concerning the appearance of specific protein in the blood of a group of patients with multiple myeloma illness. This study will assist focusing the Company's Phase II clinical trial's protocol of the Recombinant EPO drug (Hereinafter: the "**Research**"). According to the Company's management and its advisors, the statutory approval to start phase II clinical trial is predicted to be accepted at the second half of 2012.

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## **Company Overview**

### **General**

### **Holdings Structure**

The following chart presents the structure of the Company's holdings as of December 31, 2011:

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## Company Overview

### Field of Activity

#### *General*

Given the completion of the exchange of shares agreement the Company (the Company, subsidiaries, including XTEPO, hereinafter jointly: "**Group**") is focused on the planning, research and development for the commercialization of a new indication for use of Recombinant EPO for the treatment of multiple myeloma patients.

Along with compliance with all pending conditions and completion of the exchange of shares agreement, transferred to the Group, via XTEPO, was exclusive usage license of a patent for using the drug Recombinant EPO to treat patients with multiple myeloma that is based on a series of studies that included, inter alia, an empirical observation of patients treated with Recombinant EPO by Prof. Moshe Mittelman. Prof. Moshe Mittelman who serves as a medical director in the Company is an internationally renowned haematologist who found in empirical observations that treatment with recombinant EPO may extend the life expectancy of patients with multiple myeloma while significantly improving their quality of life while causing less side effects than those caused by current treatments. During their lab work, Prof. Mittelman and his team found that recombinant EPO had an anticancer effect based on the strengthening of the immune system.

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## Company Overview

**Field of Activity*****Recombinant EPO Drug***

Recombinant EPO is a drug that is, as of the date of this report, used to treat (i) anemia in patients with renal failure (dialysis) and (ii) anemia in cancer patients. Recombinant EPO was developed, manufactured and marketed by Johnson & Johnson, Hoffman La Roche and Amgen, and generates billions of dollars in sales every year, and is therefore considered a drug with an extremely large market scope. The drug has been administered to millions of patients over the past 20 years, resulting in extensive clinical experience with the drug and safety information about it. As of December 31, 2011 the Company began preparing for a Phase II clinical trial on multiple myeloma patients.

The Company has exclusive license of the patents and patent applications, as detailed in the table below:

Patent Name	Countries in which Application Was Filed	Priority Date	Application No.	Patent No.	Status	Expiration Date
BIOGAL-001 EP (*)	Europe	30.03.1999	99 91 2039.7	1 067 955	Granted	30.03.2019
BIOGAL-001 CA	Canada	30.03.1999	2,366,674	-	Allowed	30.03.2019
BIOGAL-001 IL2	Israel	30.03.1999	138705	138705	Granted	30.03.2019
BIOGAL-001 JP	Japan	30.03.1999	2000-543153	4456271	Granted	30.03.2019
BIOGAL-001 HK	Hong-Kong	30.03.1999	01104635.2	HK1033910	Granted	30.03.2019
BIOGAL-001 US	USA	30.03.1999	09/647,761	6,579,525	Granted	30.03.2019

\* Valid in Austria, Belgium, France, Germany, Britain, Ireland, Italy, Holland, Spain, Switzerland and Sweden (Hereinafter: "**E**urope").

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## Company Overview

### Patent List

#### Licensing Agreement with Bio Gal

On 31 December, 2009 the Group, through XTEPO, entered a contractual arrangement with Bio Gal in an agreement to an exclusive license for a patent, that was signed between Bio Gal and Yeda and Mor Research Applications (Hereinafter: "**Mor**") (Yeda and Mor hereinafter jointly known as "**License Owners**") in 2002 (Hereinafter: "**Original Licensing Agreement**"), for exclusive use of the registered patent of the license owners for the drug recombinant EPO in order to develop a new indication that aims to extend the life of patients with multiple myeloma as well as improve their quality of life (Hereinafter: the "**Patent**").

In accordance with the terms of the original licensing agreement, Bio Gal undertook to manage the study in terms of further development of patents owned by the license owners, including full financing of the study extension, and will own exclusive international licensing rights to development use, marketing, distribution and sale of drugs used to treat multiple myeloma and other types of cancer, as much as the study permits. According to the licensing agreement, Bio Gal will bear all expenses related to preparation, filing, preserving and protecting every patent that will be registered as a result of the study. The exclusive license given to the Company (via XTEPO) as previously stated will remain valid for 15 years from the first commercial sale of the drug by Bio Gal or until the end of the patent period in the countries where the patent is registered (whichever is later).

It should be noted that the patent is a registered patent in the US since 1999 and in Europe, Israel and Hong Kong, Japan and others as well as in Canada, it should be noted that the Company obtained approval for all patent registration requests that it requested. The patent validity is expected to expire in countries in which it is registered in 2019.

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Company Overview

**Licensing Agreement with Bio Gal**

In return for said assignment of license and in accordance with the amendments made to the original licensing agreement (the last of which was made in April 2008), the Group will pay Yeda:

· Annual licensing fee of one percent (1%) of net sales of the EPO drug ;

· A one-time payment of \$ 350 thousands at the successful completion of Phase II of the clinical trial. The Payment's conditions are according to the earlier of:

ü Capital raising of at least \$ 2 million by the Company or by XTEPO following successful completion of Phase II clinical trial;

ü Six months from the date of successful completion of Phase II clinical trial.

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Section 2

Market Overview

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## Market Overview

### **General**

As described above, the Company is focused on the planning, research and development for the commercialization of a new indication for use of Recombinant EPO for the treatment of multiple myeloma patients. Accordingly, trends and events in the cancer drug market, in general, and in the multiple myeloma drug market in particular, have an essential affect on the Company's operation and financial outcomes. Following is an overview of the market in which the Company operates.

### **The Multiple Myeloma Drug Market**

#### *General*

The cancer drugs market in general, and the treatment of multiple myeloma in particular that is the focus of the Company's drug, is facing an increasing need for new developments to treat patients with various forms of cancer. Despite the progress of the pharmaceutical industry in general, and its impressive achievements over the past several decades drugs for many diseases, including various cancers, are still insufficient treatment both in terms of limited range of action, inefficacy and serious side effects. The increase in average age of the population, which is accompanied by a parallel increase in the number of cancer patients in general, and multiple myeloma cancer in particular, increases the need for new drugs in this field.

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## Market Overview

### **The Multiple Myeloma Drug Market**

In the Western world, the cancer drug market in general, and the market for multiple myeloma in particular, is characterized by drugs that have been approved for use generally for specific indications. For example, a drug will not be approved to treat multiple myeloma without a specific definition of the type of patients entitled to receive the drug. This definition includes the stage of the disease the patient is in, definition of patients based on previous therapies, etc. The result essentially is that the cancer drug market is composed of multiple patient populations. One of the challenges in developing cancer drugs is the definition of the field being targeted by the drug since there are numerous forms of cancer, each of which has several different stages of disease progression. Any drug that is approved for use is designed for a specific stage in the progression of the type of disease the drug was designed for.

In cancer, there are many patient populations for whom there is no suitable treatment and the diseases they have do not have any suitable therapy. Furthermore, the efficiency of all currently available drugs is limited. Every one of the existing drugs has a significant percentage of patients who fail to respond to them. In addition, the response of many of the patients considered to be responders was extremely partial, not long-lasting, and required taking several drugs concomitantly to achieve the desired clinical result. Cancerous tumours are occasionally so violent that the average life expectancy of patients is limited to months, or occasionally, a mild improvement in the patients' quality of life is sufficient reason for the drug to be considered efficient. Based on the aforementioned, there is a clinical need for drugs to treat multiple myeloma that will be, on the one hand, efficient and have limited side effects on the other hand. The new indication that the Company intends to develop for recombinant EPO in the treatment of patients with multiple myeloma will try to provide a certain response to this need.

The target market of the Company's drug is unique. The Company believes that the ability of any drug to capture a market share depends on the drug's short-term and long-term efficacy as well as on its side effects, both absolutely and relative to its competing drugs.

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## **Market Overview**

### **The Multiple Myeloma Drug Market**

#### ***Multiple Myeloma***

Multiple myeloma is a form of blood cancer. The disease is characterized by uncontrollable proliferation of a type of white blood cells known as plasma cells in the bone marrow that causes the accumulation of malignant cells that damage and destroy parts of the bone. This disease has a multiple nature that is expressed in the creation of a large number of accumulations of malignant cells. The malignant cells and the secreted proteins are responsible for a series of clinical expressions and complications, including bone damage with pain and breaks, bone marrow damage accompanied by anemia (blood deficiency), sensitivity to infections, weakening of the immune system, nervous system damage, kidney failure, clotting disorders, etc. The disease is incurable, and the average life expectancy of patients is 3-5 years.

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## Market Overview

### **The Multiple Myeloma Drug Market**

#### *The Market Size*

Multiple myeloma is a blood cancer that comprises 10% of all blood cancers. As of the year 2012 in the US alone there are 74,814 multiple myeloma patients<sup>1</sup>, and Every year, 21,700 new cases are diagnosed<sup>2</sup>. This number increases in direct proportion with the average life expectancy around the world. Accordingly, approximately 10,710 patients die in the US every year<sup>3</sup>. Multiple myeloma is largely considered an old person's cancer, since the disease largely appears between the ages of 65-70, although diagnosis of the disease in 50 year olds is not uncommon. In addition, multiple myeloma comprises approximately 1% of all cancer cases and approximately 2% of all cancer-related deaths<sup>4</sup>.

