

XTL BIOPHARMACEUTICALS LTD
Form 6-K
March 30, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

Report of Foreign Private Issuer

**Pursuant to Rule 13a-16 or 15d-16
of the Securities Exchange Act of 1934**

For the month of March, 2012

Commission File Number: **000-51310**

XTL Biopharmaceuticals Ltd.
(Translation of registrant's name into English)

**85 Medinat Hayehudim St., Herzliya
Pituach, PO Box 4033,**

Herzliya 46140, Israel
(Address of principal executive offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):
82- N/A

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. dated March 30, 2012 is hereby incorporated by reference into the registration statements on Form F-3 (File No. 333-141529, File No. 333-147024 and File No. 333-153055) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007 , October 30, 2007 and August 15, 2008, respectively, and the registration statements on Form S-8 (File No. 333-148085, File No. 333-148754 and File No. 333-154795) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on December 14, 2007, January 18, 2008, and October 28, 2008, respectively.

XTL Biopharmaceuticals Ltd. (the “Company”) Presents Its Translated From Hebrew Financial Statements For The Year Ended On December 31, 2011

Attached hereto is an English translation (from Hebrew) of our financial statements and additional information as submitted on Tel Aviv Stock Exchange. The following documents are included:

1. Chapter A – Description of the Company's Business for the year ending December 31, 2011.
2. Chapter B – Board of Directors' Report on the Status of the Company for the Year Ending December 31, 2011.
3. Chapter C – Consolidated Financial Statements as of December 31, 2011, incorporated by reference from Form 20-F filed by XTL Biopharmaceuticals Ltd. on March 29, 2012, as amended.
4. Chapter D – Additional Company Information.
5. Chapter E – Report on the Effectiveness of Internal Control Over the Auditing of Financial Statements and Disclosures.
6. Chapter F – Separate Financial Information in accordance with Article 9c of the Israeli Securities Regulations (Periodical and Immediate Reports).

Chapter A
Description of the Company's Business for the Year ending December 31, 2011

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**Chapter A –
Description of the Company's Business**

1. **Glossary**

1.1 For the purpose of this report, the following terms will be defined as follows:

Multiple Myeloma Multiple Myeloma is one of the forms of blood cancer diseases comprising 10% of all blood cancers and approximately 1% of all malignancies. The disease is characterized by an uncontrollable proliferation of white blood cells of plasma cells type in the bone marrow that result in the formation of malignant cells that damage and destroy parts of the bone. The disease is multiple in its nature as reflected in the formation of a large number of malignant cells. The malignant cells and the secreted proteins are responsible for a series of clinical expressions and complications including bone damage accompanied by pain and fractures, bone marrow damage with anemia (blood deficiency), sensitivity to infections, weakened immune system, damage to the nervous system, renal failure, clotting mechanism disorders, etc. Multiple Myeloma is incurable. Patients diagnosed with the disease have an average life expectancy of 4-5 years.

Plasma Cells A group of cells comprising approximately 2-5% of all white blood cells in the human body. The plasma cells produce immunoglobulin proteins in the body that serve as antibodies in the immune system.

Erythropoietin - EPO A hormone produced in the human body by the kidneys. Its known role is to induce the formation of red blood cells in the bone marrow.

Recombinant EPO (Recombinant Erythropoietin) A genetically engineered hormone that is primarily designed to act against various types of anemia, particularly anemia experienced by patients with renal failure (and who are being treated with dialysis), as well as patients suffering from various forms of cancer accompanied by anemia.