The following chart presents the estimated number of multiple myeloma incidences in the USA and the number of multiple myeloma deaths in 2012:

Source: Cancer & Figures 2012, American Cancer Society.

<sup>1</sup> Myeloma facts and statistics from facts 2012, The Leukemia & Lymphoma Society Fighting Blood Cancer.

<sup>2</sup> National Cancer institute, Cancer Facts & Figures – 2012, American Cancer Society (ACS) Atlanta, Georgia, 2012.

<sup>3</sup> National Cancer institute, Cancer Facts & Figures – 2012, American Cancer Society (ACS) Atlanta, Georgia, 2012.

<sup>4</sup> National Cancer institute, Cancer Facts & Figures – 2012, American Cancer Society (ACS) Atlanta, Georgia, 2012.

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## Market Overview

### **The Multiple Myeloma Drug Market**

#### *Drug Development Processes*

Drug development is a complex process that generally includes the following primary stages. Each stage must comply with the health agencies' criteria before the next stage can begin, as follows:

**Preclinical Phase** - this phase includes trials in labs and on animals in order to demonstrate the efficiency of the drugs in models that simulate the disease for which the drug is being investigated. The preclinical phase also includes trials under meticulous conditions in order to determine whether the drug has any toxic adverse events and to learn about the various characteristics in animals. In addition, the preclinical stage includes development of manufacturing methods under GMP (Good Manufacturing Practice - which is a collection of manufacturing requirements that the drug must comply with in order to allow the administration of the drug to patients in the future).

**Phase I** - this is the first clinical phase in drug development in which an initial test is carried out on humans. The phase is designed to assess the safety of the drug as well as the maximum dosage that can be safely administered to patients. This phase may also include additional tests such as drug dispersal in the body and how long the drug remains in the blood, measurements that will help assess its biological availability, etc. There are instances in which this trial phase is carried out on healthy individuals and in other cases; the trial is carried out on patients with the investigated disease.

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## Market Overview

### **The Multiple Myeloma Drug Market**

**Phase II** - In this phase, an initial test of the efficiency of the drug is carried out in patients. In addition, this phase attempts to determine the optimal dosage of the drug to treat patients. At the same time, the phase continues to test its safety. These Several Phase II trials are often carried out while the first Phase II trial (Phase 2a) is designed to serve as proof of concept and the second Phase II trial (Phase 2b) is a broader trial that includes a larger number of patients and that is carried out in a larger number of medical centers than was Phase 2a.

**Phase III** - the decisive phase of multinational, multicenter, randomized, placebo controlled, double blind trials. This phase includes the largest number of subjects (hundreds and even thousands) and the trial is carried out in a large number of medical centers around the world. The purpose of this phase is to prove the efficiency and safety of the drug in a large number of patients in a way which simulates as much as possible (more than the previous phases) the manner in which the drug will be used in the clinical practice. Following successful conclusion of this phase, applications can be submitted to the health agencies for receipt of approval to register the drug.

It should be emphasized that the conduct of clinical trials on human beings in each of the phases, Phase I, Phase II and Phase III requires the prior approval of the Helsinki Committee/ IRB and of the regulatory agencies in the countries where the clinical trials are being conducted. It should be noted that only successful results in the preliminary phases will guarantee the possibility of moving on to the next stage.

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## **Market Overview**

### **The Multiple Myeloma Drug Market**

Once all of the said phases (including completion of Phase III) have been successfully completed, the Company can submit an application for approving the drug's registration by the relevant regulatory agency, e.g. the FDA in the US.

The development process, as previously mentioned, takes many years and requires extensive funding due to the prolonged duration of the trials, the process for obtaining approval, and obtaining information and results from the trials, at the end of which the Group will be able to submit an application for approval to register the drug by the FDA or any corresponding regulatory agency in any other country. Occasionally, the clinical development, including the conduct of clinical trials, is carried out with the assistance of expert subcontractors who are entrusted with operating under the meticulous professional standards dictated by the regulatory requirements.

In light of the fact that the Company is developing a new indication for EPO, a drug that already exists and that has been approved for treatment of anemia, the Company expects to receive an exemption for the preclinical trials as well as from the Phase I clinical trial. The Company has a preliminary plan to initiate Phase II clinical trial in patients with multiple myeloma. It should be noted that the company received a preliminary plan as part of the assignment of the patent license agreement. At the same time, and in light of the fact that a prolonged period of time has passed since the date of the preparation of this report, the Company immediately began completion of the transaction in preparation of the trial that includes, inter alia, updating the plan that will be brought before medical agencies for approval prior its implementation.

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## Market Overview

### **The Multiple Myeloma Drug Market**

#### *Orphan Drug*

There is a special track for approval and marketing of pharmaceutical preparations that is designed to respond to the need to develop drugs for certain populations and for incurable and relatively rare diseases.

In the USA this approval is given to drugs for diseases with a maximum number of patients of 200,000. Recognition of a drug as an orphan drug in the USA grants the manufacturer with a regulatory exclusivity in marketing the drug for a period of 7 years<sup>6</sup>.

In Europe this approval is given to drugs for diseases with a maximum number of patients of 185,000. Recognition of a drug as an orphan drug in Europe grants the manufacturer with a regulatory exclusivity in marketing the drug for a period of 10 years<sup>7</sup>.

In Japan this approval is given to drugs for diseases with a maximum number of patients of 50,000. Recognition of a drug as an orphan drug in Japan grants the manufacturer with a regulatory exclusivity in marketing the drug for a period of 10 years<sup>8</sup>.

As mentioned in the company overview section, on May 29, 2011 the Company announced that it was granted an orphan drug designation from the FDA for its EPO drug for the treatment of multiple myeloma blood cancer.

<sup>6</sup> Canadian Organization for Rare Disorders, "Canadian Orphan Drugs Policy", 2005.

<sup>7</sup> Canadian Organization for Rare Disorders, "Canadian Orphan Drugs Policy", 2005.

<sup>8</sup> Pacific Bride in Asia, "Orphan Drugs in Asia", September/October 2006.



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## Market Overview

### The Multiple Myeloma Drug Market

#### *Competition in the Multiple Myeloma Drug Market*

As of today, there are several recognized therapies used to treat multiple myeloma, including chemotherapy, radiation therapy, bone marrow transplantation and new drugs. Chemotherapy kills cancer cells but also healthy cells in the patient's body, especially active cells such as mucous cells, connective tissue cells, blood cells including immune system cells, reproductive cells, etc. This damage is caused by the treatment, which damages the cancer cells but also the healthy cells in the body and is accompanied by serious side effects, including nausea, vomiting, hair loss, acute pain, etc.

In addition, there are biological drugs that are more to cancer cells that are known to have milder adverse events than chemotherapy. The leading drugs in the market are: Revlimid, manufactured by Celgene Corporation (Hereinafter: "**Celgene**"), Velcade (Bortezomid) developed by Millennium Pharmaceuticals (Hereinafter: "**Millennium**"), and Thalidomide/Thalomid, manufactured by Celgene. These biological drugs are characterized by extremely high prices. It should be noted that despite the aforementioned, not one of these drugs cures the disease.

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## Market Overview

### **The Multiple Myeloma Drug Market**

In 2003, the Velcade drug had approved for use as a treatment for the multiple myeloma illness and its marketing begun. In 2006, the Revlimid and Thalidomide drugs had approved for use as a treatment for the multiple myeloma illness and their marketing begun.

According to Decision Resources report published in 2010, in 2008, the total sales of the multiple myeloma drugs in the USA, France, Germany, Italy, Spain, England and Japan were amounted to \$2.1 billion and predicted to increase to \$5.3 billion in 2018<sup>9</sup>.

According to Decision Resources estimations published in 2011, the multiple myeloma market is predicted to grow by a Compounded Average Growth Rate of 5.6% between the years 2010 and 2020 in the leading markets in USA, France, Italy, Spain, England and Japan<sup>10</sup>.

According to Bloomberg company's analyst report<sup>11</sup>, the Velcade Sales were 40% out of the total sales of multiple myeloma drugs, while the actual sales of Johnson & Johnson company, which markets the Velcade drug outside the USA, and the Takada company, which markets the Velcade drug in the USA, were \$ 1.2 billion. In addition, according to Celgene financial reports, the total sales of Revlimid in 2010 were approximately \$ 2.47 billion<sup>12</sup>.

<sup>9</sup> The Pharma Letter, "5.6% Annual Growth Forecast for Multiple Myeloma Drug Market to 2020", December 21, 2011.

<sup>10</sup> The Pharma Letter, "5.6% Annual Growth Forecast for Multiple Myeloma Drug Market to 2020", December 21, 2011.

<sup>11</sup> <http://bloomberg.com/apps/news?pid=newsarchive&sid=aQHENps19ldg>.

<sup>12</sup> <http://ir.celegene.com/phoenix.zhtml?c=111960&p=irol-newsArticle&ID=1520733&highlight=>

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## **Market Overview**

### **The Multiple Myeloma Drug Market**

The following chart presents the current Revlimid, Velcade and Thalomid market share by line of therapy, as of January 2010:

Source: Bernstein Research, "Celgene: SCB MM Survey Pt II – Maintenance is Key Driver for Revlimid Growth and Upside; Raising Estimates, TP \$78, February 16, 2010.

According to SCB survey's data, across all lines of therapy, Velcade and Revlimid have both increased their share since February 2007. Some of Velcade's and Revlimid's market share increases have come from increased use of combination regimens.

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## Market Overview

### **The Multiple Myeloma Drug Market**

The following chart presents the current Revlimid, Velcade and Thalomid market share across all lines of therapy, as of January 2010:

Source: Bernstein Research, "Celgene: SCB MM Survey Pt II – Maintenance is Key Driver for Revlimid Growth and Upside; Raising Estimates, TP \$78, February 16, 2010.

An analysis that was published by Pharma Letter on December 2011<sup>13</sup> found that despite the continued expansion of Velcade in the first-line settings, sales of Velcade will be rapidly eclipsed by Revlimid's dramatic growth. The approval of Revlimid in the first-line setting will also aggressively erode patient share and sales of Celgene's Thalidomide. In 2020, Revlimid will hold a 62% market share of the total myeloma market.

<sup>13</sup> The Pharma Letter, "5.6% Annual Growth Forecast for Multiple Myeloma Drug Market to 2020", 21 December, 2011.

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## Market Overview

### The Multiple Myeloma Drug Market

According to the aforementioned analysis' findings, Revlimid and Velcade will experience increasing uptake in the relapsed/refractory setting as they will be used in combination with emerging therapies. Revlimid will be used in combination with Onyx Pharmaceuticals/Ono Pharmaceutical's carfilzomib, anticipated to be approved by the US Food and Drug Administration as early as 2012, and Bristol-Myers Squibb/Abbott's elotuzumab, which will launch later (in 2015) in the USA and Europe. Velcade will also experience increased uptake in combination with AEterna Zentaris/Keryx Biopharmaceuticals/Yakult Honsha's perifosine, Merck & Co.'s Zolinza (vorinostat) and Novartis's panobinostat<sup>14</sup>.

In addition, overall, Revlimid will emerge as the clear market leader in the multiple myeloma market over the next decade. Velcade will remain the second highest selling agent but will suffer from the entry of generics towards the end of 2020<sup>15</sup>. In addition, emerging therapies for multiple myeloma, Carfilzomib and Pomalidomide, are commercially promising, and together are expected to reach sales to \$ 800 million in 2020<sup>9</sup>.

The findings also reveal that significant opportunity lies in the development of agents that improve survival and reduce toxicities compared with currently available therapies<sup>16</sup>.

<sup>14</sup> The Pharma Letter, "5.6% Annual Growth Forecast for Multiple Myeloma Drug Market to 2020", 21 December, 2011.

<sup>15</sup> The Pharma Letter, "5.6% Annual Growth Forecast for Multiple Myeloma Drug Market to 2020", 21 December, 2011.

<sup>16</sup> The Pharma Letter, "5.6% Annual Growth Forecast for Multiple Myeloma Drug Market to 2020", 21 December, 2011.

## Market Overview

### **The Multiple Myeloma Drug Market**

Recently, a number of screening methods have been developed to identify small molecules that might mimic the biological effects of hematopoietic growth factors. The potential advantages of small molecule mimics include lack of immunogenicity, fewer drug side-effects, and non-parenteral routes of administration. Small molecules might also be less expensive to produce<sup>17</sup>.

#### *Methods to Cope with Competition*

Studies conducted by Prof. Mittelman revealed that use of recombinant EPO in patients in advanced stages of multiple myeloma significantly contributed to suppression of symptoms of the disease, improved the immune system, stabilized patients health, prolonged their survivability and significantly improved their lives, without causing serious side effects.

These properties grant this drug an advantage in most therapeutic properties for which the drug is designed. The Company anticipates that if these properties are expressed in clinical trials as well, a medical agency criteria for drug approval, the drug will capture a large market share in the drug market for treatment of multiple myeloma, including providing a solution to terminally ill patients in the advanced stage of the disease who do not respond well or who demonstrate an insufficient response to currently available treatments.

<sup>17</sup> K. Kaushansky, "Small molecule Mimics of Hematopoietic Growth Factors: Improving on Mother Nature?", April, 2001.



## Market Overview

### **The Multiple Myeloma Drug Market**

In addition, the Company expects the drug to capture another market share of combining the drug with currently available drugs and therapies. If these projects are realized, the drug's market is estimated at hundreds of millions of dollars a year.

However, it should be emphasized that clinical studies include many elements of uncertainty, and the possibility of the Company not succeeding in its attempts to continue to demonstrate the efficiency and safety of the drug or that the drug will prove to be less efficient than expected cannot be ruled out. In addition, the possibility of the development of other drugs by the competition that will compete with the Company's drugs cannot be ruled out.

In order to successfully cope with the anticipated competition, the Company must position its drug by emphasizing its advantages over the competition. According to the Company, the anticipated advantages of its drug, once it is approved, is based on the premise of a longer life expectancy of patients who take the drug coupled with improved quality of life without any significant side effects. The Company believes that the fact that the drug's possible efficacy in a combination treatment with or after other currently available therapies will reinforce the drug's position and give the Company a marketing advantage. Later on, if and when the drug is approved for marketing, these advantages are expected to provide the Company with a significant preference that, with the right marketing, will guarantee, according to the Company's estimation, an advantage in the multiple myeloma therapy market.

In addition, among the main factors affecting the ability of a new product to penetrate the drug market and the competition in it are clinical advantages that the product provides and the ability to protect its intellectual property rights. In light of the fact that the Company has the license for exclusive use of the patent for the drug recombinant EPO to treat patients with multiple myeloma, the Company believes that its drugs contains the right properties to withstand expected competition.

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Market Overview

### **The Multiple Myeloma Drug Market**

Several years will pass until the Company's product reaches the market but until it reaches this stage, the chances are that one of the giant pharmaceuticals in the field will try to seek collaboration with the Company in the drug's development and/or marketing.

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Section 3

**Financial Data**

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## Financial Data

**Balance Sheet**

The following table presents the Company's balance sheets as of 31/12/09, 31/12/10 30/09/10, and 30/09/11 (dollars in thousands):

Dollars in thousands	31.12.09	31.12.10	30.09.10	30.09.11
<b>Assets</b>				
Cash and Cash Equivalents	412	1,066	1,377	200
Short-Term Deposits				1,590
Taxes	72			
Account Receivable	33	110	19	49
Restricted Deposits	40	46		21
Total Current Assets	557	1,222	1,396	1,860
<b>Non-Current Assets</b>				
Restricted Deposits			20	
Property, Plant and Equipment	23	35	15	36
Intangible Assets		2,540	2,564	2,468
Other Investments	135			
Total Non-Current Assets	158	2,575	2,599	2,504
Total Assets	715	3,797	3,995	4,364
<b>Current Liabilities</b>				
Trade Payables	192	203	200	118
Other Account Payables	516	760	687	525
Total Current Liabilities	708	963	887	643
Total Equity	7	2,834	3,108	3,721
Total Liabilities and Equity	715	3,797	3,995	4,364

*Source: The Company's Financial Statements.*

## Financial Data

**Profit & loss**

The following table presents the Company's income statements for 2009-2010 and for the period ended September 30 in the years 2010-2011 (dollars in thousands):

Dollars in thousands	2009	2010	1-9/2010	1-9/2011
Research and Development Expenses		64		127
General and Administration Expenses	(2,429)	1,222	948	814
Other Gains, Net	139	30		
Operating Profit (Loss)	2,568	(1,256)	(948 )	(941 )
Finance Income	6	6	11	27
Finance Expenses	10	7	5	5
Finance Income (Expenses), Net	(4 )	(1 )	6	22
Profit (Loss) Before Taxes on Income	2,564	(1,257)	(942 )	(919 )
Tax Benefit	23			
Net Profit (Loss)	2,587	(1,257)	(942 )	(919 )

*Source: The Company's Financial Statements.*

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Section 4

Methodology

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## Methodology

### IAS 38

#### *General*

The objective of this Standard is to prescribe the accounting treatment for intangible assets that are not dealt with specifically in another Standard. This Standard requires an entity to recognise an intangible asset if, and only if, specified criteria are met. The Standard also specifies how to measure the carrying amount of intangible assets and requires specified disclosures about intangible assets.

#### *Definitions*

The following terms are used in this Standard with the meanings specified:

**An asset is a resource:**

- (a) Controlled by an entity as a result of past events; and
- (b) From which future economic benefits are expected to flow to the entity.

**Carrying amount** is the amount at which an asset is recognised in the statement of financial position after deducting any accumulated amortisation and accumulated impairment losses thereon.