Stem Cells	<p>Stem cells are undeveloped cells that produce the three types of blood cells. Most stem cells are found in the bone marrow, but some – known as Peripheral Blood Stem Cells (PBSC) – are collected from the bloodstream.</p> <p>Self (autologous) transplant – the patient receives stem cells from his/her own bone marrow or from his/her peripheral blood.</p>
Neuropathy / Peripheral Neuropathy	<p>Damage to the functioning of the nerves responsible for transmitting sensations from the fingertips and legs. In mild cases, neuropathy might cause a feeling of numbness in the hands and feet. In severe cases, pains and stabbing sensation throughout the body to the point where it interferes with the extremities' functioning and movement.</p>
T-Lymphocytes	<p>Cells (white blood cells) in the circulatory system that serve as an important component of the immune system. Operates in several ways and is responsible for helping the body fight infections, malignant cells, etc.</p>
Anticancer Effect	<p>Anticancer effect is any phenomenon that causes cancer cells to stop reproducing, that eliminates them or 'freezes' their growth and spreading.</p>
Schizophrenia	<p>A severe chronic (psychotic) mental illness which is one of the most prevalent mental diseases. It affects most of the mental and social functions, the state of mind, perception and thought as well as cognitive functions.</p>
Antipsychotic Drugs	<p>Drugs used to treat psychotic disorders such as schizophrenia and bipolar disorder. These drugs do not cure the disorder but rather manage the psychotic symptoms arising from the disease such as hallucinations and delusions. The drugs are classified into two main categories: typical, also known as first-generation drugs and atypical, also known as second-generation drugs which are more efficient.</p>

Psychosis	An abnormal mental state often described as involving a complete or partial "loss of contact with reality". Psychosis is characterized by behavior perceived as strange or irregular and incomprehensible which might sometimes arouse feelings of anxiety and social rejection.
Bipolar Disorder	A mental illness which causes dramatic mood swings and sparks manic-depressive episodes.
Minocycline	<p>A broad-spectrum tetracycline antibiotic that has been used for over 20 years and today is mainly used to treat acne.</p> <p>Minocycline is a small molecule with a molecular weight of 495 that is highly lipophilic and can therefore easily traverse the blood-brain barrier.</p>
Helsinki Committee	A committee that operates by virtue of the Public Health Regulations (Clinical Trials on Human Subjects), 1980 and that is responsible for approving and monitoring clinical trials – for additional information, see Article 17.1 below.
IRB	Institutional Review Board – the corresponding committee to the Helsinki Committee in the US and around the world.
FDA	Food and Drug Administration – the agency in the United States that inspects and regulates development and registration of drugs in that country.
EMA	European Medicines Agency – the European agency responsible for regulating the development and registration of drugs in the EU member nations. To date, approximately 35 countries are members of the EMA ¹ .
Serious Adverse Events	Serious Adverse Event (SAE) or Serious Adverse Drug Reaction – any troublesome clinical event, in any dosage, that results in death or causes life-threatening complications or that requires hospitalization or further hospitalization or that ends in a permanent disability or handicap.
Activity	The laboratory or clinical result that provides an indication of the clinical efficacy of the drug.

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Based on information in the organization's website -

<http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm>.

Efficacy Proof of the clinical effect of the drug in human clinical trials.

Orphan Drug A special track for approval and marketing of pharmaceutical preparations by the American Food and Drug Administration, the FDA. The track is designed to respond to the need to develop drugs for certain populations and for incurable and relatively rare diseases (in the US – diseases with a maximum number of patients of 200,000 and in the EU – diseases that occur in up to 5 patients out of 10,000 patients). Recognition of a drug as an orphan drug grants the manufacturer with a regulatory exclusivity in marketing the drug for a period of 7 years in the US and of 10 years in the EU.

Ethical Drug A patent-protected drug that can only be manufactured and sold by the pharmaceutical that developed it.

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2. **Description of the General Development of the Company's Business**

2.1

General

The Company was incorporated in Israel on March 9, 1993 as a private company in accordance with the Israeli Companies Law, 1999 ("**the Companies Law**"), under the name Xenograft Technologies Ltd. On 3 July 1995, the Company changed its name to XTL Biopharmaceuticals Ltd., with its defined objectives being the practice of any legal activity. As of the date of this report, the Company is engaged in the development of drugs, among others for the treatment of unmet medical needs as well as improvement of existing medical treatments and business ventures in the medical industry.

In September 2000, the Company's shares were listed on the London Stock Exchange and the Company raised approximately US\$ 50.9 million in a public offering. In August 2004, the Company raised US\$ 17.8 million in another offering on the London Stock Exchange. Between that date and October 2007, the Company's shares were listed for trade on the London Stock Exchange. In October 2007, the Company's shares were delisted from trade on the London Stock Exchange.