**Fair value of an asset** is the amount for which that asset could be exchanged between knowledgeable, willing parties in an arm's length transaction.

**An intangible asset** is an identifiable non-monetary asset without physical substance.

**Useful life is:**

- (a) The period over which an asset is expected to be available for use by an entity; or
- (b) The number of production or similar units expected to be obtained from the asset by an entity.

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Methodology

**IAS 38**

*Identifiability*

According to **Section 12**, an asset is identifiable if it either:

- Is separable, i.e. is capable of being separated or divided from the entity and sold, transferred, licensed, rented or (a) exchanged, either individually or together with a related contract, identifiable asset or liability, regardless of whether the entity intends to do so; or
- (b) Arises from contractual or other legal rights, regardless of whether those rights are transferable or separable from the entity or from other rights and obligations.

According to **Section 17**, the future economic benefits flowing from an intangible asset may include revenue from the sale of products or services, cost savings, or other benefits resulting from the use of the asset by the entity. For example, the use of intellectual property in a production process may reduce future production costs rather than increase future revenues.

According to **Section 21**, an intangible asset shall be recognised if, and only if:

- (a) It is probable that the expected future economic benefits that are attributable to the asset will flow to the entity; and
- (b) The cost of the asset can be measured reliably.

According to **Section 22**, an entity shall assess the probability of expected future economic benefits using reasonable and supportable assumptions that represent management's best estimate of the set of economic conditions that will exist over the useful life of the asset.

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Methodology

**IAS 38**

According to section 57, an intangible asset arising from development (or from the development phase of an internal project) shall be recognised if, and only if, an entity can demonstrate all of the following:

- (a) The technical feasibility of completing the intangible asset so that it will be available for use or sale.
- (b) Its intention to complete the intangible asset and use or sell it.
- (c) Its ability to use or sell the intangible asset.  
How the intangible asset will generate probable future economic benefits. Among other things, the entity can
- (d) demonstrate the existence of a market for the output of the intangible asset or the intangible asset itself or, if it is to be used internally, the usefulness of the intangible asset.
- (e) The availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset.
- (f) Its ability to measure reliably the expenditure attributable to the intangible asset during its development.

**IAS 36**

*General*

The International Accounting Standard 36 Impairment of Assets (Hereinafter "**IAS 36**") objective is to prescribe the procedures that an entity applies to ensure that its assets are carried at no more than their recoverable amount. An asset is carried at more than its recoverable amount if its carrying amount exceeds the amount to be recovered through use or sale of the asset. If this is the case, the asset is described as impaired and the Standard requires the entity to recognize an impairment loss.

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Methodology

**IAS 36**

This Standard shall be applied in accounting for the impairment of all assets (other than exceptions as they appear in the standard content) or cash generating unit(s) including goodwill acquired from business combination. Goodwill acquired in business combination represents the value of the intangible assets which cannot be separately identified or separately recognized.

*Definitions*

The following terms are used in this Standard with the meanings specified:

**Carrying amount** is the amount at which an asset is recognized after deducting any accumulated depreciation (amortization) and accumulated impairment losses thereon

**A cash-generating unit** is the smallest identifiable group of assets that generates cash inflows that are independent of the cash inflows from other assets or groups of assets.

**Fair value less costs to sell** is the amount obtainable from the sale of an asset or cash-generating unit in an arm's length transaction between knowledgeable, willing parties, less the costs of disposal.

The recoverable amount of an asset or a cash-generating unit is the higher of its fair value less costs to sell and its value in use.

Value in use is the present value of the future cash flows expected to be derived from an asset or cash-generating unit.

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Methodology

## IAS 36

### *Determining An Impairment Loss*

Timing of impairment tests for goodwill

The Standard permits:

- (a) The annual impairment test for a cash-generating unit (group of units) to which goodwill has been allocated to be performed at any time during an annual reporting period provided the test is performed at the same time every year.

- (b) Different cash-generating units (groups of units) to be tested for impairment at different times. However, if some of the goodwill allocated to a cash-generating unit (group of units) was acquired in a business combination during the current annual period, the Standard requires that unit (group of units) to be tested for impairment before the end of the current period.

The Standard permits the most recent detailed calculation made in a preceding period of the recoverable amount of a cash-generating unit (group of units) to which goodwill has been allocated to be used in the impairment test for that unit (group of units) in the current period, provided specified criteria are met.

The Standard defines number of steps for the identification, recognition and measurement of value loss of an asset or cash generating unit. Moving on to the next step is subjected to the fulfillment of the previous step.

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Methodology

## IAS 36

### *Identifying an asset that may be impaired*

An entity shall assess at each reporting date whether there is any indication that an asset may be impaired. In assessing whether there is any indication that an asset may be impaired, an entity shall consider, as a minimum, the following indications:

#### **External sources of information**

§ During the period, an asset's market value has declined significantly more than would be expected as a result of the passage of time or normal use.

§ Significant changes with an adverse effect on the entity have taken place during the period, or will take place in the near future, in the technological, market, economic or legal environment in which the entity operates or in the market to which an asset is dedicated.

§ Market interest rates or other market rates of return on investments have increased during the period, and those increases are likely to affect the discount rate used in calculating an asset's value in use and decrease the asset's recoverable amount materially.

The carrying amount of the net assets of the entity is more than its market capitalization.

#### **Internal sources of information**

· Evidence is available of obsolescence or physical damage of an asset.

Significant changes with an adverse effect on the entity have taken place during the period, or are expected to take place in the near future, in the extent to which, or manner in which, an asset is used or is expected to be used.

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## Methodology

### **IAS 36**

Evidence is available from internal reporting that indicates that the economic performance of an asset is, or will be, worse than expected.

If any indication of value loss exists, the entity shall estimate the recoverable amount of the asset. In case the value of the recoverable amount found is lower than the respective Carrying amount, the entity shall depreciate the value of the asset or the Cash-generating unit accordingly.

The standard requires an intangible asset with an indefinite useful life or not yet available for use and goodwill to be tested for impairment, once a year, regardless to the existence of indication of value loss.

### ***Measuring Recoverable Amount***

#### **General**

This Standard defines recoverable amount as the higher of an asset's or cash-generating unit's fair value less costs to sell and its value in use.

It is not always necessary to determine both an asset's fair value less costs to sell and its value in use. If either of these amounts exceeds the asset's carrying amount, the asset is not impaired and it is not necessary to estimate the other amount.

If there is no reason to believe that an asset's value in use materially exceeds its fair value less costs to sell, the asset's fair value less costs to sell may be used as its recoverable amount.



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## Methodology

### **IAS 36**

This will often be the case for an asset that is held for disposal. This is because the value in use of an asset held for disposal will consist mainly of the net disposal proceeds, as the future cash flows from continuing use of the asset until its disposal are likely to be negligible.

### **Fair value less costs to sell**

The best evidence of an asset's fair value less costs to sell is a price in a binding sale agreement in an arm's length transaction, adjusted for incremental costs that would be directly attributable to the disposal of the asset.

If there is no binding sale agreement but an asset is traded in an active market, fair value less costs to sell is the asset's market price less the costs of disposal.

If there is no binding sale agreement or active market for an asset, fair value less costs to sell is based on the best information available to reflect the amount that an entity could obtain, at the end of the reporting period, from the disposal of the asset in an arm's length transaction between knowledgeable, willing parties, after deducting the costs of disposal. In determining this amount, an entity considers the outcome of recent transactions for similar assets within the same industry.

Costs of disposal, other than those that have been recognized as liabilities, are deducted in determining fair value less costs to sell.

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## Methodology

### IAS 36

#### Value in use

The following elements shall be reflected in the calculation of an asset's value in use:

- (a) An estimate of the future cash flows the entity expects to derive from the asset;
- (b) Expectations about possible variations in the amount or timing of those future cash flows;
- (c) The time value of money, represented by the current market risk-free rate of interest;
- (d) The price for bearing the uncertainty inherent in the asset; and
- (e) Other factors, such as illiquidity, that market participants would reflect in pricing the future cash flows the entity expects to derive from the asset.

Estimating the value in use of an asset involves the following steps:

- (a) Estimating the future cash inflows and outflows to be derived from continuing use of the asset and from its ultimate disposal; and
- (b) Applying the appropriate discount rate to those future cash flows.

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Methodology

**IAS 36**

In measuring value in use an entity shall:

Base cash flow projections on reasonable and supportable assumptions that represent management's best estimate of (a) the range of economic conditions that will exist over the remaining useful life of the asset. Greater weight shall be given to external evidence.

Base cash flow projections on the most recent financial budgets/forecasts approved by management, but shall (b) exclude any estimated future cash inflows or outflows expected to arise from future restructurings or from improving or enhancing the asset's performance. Projections based on these budgets/forecasts shall cover a maximum period of five years, unless a longer period can be justified.

Estimate cash flow projections beyond the period covered by the most recent budgets/forecasts by extrapolating the (c) projections based on the budgets/forecasts using a steady or declining growth rate for subsequent years, unless an increasing rate can be justified. This growth rate shall not exceed the long-term average growth rate for the products, industries, or country or countries in which the entity operates, or for the market in which the asset is used, unless a higher rate can be justified.