In July 2005, immediately following the amendment of the third addendum of the Securities Law, 1968 ("**the Law**") and the addition of the London Stock Exchange as the stock exchange from which a dual listing can be carried out, the Company performed a dual listing of its shares on the Tel-Aviv Stock Exchange Ltd. ("**the TASE**"). Since that date and to the date of this report, the Company's shares are listed for trade on the TASE. Accordingly, since the date of its listing for trade on the TASE and until July 2009, the Company filed reports in compliance with the provisions of foreign law (by virtue of Chapter E3 of the Law). For more information, see the immediate report published by the Company on 7 July 2005.

On 1 September 2005, the Company filed an application for listing the Company's American Depositary Receipts ("**ADRs**") on the Nasdaq under the Nasdaq Global Market list with the Securities & Exchange Commission in the United States ("**the SEC**"). Beginning on that date and until 17 April 2009, the Company's ADRs were traded on the Nasdaq. For more information, see the immediate report published by the Company on 17 April 2009.

In 2005, the Company acquired from VivoQuest Inc. ("**VivoQuest**") an exclusive worldwide and perpetual license to use VivoQuest's intangible assets, covering a compound library including certain compounds ("**DOS**") for the treatment of Hepatitis C, and other assets. In the course of 2008, the Company sublicensed the use of the DOS technology to Presidio Pharmaceuticals Inc. ("**Presidio**"). For further information on the Company's engagement, see item 18.2 below and also the immediate report published by the Company on 20 March 2008.

In March 2006, the Company raised approximately US\$ 28 million in a private placement in consideration for the allocation of 4.7 million ADRs and 4.7 million options (to acquire 4.7 million Company shares following the capital consolidation effected in June 2009, or 2.3 million Company ADRs). It should be noted that all the said options expired on 22 March 2011.

In November 2007, the Company raised approximately US\$ 9.8 million in a private placement in consideration for the allocation of 14.5 million Ordinary shares of the Company of NIS 0.1 par value each (following the capital consolidation effected in June 2009).

In July 2009, the Company's shares were delisted from trade on the Nasdaq due to a claim by the Nasdaq Audit Committee that the Company had failed to comply with some of the listing criteria. Shortly after, the Company's ADRs began being quoted over the counter ("**OTC**"²) on the Pink Sheets, and accordingly, from this date on, the Company files reports in accordance with Chapter F of the Securities Law as well as reports 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 delisting of the Company's ADRs from the Nasdaq, the Company is no longer subject to the Nasdaq provisions (for more information, see the immediate report published by the Company on 12 July 2009).

² The OTC is an electronic quoting system between brokers that displays quotes, prices and trading volumes of securities traded over the counter.

Despite the aforementioned, as of the date of this report, the Company is listed for trade on the SEC as a reporting company and is therefore required to issue reports to the SEC in accordance with the U.S. Securities Exchange Act of 1934 provisions. Since the Company is not incorporated in the US, these requirements consist of the filing of a 20-F report (annual report for a foreign company) once a year as well as immediate reports regarding any changes in the Company's capital structure. As a result, the Company incurs expenses attributed to reporting requirements to the SEC, as aforementioned, that include, inter alia, the cost of legal advisors in the US, Bank of New York (BONY) costs, and other various costs that were estimated, at the time of this report, at US\$ 100,000 a year. The Company's costs mentioned above are as of the date of the report only. Said costs might change in the future based on a change in status, the Company's market value and size and/or in accordance with changes in provisions and reporting obligations imposed on the Company, as the case may be from time to time.

The Company holds 100% of the issued and paid-up share capital of XTL Biopharmaceuticals Inc. ("**XTL Inc.**"), a US company 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. ("**XTEPO**"), which was founded in Israel in November 2009.

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 discontinued the research and development plans of these drugs (with the exception of the development of DOS technology, see information in this item) and an agreement was signed with Yeda Research and Development Ltd. (the commercial arm of the Weizmann Institute of Science) ("**Yeda**") for the recovery of all the rights to the Company's original technologies. For additional information, see the Company's reports from 6 June 2007 and from 29 March 2007.