When the carrying amount of an asset does not yet include all the cash outflows to be incurred before it is ready for use or sale, the estimate of future cash outflows includes an estimate of any further cash outflow that is expected to be incurred before the asset is ready for use or sale.

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Methodology

**IAS 36**

Estimates of future cash flows shall not include estimated future cash inflows or outflows that are expected to arise from:

- (a) A future restructuring to which an entity is not yet committed; or
- (b) Improving or enhancing the asset's performance.
- (c) Cash inflows or outflows from financing activities; or
- (d) Income tax receipts or payments.

Future cash flows are estimated in the currency in which they will be generated and then discounted using a discount rate appropriate for that currency. An entity translates the present value using the spot exchange rate at the date of the value in use calculation.

**Discount rate**

The discount rate (rates) shall be a pre-tax rate (rates) that reflect(s) current market assessments of:

- (a) The time value of money; and
- (b) The risks specific to the asset for which the future cash flow estimates have not been adjusted.

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Methodology

## IAS 36

### *Recognizing and measuring an impairment loss*

If, and only if, the recoverable amount of an asset is less than its carrying amount, the carrying amount of the asset shall be reduced to its recoverable amount. That reduction is an impairment loss.

An impairment loss shall be recognized immediately in profit or loss, unless the asset is carried at revalued amount in accordance with another Standard.

The impairment loss shall be allocated to reduce the carrying amount of the assets of the unit (group of units) in the following order:

- (a) First, to reduce the carrying amount of any goodwill allocated to the cash-generating unit (group of units); and
- (b) Then, to the other assets of the unit (group of units) pro rata on the basis of the carrying amount of each asset in the unit (group of units).

In allocating an impairment loss, an entity shall not reduce the carrying amount of an asset below the highest of:

- (a) Its fair value less costs to sell (if determinable);
- (b) Its value in use (if determinable); and
- (c) Zero.

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Section 5

Estimating an Impairment Loss of Intangible Asset

Section 5: Estimating an Impairment Loss of Intangible Asset | XTL Biopharmaceuticals Ltd. |

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## Estimating an Impairment Loss of Intangible Asset

### **General**

#### **Frequency of impairment testing**

As requested by XTL management, We were performed the Impairment Examination Study of its Intangible asset under the requirements of Statement of International Accounting standards 38 (IAS 38) and Statement of International Accounting standards 36 (IAS 36).

In accordance with IAS 36, the recoverable amount of an intangible asset with an indefinite useful life to be measured annually, provided that the annual examination will be performed in the same date. The company's management determined the annual impairment testing date, to December 31, 2011.

#### **Identifying an intangible asset**

In accordance with IAS 38, an intangible asset is an identifiable non-monetary asset without physical substance. The recognition of an item as an intangible asset requires an entity to demonstrate that the item meets the two recognition criteria (please see section 4 – Methodology).

In accordance with IAS 38 and IAS 36, we tested the Company's IP impairment loss, namely the Patents for using the EPO drug to treat patients with Multiple Myeloma.

Section 5: Estimating an Impairment Loss of Intangible Asset |XTL Biopharmaceuticals Ltd. |

## Estimating an Impairment Loss of Intangible Asset

### **General**

#### **Identifying the cash-generating unit to which an asset belongs**

IAS 36, defines A cash-generating unit as the smallest identifiable group of assets that generates cash inflows that are largely independent of the cash inflows from other assets or groups of assets. According to the company's management, the smallest cash-generating unit for which the test was performed is the group of patents expected to generate positive cash flows (Hereinafter: the "IP").

#### **Recoverable amount of a cash-generating unit**

According to IAS 36, the value in use of IP shall comprise its recoverable amount. This amount will be compared to the carrying amount of the IP.

As of December 31, 2011, the fair value from the sale of the asset cannot be estimated; the Company is not aware of the sale of an identical asset, and the asking price in sale transactions of a similar asset - namely IP in the biopharmaceuticals sector executed recently, varies within a very wide range, as the price is dependent on various factors, differing significantly from one asset to another - such as the drug treatment administered, side effects, number of potential patients, etc.

As no fair value less costs to sell of the IP was found, the recoverable amount of the IP will be determined by calculating its value in use.

We applied the discounted cash flow (DCF) approach to estimate the IP's value in use, based on the Management's valuations of the data and documents provided by the Company and its consultants, coupled with our own assumptions as discussed below. The cash flows were discounted at the pre-tax price of capital considered to be proper for the IP activity. The DCF expense is the value in use of the IP



## Estimating an Impairment Loss of Intangible Asset

### **General**

#### **Book value of a cash-generating unit**

According to IAS 36, the carrying amount of a cash-generating unit shall be determined on a basis consistent with the way the recoverable amount of the cash-generating unit is determined. The carrying amount of a cash-generating unit includes the carrying amount of only those assets that can be attributed directly, or allocated on a reasonable and consistent basis, to the cash-generating unit and will generate the future cash inflows used in determining the cash-generating unit's value in use.

According to the financial statement of the Company as of December 31, 2011 the carrying amount of the IP is in the amount of \$2,452 thousands. Thus amount includes capitalized current expenses on behalf of the IP (e.g. legal expenses, advisors, fees, etc.) which capitalized in accordance to IAS 38.

#### **An impairment of an intangible asset**

According to IAS 36, impairment will perform by comparing the carrying amount of the asset, with its recoverable amount. If the recoverable amount of the asset exceeds its carrying amount, the asset shall be regarded as not impaired. If the carrying amount of the asset exceeds its recoverable amount, the entity shall recognize an impairment loss.

As mentioned above, the value in use of IP shall comprise its recoverable amount. This amount will be compared to the carrying amount of the IP, accordingly to the company's financial statements, as of December 31, 2011.

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## Estimating an Impairment Loss of Intangible Asset

### General

#### Estimating IP Value in Use in the DCF Method

As aforesaid, we applied the discounted cash flow (DCF) approach to estimate the IP's value in use.

To establish IP value, we estimated the Company's future cash inflows from use of the EPO in Multiple Myeloma patients in advanced stages of the disease for the period between 2012 (the Valuation Date) and 2025 (the end of the recognition of the drug as an orphan drug) .

The future cash inflows were built under the assumption that the Company will sign on a distribution agreement only after the completion of the drug's development, meaning the completion of Phase III clinical trial. After the completion of phase III clinical trial the Company will receive from the distributor a down payment and royalties from the distributor's drug sales.

To succeed in the trial and generate future cash flows, a number of milestones must be met. The probability of each was estimated separately, when compliance with each milestone of the following items is dependent on all the milestones preceding it. The milestones are:

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

· Completing Phase II of EPO development and obtaining approvals to move to Phase III;

· Completing Phase III of EPO development;

· Successful completion of all the clinical trial stages and registrations and the drug's entry into the market for worldwide sales;

· Recognizing EPO as an "Orphan Drug" in the rest of the world (as described in the company overview section, the Company's drug was recognized as an orphan drug in USA).

The revenues flow takes into consideration the successes expectancy of drugs development in each of the milestones described above by multiplying the predicted revenues by the probability to successes. For example, the predicted down payment was multiplied by the accumulated probability to success in phase II and phase III clinical trials. Eventually, the Company's predicted revenues are the expectancy of revenues.

The expenses on behalf of the development of a new indication for the EPO drug include the Company's predicted expenses due to the performance of Phase II and Phase III clinical trials. In addition, it was taken under account that the Company will bear a general and administration expenses, which reflects its operational existence. These expenses reflect the Company's necessity to manage a collection system for future covenants, to maintain its patents, to identify new technologies, etc.

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

In addition to these expenses and according to the Bio Gal transaction, the Company will pay Yeda a onetime payment at the completion of the Phase II clinical trial and a yearly payment of 1% of the Company's and/or its distributors' net revenues from the EPO drug's sales.

The predicted expenses were multiplied by the accumulated probability to success in each of the milestones. Eventually, the Company's predicted expenses are the expectancy of expenses.

The cash flow multiplied by the accumulated probability of success was discounted at the relevant price of capital estimated by us. The discounted cash flow constitutes the IP's value in use.

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## Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method**

The following table presents the Company's predicted future cash flows from its IP for the years 2012-2025 (dollars in thousands):

	Beginning		End of Phase II and Beginning of Phase III		End of Phase III		Filing and Beginning of the Orphan Drug Immunity					
Dollars in thousands	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Royalties Potential												
Royalties Potential – USA								3,174	9,521	20,629	34,910	49,000
Royalties Potential - Rest of the World								3,408	10,223	22,150	37,484	52,000
Total Royalties Potential								6,581	19,744	42,778	72,394	102,000
Revenues Expectancy Covenants Expectancy							5,795	–				
Royalties Expectancy – USA								669	2,008	4,351	7,364	10,000
Royalties Expectancy – Rest of the World								482	1,445	3,130	5,298	7,400
Total Revenues' Expectancy							5,795	1,151	3,453	7,482	12,661	17,400

Expectancy Expenses													
Expectancy Cost Phase II	150	600	600	150	–	–	–	–	–	–	–	–	–
Expectancy Cost Phase III	–	–	–	1,303	1,737	1,737	1,303	–	–	–	–	–	–
Expectancy R&D (excluding clinical trails' costs) and G&A Expenses	500	500	500	190	190	190	116	91	91	91	91	91	91
Expectancy Payment to YEDA if Phase II is successfully completed	–	–	–	133	–	–	–	–	–	–	–	–	–
Royalties Expectancy to Yeda	–	–	–	–	–	–	58	12	35	75	127	178	178
Total Expectancy Expenses	650	1,100	1,100	1,776	1,927	1,927	1,477	102	125	166	218	269	269
Profit (Loss) Before Tax	(650)	(1,100)	(1,100)	(1,776)	(1,927)	(1,927)	4,318	1,049	3,328	7,316	12,444	17,500	17,500

### General Note

In the projection the expression "rest of the world" is attributed to the countries in which the Company has patent and therefore it intends to sale the drug, including: Germany, England, Italy, France, Spain, Austria, Belgium, Ireland, the Netherlands, Swiss, Sweden, Japan, Canada and Israel.