XTL Inc. was involved in the development of activities and business pertaining to pharmaceutical development. XTL Inc. has a wholly-owned subsidiary, XTL Development Inc. ("**XTL Development**"), which was founded in 2007 in accordance with the laws of the State of Delaware and was involved in business development, pharmaceutical development and primarily in clinical trial management of Bicifadine, a drug for treating 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. ("**DOV**") to obtain an international license for the Bicifadine. For information about this agreement, see the Company's report from 16 January 2007.

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 a reorganization process in order to develop the Company's business ("the plan"). The plan included, inter alia, terminating most of the Company's employees (who were then employed in the Bicifadine development project), engaging in investment activities, collaborations and acquisitions of holdings particularly in companies involved in applicable life science research and in pharmaceutical research and development (biotechnology and pharmaceuticals). For more information about the plan, see the Company's report from 9 December 2008.

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 the date of this report, 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 a sublicense to Presidio in 2008 for a cash payment, development milestone payments totaling US\$ 59 million by Presidio and royalties from sales. For information about said agreement, including milestones and actions adopted by the Company to control progress in development, see item 18.5 below.

On 19 March 2009, the Company entered into an agreement with Bio Gal Ltd. ("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, the latest being until 31 August 2010, in order to enable completion of the transaction, which was consummated on 3 August 2010 (see below).

On 31 December 2009, the Company's board of directors approved the Company's agreement to acquire 100% of the shares of XTEPO, a private Israeli company founded by the shareholders of 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 US\$ 1.5 million by 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's shareholders against 100% of their holdings in XTEPO by issuing the Company's Ordinary shares in an extraordinary private placement in accordance with the Securities Regulations (Private Placement of Securities in a Listed Company), 2000 to XTEPO's shareholders ("**share swap agreement**") that was approved by an extraordinary shareholders' meeting on 2 March 2010 so that upon completion of said share swap agreement, XTEPO's shareholders held (along with their holdings of Company shares on the eve of the share swap agreement) approximately 70.64% of the issued and paid-up share capital of the Company and the balance, of 29.36%, was held by the Company's shareholders on the eve of implementation of the share swap agreement. The consummation of the share swap agreement was subject to meeting certain prerequisites which had been completed on 3 August 2010 as well as all the measures required as per the share swap agreement.

On 27 February 2011, the Company published a prospectus ("**the prospectus**") for completion on the TASE in which the Company offered up to 13,210,000 Ordinary shares of NIS 0.1 par value each of the Company and up to 6,605,000 registered warrants (Series 1), exercisable into up to 6,605,000 Ordinary shares of the Company during every trading day on the TASE, from their listing date on the TASE through 27 November 2011, and up to 19,815,000 registered warrants (Series 2), exercisable into up to 19,815,000 Ordinary shares of the Company during every trading day on the TASE, from the listing date on the TASE through 27 February 2013. For more information, see item 1.1 to the Company's board of directors' report and the Company's report from 27 February 2011.

On 7 March 2011, and in accordance with the prospectus published by Company as above, the Company published a supplementary notice which, inter alia, reduced the number of securities being offered by the Company in accordance with the prospectus to up to 10,700,000 Ordinary shares of NIS 0.1 par value each of the Company and up to 5,350,000 registered warrants (Series 1), exercisable into up to 5,350,000 Ordinary shares of the Company during every trading day on the TASE, from their listing date on the TASE through 27 November 2011 and up to 16,050,000 registered warrants (Series 2), exercisable into up to 16,050,000 Ordinary shares of the Company.

On 7 March 2011, the Company published an immediate report regarding the results of the bid in accordance with the aforementioned supplementary notice ("**the bid**") as detailed below:

58 orders were received in the bid to purchase 79,004 units with a total monetary value of NIS 10,553,017.

Excess demand in the offering was 185% higher and the unit price set in the bid was NIS 132.25.

In addition, 19 orders were fully met to purchase 19,953 units at a unit price that is higher than the unit established in the bid.