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Estimating an Impairment Loss of Intangible Asset

Estimating IP Value in Use in the DCF Method

***Revenues Expectancy Forecast***

**Drug Development processes and Revenues' Timeline**

The FDA'S Drugs approval process is strict and obligating performance and completion of three clinical trials.

The following table presents the drugs development processes' timeline:

Development Stage	Length of Development Stage
Discovery	1
Patent Process Initiated	4-5
Pre-Clinical Trials	4-15
Phase I	1-2
Phase II	2-3
Phase III	3
Total Clinical Trials	6-8
Registration	1-4
Total	12-28

Source: [www.pfizer.com](http://www.pfizer.com), Kellogg and Charnes, 2000, Myers and Howe, 1997.

The date of launching the EPO on the market is likely to change significantly, and ranges over a relatively wide span of years. Accordingly, the Company's revenues from manufacturing and marketing the drug depend critically on the success of its clinical trials and on obtaining all the necessary permits.



Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

As described in the market overview section, in light of the fact that the Company is developing a new indication for EPO, a drug that already exists and that has been approved for treatment of anemia, the Company expects to receive an exemption for the preclinical trials as well as from the Phase I clinical trial.

As described in the Company overview section, according to Management and the Company's advisors, the statutory approval to start phase II clinical trial is predicted to be accepted at the second half of 2012. Accordingly, the Company estimates that Phase II clinical trial will begin in the fourth quarter of 2012 and will last 2.5 years, meaning will end in the first quarter of 2015.

According to Management and the Company's medical advisors, phase III clinical trial is predicted to start (under the assumption that the Company will complete Phase II clinical trial) at the second half of 2015 and to last 3-4 years. For the purpose of this analysis it was assumed that the Company's Phase III clinical trial will last 3.5 years and will end in the third quarter of 2018.

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## Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method**

At the beginning of 2019, it was assumed that the Company will receive all regulatory registration and start to market the drug. In this year the Company's patents will expire, but since the Company was granted an orphan drug designation from the FDA for its EPO drug for the treatment of multiple myeloma blood cancer on May 29, 2011 the Company gained seven years marketing exclusivity from the date of approval by the FDA. Accordingly, the Company will benefit from marketing exclusivity of its drug in the USA until 2025. In addition, based on discussion with the Management, the Company intends to act to receive an orphan drug recognition in the rest of the world immediately after it will successfully complete Phase II clinical trial. In light of the fact that the Company's drug received from the FDA an orphan drug designation, there is a better chance that the Company's drug will recognized as an orphan drug in the rest of the world. Despite of the fact that the orphan drug designation in Europe and Japan grants a ten years of marketing exclusivity, since as of the Analysis Date the Company's drug recognized as an orphan drug only in the USA we assumed in our analysis an exclusivity period of seven years. Since at the end of 7 years, the price of the drug and number of patients taking it will be considerably reduced; hence the Company's cash inflow from the EPO will not be significant, it was assumed that the Company won't have revenues from the EPO drug starting 2026.

The following table summarizes the drug development stages' and revenues acceptance from the sale of the recombinant EPO's timeline:

Development Stages and commercialization of the EPO Drug	
Beginning of Phase II	Q4 2012
End of Phase II and Beginning of Phase III	Q1 2015
End of Phase III	Q3 2018
Filing and Beginning of the Orphan Drug Immunity	Q1 2019
End of the Orphan Drug Immunity	Q4 2025

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

#### *Size of Relevant Market*

As described in the company overview section, the Company is focused on the planning, research and development for the commercialization of a new indication for use of Recombinant EPO for the treatment of terminal multiple myeloma patients.

To evaluate the size of the target market, we assumed that the number of U.S. patients comprises almost half that number globally, to whom the Company intends to sell its products.

As described in the market overview section, as of the year 2012 in the USA alone 21,700 new cases of multiple myeloma are diagnosed<sup>18</sup>. Accordingly, the number of new cases diagnosed with Multiple Myeloma globally, which is the basis for calculating the overall number of patients treated with the drug therapy developed by the Company, is estimated by us at approximately 45,000 persons per annum.

It should be noted that in estimating the number of potential patients requiring the treatment, we have not taken into consideration those diagnosed with the disease at present, as Multiple Myeloma is considered to be incurable, and patients' mean survival rate does not exceed 3-5 years.

<sup>18</sup> National Cancer institute, Cancer Facts & Figures – 2012, American Cancer Society (ACS) Atlanta, Georgia, 2012.

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Estimating an Impairment Loss of Intangible Assets

Estimating IP Value in Use in the DCF Method

***The Company's Number of Potential Patients***

**The Company's Market Share**

From the revenue aspect, in order to estimate the number of new patients who will be treated with the drug each year, we have assumed that the Company's penetration rate in each of the Company's markets activity will gradually increase.

As described in the market overview section, the penetration rate of the leading drugs in the market for the treatment of Multiple Myeloma (Revlimid and Velcade) reached 40% during the initial 3-4 years of their market launch. Since according to the Company's management and its medical advisors the EPO prices are expected to be lower than similar drugs available at present and with fewer side effects we have assumed a 10% penetration rate in the first year's market launch, gradually increasing to 55% in the fifth year and on.

**The Average Continued Drug Use**

As the medication offered by the Company must be given to patients throughout their entire life after the start of therapy, we have estimated the life expectancy predicted by the Company for patients treated with EPO. Based on the results of the latest survey conducted by the Company, coupled with the Management's forecasts and expectations, we have assumed that the average life expectancy of Multiple Myeloma patients during the period of treatment with EPO is about 4 years. The implication is that patients treated with this drug will, on average, live 4 years longer, in the course of which the Company will sell them EPO.

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## Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method**

The following table presents the Company's accumulated potential patients in the years 2019-2025:

	2019	2020	2021	2022	2023	2024	2025
Accumulated Number of Patients							
Accumulated Number of Patients – USA							
Number of New Potential Patients	21,700	21,700	21,700	21,700	21,700	21,700	21,700
Penetration Rate	10 %	20 %	35 %	45 %	55 %	55 %	55 %
The Company's New Potential Patients	2,170	4,340	7,595	9,765	11,935	11,935	11,935
Accumulated Number of Patients – USA	2,170	6,150	14,105	23,870	33,635	41,230	45,570
Accumulated Number of Patients – Rest of the World							
Number of New Potential Patients	23,300	23,300	23,300	23,300	23,300	23,300	23,300
Penetration Rate	10 %	20 %	35 %	45 %	55 %	55 %	55 %
The Company's New Potential Patients	2,330	4,660	8,155	10,485	12,815	12,815	12,815
Accumulated Number of Patients – Rest of the World	2,330	6,990	15,145	25,630	36,115	44,270	48,930

***Royalties Potential*****The Drug's Selling Price**

The drug's selling price depends on competitive market conditions. Extensive off-label use of the EPO might lead to a sharp drop in prices, which could also be affected by the launch of new competitive products. Also, launching competitive products on the market could affect the EPO's selling price. According to Management and the Company's medical advisors the selling price of the EPO drug will amount to approximately \$11,700 per treatment for an individual patient yearly, as a function of the required dosage and the drug's frequency of use.

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

#### *Revenues Expectancy's Forecast*

As described in the market overview section, the selling prices of other drugs for the treatment of Multiple Myeloma are significantly higher than the predicted selling price of the EPO drug (Revlimid - \$108,000 per year, Velcade - \$120,000 per year and Thalidomide - \$12,000 per year).

Accordingly, it was assumed that the selling price of the recombinant EPO drug will amount to \$11,700 per treatment for an individual patient yearly in each of the forecasted years, when the Company will be entitled to fixed royalty payments on sales by a large pharmaceutical company. This assumption is in line with Management's expectations.

### **Royalties Rate**

The total royalties paid to a R&D company for a drug depends on a variety of factors, and primarily:

- The risk level of the anticipated development;
- Future development costs and the company's financial position;
- Potential of market targeted by the drug;
- Competition level and substitute products available in the market.

Furthermore, as customary in this type of transactions, there is a certain exchange ratio between the advance payment/lump sum paid to the company at the time of signing the agreement, and the royalty rate payable to the company from future revenues.

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## Estimating an Impairment Loss of Intangible Asset

### Estimating IP Value in Use in the DCF Method

As the Company may reasonably sign a distribution agreement only after R&D completion (Phase III), the Company's management expects that given the commercial conditions prevailing in the market and once all the approvals have been issued, a lump sum of \$25 million (Hereinafter: the "**Down Payment**") will be paid to the Company along with a fixed royalty rate of 12.5% on EPO sales.

In order to base Management's Down Payment forecast we based on Recaps' data, as described in the following table:

Dollars in millions	Upfront
Phase II Deals	30
Phase III Deals	25
Average	28

Source: [www.recap.com](http://www.recap.com).

In order to base Management's royalty rate forecast, we based on number of data sources, as described in the following tables.

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## Estimating an Impairment Loss of Intangible Asset

### Estimating IP Value in Use in the DCF Method

The following table presents the average royalties rate in Phase III deals, as published by Medius:

Development Stage	Royalties Range
Pre-Clinical	0% - 5%
Phase I	5% - 10%
Phase II	8% - 15%
Phase III	10% - 20%
Launched Products	20%+

Source: [www.medius-associates.com](http://www.medius-associates.com).

The following chart presents the frequency of royalty rates paid by pharmaceutical companies:

Source: Nigel Borshell and Adrian Dawkes, "Pharmaceutical royalties in licensing deals: No place for the 25 per cent rule of thumb".

[http://www.palgrave-journals.com/jcb/journal/v16/n1/fig\\_tab/jcb200913f1.html#figure-title](http://www.palgrave-journals.com/jcb/journal/v16/n1/fig_tab/jcb200913f1.html#figure-title).

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

The following chart sets out the royalty rates actually paid per individual product, split according to the development phase in which the agreement was signed:

Source: Nigel Borshell and Adrian Dawkes, "Pharmaceutical royalties in licensing deals: No place for the 25 per cent rule of thumb"

. [http://www.palgrave-journals.com/jcb/journal/v16/n1/fig\\_tab/jcb200913f1.html#figure-title](http://www.palgrave-journals.com/jcb/journal/v16/n1/fig_tab/jcb200913f1.html#figure-title).

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## Estimating an Impairment Loss of Intangible Asset

## Estimating IP Value in Use in the DCF Method

The following table presents the Company's potential royalties from the sale of its recombinant EPO in the USA and in the rest of the world in the years 2019-2025 (Dollars in thousands):

Dollars in thousands	2019	2020	2021	2022	2023	2024	2025
The Company's Royalties Potential – USA							
Accumulated Patients	2,170	6,510	14,105	23,870	33,635	41,230	45,570
The Drug's Selling Price Per Patient	11.7	11.7	11.7	11.7	11.7	11.7	11.7
Total Drug's Sales	25,389	76,167	165,029	279,279	393,530	482,391	533,169
Royalties Rate	12.5 %	12.5 %	12.5 %	12.5 %	12.5 %	12.5 %	12.5 %
The Company's Royalties Potential – USA	3,174	9,521	20,629	34,910	49,191	60,299	66,646
The Company's Royalties Potential – Rest of the World							
Accumulated Patients	2,330	6,990	15,145	25,630	36,115	44,270	48,930
The Drug's Selling Price Per Patient	11.7	11.7	11.7	11.7	11.7	11.7	11.7
Total Drug's Sales	27,261	81,783	177,197	299,871	422,546	517,959	572,481
Royalties Rate	12.5 %	12.5 %	12.5 %	12.5 %	12.5 %	12.5 %	12.5 %
The Company's Royalties Potential – USA	3,408	10,223	22,150	37,484	52,818	64,745	71,560
The Company's Total Royalties Potential	6,581	19,744	42,778	72,394	102,009	125,044	138,206

**Revenues Expectancy**

As aforementioned, the Company's revenues forecast comprised of revenues from covenants, revenues from royalties in the USA and revenues from royalties in the rest of the world. Each of the mentioned categories was weighted by its accumulated probability to successes. At this manner, the predicted revenues from covenants were multiplied by the accumulated probability to success in Phase II and Phase III clinical trials and the predicted revenues from royalties were multiplied by the accumulated probability to success in Phase II and Phase III clinical trials and in the filling process.



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Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method**

We assessed the Company's success in the following drug development phases (Phase II, Phase III and registration with the authorities) on the basis of DiMasi's small molecule drugs<sup>19</sup> research, as described in the following table:

	Small Molecule Probability to Success Probability	Accumulated Probability	
Phase I	63 %	63	%
Phase II	38 %	24	%
Phase III	61 %	15	%
Filling	91 %	13	%

Source: DiMasi et Al. (2010).

As described in the market overview section, in light of the fact that the Company is developing a new indication for EPO, a drug that already exists and that has been approved for treatment of anemia, the Company expects to receive an exemption for the preclinical trials as well as from the Phase I clinical trial. Accordingly, based on DiMasi's data research the Company's probability of success in each of the development stages and the accumulated probability are, as described in the following table:

<sup>19</sup> There is a distinction between large molecule and small molecule. The Company's drug is a small molecule.

## Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method**

	Small Molecule Probability to Success		Accumulated Probability	
Phase II	38	%	24	%
Phase III	61	%	15	%
Filling	91	%	13	%

Furthermore, besides the probabilities of success of the said phases, we estimated the Company's prospects of obtaining Orphan Drug Designation in the rest of the world (as described in the company overview section, it received an orphan drug designation on May 2011). From discussions with Management and our own examinations it appears that the probability that the Company's drug will recognize as an orphan drug in Europe is higher thanks to the fact the Company's drug already recognized as an orphan drug in the USA. Accordingly, we estimated the probability that the Company's drug will recognized as an orphan drug in the rest of the world at 67%. Consequently, the Company's Accumulated probability to receive royalties was multiplied by this rate.

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## Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method**

The following table presents the Company's revenues expectancy from the sale of the recombinant EPO in the USA and in the rest of the world in the years 2018-2025 (Dollars in thousands):

Dollars in thousands	2018	2019	2020	2021	2022	2023	2024	2025
Revenue Expectancy								
Covenants Expectancy								
Down Payment	25,000							
Probability to Success	61 %	91 %						
Accumulated Probability	23 %	21 %						
Covenants Expectancy	5,795							
Revenue Expectancy – USA								
The Company's Potential Royalties		3,174	9,521	20,629	34,910	49,191	60,299	66,646
Accumulated Probability		21 %	21 %	21 %	21 %	21 %	21 %	21 %
Total Revenues Expectancy – USA		669	2,008	4,351	7,364	10,376	12,719	14,058
Revenues Expectancy – Rest of the World								
The Company's Potential Royalties		3,408	10,223	22,150	37,484	52,818	64,745	71,560
Probability to receive Orphan Drug Designation		67 %						
Accumulated Probability (Orphan Drug-Success in the Development Stages)		14.1 %	14.1 %	14.1 %	14.1 %	14.1 %	14.1 %	14.1 %
Total Revenues Expectancy – Rest of the World		482	1,445	3,130	5,298	7,465	9,150	10,113
Total Revenues Expectancy	5,795	1,151	3,453	7,482	12,661	17,481	21,870	24,172

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

#### *Expenses Expectancy*

#### **Cost of Phase II and Phase III Clinical Trails**

According to Management's estimation, the cost of Phase II clinical trial will amount to \$1.5 million, last 2.5 years, and spread evenly over the period between the fourth quarter of 2012 and the first quarter of 2015.

According to the Company's management estimation based on its medical advisors and conversations with companies in its field, which are in the stage of recruiting cancer patients for their Phase III clinical trial, the cost of Phase III clinical trial will amount approximately \$10-20 million and last 3-4 years. Accordingly, we assumed that the Company's Phase III clinical trial cost will amount to \$16 million (higher than the average range mentioned above) and spread evenly over the period between the second quarter of 2015 and the third quarter of 2018.

It should be emphasized that approval of clinical trials in Phase I, Phase II and Phase III requires the preliminary approval of the IRB/Helsinki Committee and of the regulatory health authorities in the countries where the trials are performed.

Only successful results in the advanced stages will ensure the possibility of moving from one phase to the next one. Following successful completion of the above (including Phase III), applications for approval of drug registration may be submitted to the relevant health authorities.

Accordingly, the Company's predicted Phase III clinical trial costs were multiplied by the Company's probability to success in Phase II clinical trial (the Company's predicted Phase III clinical trial costs are costs, which the Company must bear as it doesn't have to conduct Phase I clinical trial).



Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

#### **General and Administration Expenses**

Apart from the funds required to complete drug development as discussed above, the Company bear current expenses (excluding clinical trials costs) in connection with the Patent and the activity relating thereto.

According to the Company's budget for 2012, the total general and administration expenses in this year will amount to approximately \$ 1 million. These expenses include, among other: development expenses (meaning finding new technologies), management expenses on behalf of the EPO drug development, management expenses on behalf of a new drug (SAM-101) development in accordance to the exclusive license agreement with MinGuard, as described in the company overview section.