2 orders to purchase 30,600 units at the price per unit established in the bid were partially met such that each of the investors received 74.66% of their order.

37 orders to purchase 28,451 units at a unit price that is lower than the price set forth in the bid were not met.

The number of units ordered at unit price or higher or at a higher price exceeded the total units offered, resulting in oversubscription. Accordingly, the Company exercised its right to allocate additional units as stipulated in Article 2.2.6.2 of the prospectus and Article 1.4 of the supplementary notice discussed above ("**the additional allocation**"). Within the confines of the additional allocation, the Company allotted 6,420 units to ordering parties who submitted the orders at the established unit price, and 95.64% of their orders were met.

Total immediate consideration (gross) the Company received for the securities offered to the public in accordance with the supplementary notice, including the additional allocation, amounted to NIS 6,509,345.

On 24 March 2011, the Company entered into a term sheet to acquire the activity of MinoGuard Ltd. ("**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. MinoGuard was founded in 2007 in order to commercialize combination therapies for treating psychotic diseases, focusing on schizophrenia.

To the best of the Company's knowledge, based on the estimates of the United States National Institute of Mental Health, about 1.1% of the adult population in the United States has schizophrenia. According to Decision Resources, the research company, the schizophrenia treatment industry in 2010 amounted to approximately US\$ 6.4 billion³.

On 30 November 2011, the Company reported that it had closed an agreement for obtaining an exclusive global license to MinoGuard's entire technology. See more details about the exclusive license in item 18.1 below.

On 21 April 2011, the Company announced that on 20 April 2011, it had applied to the 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 for which it owns a patent through 2019. On 29 May 2011, the Company announced that it was granted an orphan drug designation from the FDA for its EPO (which is in planning and preparation towards Phase 2 clinical trial).

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<http://decisionresources.com/Products-and-Services/Reports?r=pcorcg0711>.

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On 2 November 2011, the Company entered into a term sheet by which it will acquire the NiCure technology ("**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 signing of the agreement by the parties is subject to, among others, the completion of a due diligence study, 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 Phase 2 clinical trial for the continuance of the clinical development as the drug mentioned above was approved for the treatment of reducing hypertension and is being provided to patients for already 20 years. As of the date of the approval of this report, the transaction has not been closed.

2.2 Below is a chart of the Company's holding structure as of the date of this report:

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2.3

Information about XTEPO

XTEPO is a private company incorporated and registered in Israel on 9 November 2009, in accordance with the Companies Law.

2.4. As of the date of this report, the U.S. companies XTL Biopharmaceuticals Inc. and XTL Development Inc. are inactive.

3.

Areas of activity

As of the date of this report, the Company (the Company and the subsidiary XTEPO collectively - "**the Group**") is focused on planning, research and development activities for the commercialization of the technologies owned by it as detailed below.

3.1

The Group's drugs

Recombinant EPO

Recombinant EPO is a drug that, as of the date of this report, is 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 the date of this report, the Group began preparing for a Phase 2 clinical trial on Multiple Myeloma patients in Israel and in other countries, in accordance with the clinical protocol that was received as part of the Bio Gal deal and that will be updated by the Company ahead of its approval by the FDA and other ministries of health as the case may be. The protocol is based on the information that was collected about the use of recombinant EPO and the expectation that it may prolong the life of Multiple Myeloma patients while significantly improving their quality of life and causing less side effects than currently available treatments.

SAM-101

SAM-101 is a technology developed for treating mental illnesses based on a combination of existing antipsychotics and a recognized medicinal compound (Minocycline). The drug had been developed prior to its acquisition by the Company by MinoGuard, which, to the best of the Company's knowledge, had successfully completed a Phase 2a prospective, randomized, double-blind, placebo-controlled, clinical trial conducted on about 70 schizophrenics in the Shalvata Mental Health Hospital. To the best of the Company's knowledge, the trial's endpoints were met, demonstrating 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 effect among patients. As of the date of this report, the Company intends to conduct clinical trials, develop, register, market, distribute and sell the drugs which are the product of this technology, regardless of the type of disease.

3.2

Drug development process - general description

Drug development is a complex process that generally includes the following primary stages⁴. 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 effects and a) 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).

⁴The description of the stages is general and changes might be made in various drugs. For example, in certain circumstances, Phases 1 and 2, or occasionally 2 and 3 might be merged.

Phase 1 - 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.

Phase 2 - 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. Several Phase 2 trials are often carried out while the first Phase 2 trial (Phase 2a) is designed to serve as proof of concept and the second Phase 2 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 3 – 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 1, Phase 2 and Phase 3 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. Once all of the said phases (including completion of Phase 3) have been successfully completed, the Group can submit an application for approving the drug's registration by the relevant regulatory agency, e.g. the FDA in the U.S.

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.

4. **Investment in the Company's capital and shares transactions**

With the exception of the execution of the share swap agreement stipulated in item 2.1 above and the Company's offering of shares and options on 7 March 2011 through an Israeli prospectus in which one of the interested parties participated - Mr. Alexander Rabinovich (see item 2.1 above), in the two years preceding the date of this report, no investments were made in the Company's share capital and no material transactions were carried out by any of its interested parties.

5. **Distribution of dividends**

Since the date of the Company's establishment through the date of this report, the Company has not distributed any dividends and the Company has no profits regarding the profit criterion as stipulated in Article 302 of the Companies Law.

As of the date of this report, the Company does not have a dividend distribution policy.

Chapter Two - Additional Information

6. Financial information about the Group's areas of activity

As of the date of this report, the Company is planning and preparing for the implementation of the Phase 2 clinical trial on the Recombinant EPO drug designed to treat Multiple Myeloma cancer patients (see more details about the EPO drug in Chapter Eight 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 Recombinant EPO drug. The Company also intends to conduct clinical trials and develop the SAM-101 technology which was acquired in the MinoGuard transaction for treating mental disorders with a focus on schizophrenia and combine other technologies as part of the Company's strategy to expand its technological offerings. Below is financial information about the Group:

	Condensed consolidated statements of financial position (US\$ in thousands)	
	31 December 2011	31 December 2010
Total assets	4,073	3,797
Total liabilities	629	963
Equity	3,444	2,834

	Condensed consolidated statements of comprehensive income (loss) (US\$ in thousands)		
	Year ended 31 December		
	2011	2010	2009
Research and development costs	158	64	-
General and administrative expenses	1,078	1,222	(2,429)*)
Other income, net	12	30	139
Operating income (loss)	(1,224)	(1,256)	2,568

*) Includes reduced expenses due to forfeiture of options to shares depending on performance of the Company's former CEO and former Chairman (see also Note 16b to the consolidated financial statements for 2011).

For details and explanations about the Company's operating results and changes that have taken place during the reporting period, see the Company's board of directors' explanations about the state of the Company that are attached as Part B of this report.

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7. General environment and impact of external factors on the Group's operations

The biopharmaceutical industry which is the focus of the Group's products is facing an increasing need for new developments to treat patients of various diseases. Despite the progress of the pharmaceutical industry in general, and its impressive achievements over the past several decades, as of the date of this report, drugs for many diseases, including various cancers and schizophrenia, are still insufficient 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 different patients in general increases the need for new drugs in the fields underlying the Company's products.

As good as any drug may be in alleviating the symptoms of the disease, they are not efficient in all patients. Frequently, many patient populations lack an efficient drug to treat their disease or the phase of the disease that they are in. Furthermore, the drug often positively affects the patient for a certain period of time but then its positive effect wanes. In addition, many drugs trigger extremely serious side effects that occasionally prevent patients from taking the drug and even a market that offers a large variety of drugs is constantly in need of introducing new drugs.

The target markets of the Group's drugs is unique. The Group 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.

In light of the fact that the Group is developing a new indication for the Recombinant EPO, a drug that already exists and that has been approved for treatment of anemia, the Group expects to receive an exemption for the preclinical trials as well as from the Phase 1 clinical trials. As of the date of this report, the Group has a preliminary plan to initiate Phase 2 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 plan, the Company immediately began after the 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.

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 Group 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. In addition, the Group 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.