The Management estimates that the total amount of general and administration expenses, which are attributed to the EPO drug development, will be approximately \$500 thousands per year. Accordingly, it was assumed that the Company's general and administration expenses will total to approximately \$500 thousands in the projected years. The predicted general and administration expenses were multiplied by the Company's accumulated probability to success in the development stages and to receive an orphan drug designation in accordance with the relevant reference in each of the forecasted years.

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***Payments and Royalties to Yeda***

According to the licence agreement with Yeda, the Company will pay Yeda a one-time payment of \$ 350 thousands six months after the successful completion of Phase II of the clinical trial, and annual licensing fee of one percent (1%) of net sales of the EPO drug.

Accordingly, it was assumed that at the completion of Phase II clinical trial in 2015, the Company will pay Yeda a payment of \$350 thousands. This amount was multiplied by the probability to success in this clinical trial.

The Company's predicted royalties in each of the forecasted years was multiplied by the Company's accumulated probability to success in its clinical trials and the recognition of its drug as an orphan drug in the rest of the world, in accordance to the relevant reference in each of the forecasted years.

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## Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method**

The following table presents the Company's expenses expectancy on behalf of the recombinant EPO drug development, the current expenses and the payments to Yeda in the years 2012-2025 (Dollars in thousands):

Dollars in thousands	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Expenses Expectancy													
Cost Phase II													
Phase II Cost	150	600	600	150									
Probability Expectancy	100%	100%	100%	100%									
Cost Phase II	150	600	600	150									
Phase III Cost				3,429	4,571	4,571	3,429						
Accumulated Probability Expectancy				38%	38%	38%	38%						
Cost Phase III				1,303	1,737	1,737	1,303						
R&D Expenses (excluding clinical trails' costs) and G&A	500	500	500	500	500	500	500	500	500	500	500	500	500

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G&A Expenses																								
Accumulated Probability Expectancy	100%	100	%	100	%	38	%	38	%	38	%	23	%	18	%	18	%	18	%	18	%	18	%	18
R&D (excluding clinical trials' costs) and G&A Expenses																								
Expectancy																								
Payment to YEDA if Phase II is successfully completed																								
Probability Expectancy																								
Payment to YEDA if Phase II is successfully completed																								
Royalties																								
Expectancy																								
Royalties																								
Expectancy																								
Total Expenses	650	1,100		1,100		1,776		1,927		1,927		1,477		102		125		166		218		269		310
Expectancy																								

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

#### ***Taxes***

In the calculation of the after tax cash flows a 25% tax rate was taken into account, similar to the tax rate in Israel. It is important to indicate that in accordance with with international standards (IAS 36) the cash flows are presented before income taxes.

#### ***Investment Forecast***

#### **Fixed Assets Investment**

In conformity with international standards, future negative cash flows that improve or increase the asset's performance level, must not be taken into account when estimating the asset's value in use, and positive cash flows deriving from such investments must be neutralized. While it is necessary, in the context of cash flows, to take cash outflows necessary for maintaining the level of future projected economic benefits likely to derive from the asset in its present situation, however, in this case, we do not anticipate a need for investment in structures and/or office equipment and/or computers etc.

#### **Working Capital Investment**

There is no need for the Company to invest in working capital.

#### **WACC**

When applying the Income Approach, the cash flows expected to be generated by a business are discounted to their present value equivalent using a rate of return that reflects the relative risk of the investment, as well as the time value of money. According to IAS 36, while measuring the recoverable amount, no income tax receipts or payments should be included. Therefore, we should measure a Pre-tax discount rate. According to our estimation the pre-tax discount rate totals to approximately 25%..

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Estimating an Impairment Loss of Intangible Asset

### **Estimating IP Value in Use in the DCF Method**

This return, known as the weighted average cost of capital (“**WACC**”) is calculated by weighting the required returns on interest-bearing debt and common equity capital in proportion to their estimated percentages in an expected industry capital structure.

The general formula for calculating the WACC is:

$$\text{WACC} = K_d (D\%) + K_e (E\%)$$

Where:

**WACC**=Weighted average rate of return on invested capital;

**K<sub>d</sub>**=After-tax rate of return on debt capital;

**D%**= Debt capital as a percentage of the sum of the debt, preferred and common equity capital (“Total Invested Capital”);

**K<sub>e</sub>**=Rate of return on common equity capital; and

**E%**=Common equity capital as a percentage of the Total Invested Capital.

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## Estimating an Impairment Loss of Intangible Asset

### Estimating IP Value in Use in the DCF Method

CAPM has been empirically tested and is widely accepted for the purpose of estimating a company's required return on capital. In applying the CAPM, the rate of return on capital is estimated as the current risk-free rate of return on Israeli Governmental bonds, plus a market risk premium expected over the risk-free rate of return, multiplied by the "beta" for the valued company. Beta is defined as a risk measure that reflects the sensitivity of a company's stock (or capital) price to the movements of the stock market as a whole.

The CAPM rate of return on capital is calculated using the following formula:

$$K_e = R_f + \beta (R_m - R_f) + S_{CP} + S_p \text{ Where;}$$

**$K_e$** =Rate of return on capital (in this case, Total Invested Capital);

**$R_f$** =Risk free rate of return;

**$\beta$** =Beta or systematic risk for this type of capital investment (in this case, asset beta);

In order to calculate the beta we based on Damodaran's data on company's operating in the drug market and on comparable companies operating in the drug market (Celgene, ONYX Pharmaceuticals Inc., AstraZeneca PLC, Bristol-Myers Squibb Company and Novartis AG).

**$R_m - R_f$** =Market risk premium; the expected return on a broad portfolio of stocks in the market ( $R_m$ ) less the risk free rate ( $R_f$ ).

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Estimating an Impairment Loss of Intangible Asset

Estimating IP Value in Use in the DCF Method

SCPSmall cap premium - Ibbotson valuation edition 2011 yearbook

SpSpecific Premium

Since most of biotechnology companies are unleveraged the debt weight was determined to be 0%.

Following are the parameters that served for the calculation of the Company's WACC as of December 31, 2011:

Parameters	Symbolization	Value	Source
Beta		1.08	Damodaran and comparable companies
Rf	Rf	2.25 %	www.rbt.co.il
Risk Premium	Rm-RF	7.28 %	Israeli market risk premium as of 2012
Additional Risk Small Company	SRP	10.06 %	Ibbotson 2011
Additional Specific risk	SRP	2.00 %	Specific Risk Premium due to uncertainty in recruitment of financing source
Cost of Capital	Ke	22.2 %	$Rf + (Rm-RF) + SRP$
WACC	WACC	22.2 %	$(1-T) * Kd + (E/V) * Ke$

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## Estimating an Impairment Loss of Intangible Asset

## Estimating IP Value in Use in the DCF Method

The following table presents the IP's free cash flows forecast in the years 2012-2025 based on the assumptions detailed above (Dollars in thousands):

Dollars in Thousands	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Profit (Loss) Before Taxes	(650 )	(1,100)	(1,100)	(1,776)	(1,927)	(1,927)	4,318	1,049	3,328	7,316	12,444	17,572	21,5
Changes in Working Capital	—	—	—	—	—	—	—	—	—	—	—	—	—
Free Cash Flows	(650 )	(1,100)	(1,100)	(1,776)	(1,927)	(1,927)	4,318	1,049	3,328	7,316	12,444	17,572	21,5
Capitalized Cash Flows	(581 )	(786 )	(629 )	(812 )	(704 )	(563 )	1,009	196	497	874	1,188	1,342	1,31
Recoverable Amount	3,510												

As presented in the table above, the IP's recoverable amount is \$ 3,510 thousands.

\*Due to the fact that the date of the asset's amortization is unknown, we didn't take under consideration tax asset, which reflects the Company's future tax benefit.

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## Estimating an Impairment Loss of Intangible Asset

**Estimating IP Value in Use in the DCF Method***Sensitivity Analysis*

The following table presents the sensitivity analysis for the IP's recoverable amount, according to growth and discount rates (Dollars in thousands):

Royalties Rate	<b>Pre-Tax WACC</b>							
	22 %	23 %	24 %	25 %	26 %	27 %	28 %	
10%	3,331	2,800	2,325	1,900	1,518	1,176	870	
11%	4,037	3,444	2,913	2,437	2,009	1,626	1,281	
12%	4,743	4,088	3,501	2,973	2,500	2,075	1,693	
13%	5,449	4,732	4,088	3,510	2,991	2,524	2,104	
14%	6,155	5,376	4,676	4,047	3,482	2,974	2,516	
15%	6,861	6,019	5,264	4,584	3,973	3,423	2,928	
16%	7,567	6,663	5,851	5,121	4,464	3,872	3,339	

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Section 6

Determining an Impairment Loss

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## Determining an Impairment Loss

### Carrying Amount

In order to determine whether there is an impairment loss we compared the IP's recoverable amount to its carrying amount.

If, and only if, the recoverable amount of an asset is less than its carrying amount, the asset shall be reduced to its recoverable amount.

## **Determining an Impairment Loss**

Based on our study the IP's recoverable amount is higher than its carrying amount, and therefore we have concluded that the Company's IP isn't deemed to be impaired

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