In addition, the SAM-101 technology successfully completed a Phase 2a prospective, randomized, double-blind, placebo-controlled clinical trial conducted on about 70 schizophrenics in the Shalvata Mental Health Hospital in Israel. To the best of the Company's knowledge, the trial's endpoints were met, demonstrating 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 effect among patients. The Group intends to continue developing the SAM-101 technology which is based on a combination of existing antipsychotics and a recognized medicinal compound (Minocycline).

The Group anticipates that if the clinical trials reinforce the Phase 2a clinical trial results as described above, the SAM-101 drug is expected to capture a significant market share in the schizophrenia drug industry mainly due to the side effects of consuming the existing drugs and due to the limited efficacy of the existing drugs in treating the negative and cognitive symptoms of schizophrenia patients. Decision Resources, the research company, estimated the size of the schizophrenia treatment industries in the U.S., France, Germany, Italy, Spain, the UK and Japan in 2010 at approximately US\$ 6.4 billion ⁵.

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<http://decisionresources.com/Products-and-Services/Reports?r=pcorcg0711>.

Due to the partial success of new drugs which have recently been introduced into the market and the loss of the patents for the leading ethical drugs by large pharmaceutical companies such as Eli Lilly, the Group anticipates that the commercialization of the SAM-101, if and when it occurs, will achieve a significant market share of the schizophrenia treatment industry, 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 Group not succeeding in its attempts to continue to demonstrate the efficacy and safety of the drugs or that the drugs 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 Group's drugs cannot be ruled out.

The Group's assessments regarding the potential of the Company's drugs to capture a large market share in the Multiple Myeloma and schizophrenia drug markets represent forward-looking information. This information is uncertain and based on the information the Group has as of the date of this report. It will be emphasized that the results of the trial phases that will be conducted in practice might significantly differ from the estimates based on this information, since the continued successful development of the Group's drugs is uncertain.

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Chapter Three - Description of the Group's Business in its Field of Operations

8. General information about the Group's areas of activity

Listed below is a detailed description of the Group's business operations including a description of trends, events and developments in the Group's macroeconomic environment that have or are expected to have a significant impact on the Group's business.

8.1 General

8.1.1 The study by Prof. Mittelman in the field of Multiple Myeloma

The clinical observations, carried out under the leadership of Prof. Mittelman, who serves as the Group's Medical Director, of patients in advanced stages of Multiple Myeloma and their analysis revealed that treatment with Recombinant EPO extended the lives of some of the patients beyond what was expected in their condition if they hadn't received the treatment. The results and conclusions derived from said observations were later examined under lab conditions in mouse models for multiple myeloma, which revealed that Recombinant EPO has an anticancer effect based on its effect on the activation of T lymphocytes in the immune system.

These finding ⁶ raised the premise that Recombinant EPO affects the immune system, regardless of the cancerous tumor.

⁶ The findings were published by Prof. Mittleman et al - 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; 72: 155–165. _ Blackwell Munksgaard 2004.

Another study conducted by the study team of Prof. Mittelman revealed prominent changes in various immune system parameters in Multiple Myeloma patients in advanced stages of the disease, and that treatment of these patients with Recombinant EPO resulted in improvements in their immune system in terms of its components and in terms of function, a fact that contributes to the prolonged lives of these patients.

It should be noted that in 2006, a study was published by the Cleveland Clinic and H. Lee Moffitt Cancer and Research Institute ⁷, which retrospectively examined 257 patients who were administered EPO to treat their anemia, that verified the findings of Prof. Mittelman's group – the general survivability of patients treated with EPO improved. The study concluded that a random prospective study would guarantee verification of these findings.

It should be noted that, in addition to the aforementioned, over the past decade, Prof. Mittelman and his research team published several articles on EPO treatment of patients with Multiple Myeloma ⁸.

R. Baz, E. Walker, T.K. Choueiri, R. Abou Jawde, C. Brand, B. McGowan, E. Yiannaki, S. Andresen, M.A. Hussein
⁷- Recombinant Human Erythropoietin Is Associated with Increased Overall Survival in Patients with Multiple Myeloma, *Acta Haematol* 2007;117:162–167, DOI: 10.1159/000097464.

⁸

The published articles are listed below:

(1) Erythropoietin treatment in advanced multiple myeloma is associated with improved immunological functions: could it be beneficial in early disease? doi:10.1111/j.1365-2141.2006.06366. *British Journal of Haematology*, 135, 660–672.; (2) Erythropoietin effects on dendritic cells: Potential mediators in its function as an immunomodulator? doi: 10.1016/j.exphem.2008.07.010. Society for Hematology and Stem Cells. Published by Elsevier Inc.; (3) Erythropoietin as an Immunotherapeutic Agent: New Uses For An Old Drug? *Medical Hypotheses and Research*, VOL. 2, NO. 4, October 2005.; (4) Erythropoietin enhances immune responses in mice. DOI 10.1002/eji.200637025. *Eur. J. Immunol.* 2007. 37: 1584–1593.; (5) Non-erythroid activities of erythropoietin: Functional effects on murine dendritic cells. doi:10.1016/j.molimm.2008.10.004. *Molecular Immunology* 46 (2009) 713–721.

8.1.2 The study of Prof. Yehiel Levkovitz and Dr. Shlomo Mendelovic in the field of mental illnesses

Minocycline has the ability to penetrate the central nervous system at an effective clinical level in addition to its microbial feature. It was discovered that the drug has neuro-protective agents in models of ischemic stroke, Multiple Sclerosis, spinal cord injuries, Parkinson's and Huntington's.

Following in vivo studies which demonstrated the efficacy of treating schizophrenic rat models with recognized antibiotics⁹ in 2004, Prof. Levkovitz and Dr. Mendelovich received a grant from the Stanley Foundation for investigating the neuro-protective effect of Minocycline in the early stages of the development of schizophrenia in humans. A prospective, randomized, double-blind, placebo-controlled clinical trial administered Minocycline to about 70 schizophrenics in the Shalvata Mental Health Hospital in Israel in addition to an antipsychotic which was administered to 2/3 of the subjects. A control group consisting of 1/3 of the patients in the trial was administered both an antipsychotic and a placebo. The antipsychotics included Risperdal, Zyprexa, Geodon, Seroquel and Leponex. In a trial conducted over a period of six months, each patient was tested for the effect of the Minocycline on various clinical and cognitive parameters.

The trial results showed that a combination of antipsychotics and Minocycline improves the positive symptoms, cognitive functions and reduces the negative symptoms and side effects of the antipsychotics (such as weight gain). The trial concluded that the proposed combined treatment enhances the regular drug that is currently offered to schizophrenia patients and is likely to slow down the clinical deterioration¹⁰.

⁹ Levkovitz Y., Levi U., Braw Y., and Cohen H., (2007) Brain Research, 1154: 154-162.
¹⁰ Levkovitz Y, Mendlovich S, et al. J. Clinical Psychiatry.

Three independent groups of researchers (from the universities of Manchester, England, Japan ¹¹ and Maryland) who have been studying the combination of these drugs have also reached similar conclusions to those of Prof. Levkovitz and Dr. Mendelovich.

8.2 Structure of the Group's operations and changes therein

8.2.1 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 4-5 years.

The National Cancer Institute estimates that in the U.S. alone, all newly diagnosed cancers in 2011 will reach 1.6 million (approximately 0.5% of the population), with the number of cancer-related deaths totaling 0.6 million (approximately 0.2% of the population) ¹². Of all forms of cancer currently known, the most common forms in the U.S. ¹³ are intestinal cancer (approximately 101,000 new patients a year), lung cancer (approximately 221,000 new patients), breast cancer in women (approximately 233,000 new patients) and prostate cancer in men (approximately 241,000 new patients).

¹¹ Miyaoka T et al. Clinical Neuropharmacology 31, October 2008.

¹² The data is taken from the National Cancer Institute in the U.S. (NCI) - <http://www.cancer.gov/cancertopics/what-is-cancer>.

¹³ The data is taken from the Cancer Facts & Figures 2011 report published by the American Cancer Society.

Multiple Myeloma is a blood cancer that comprises 10% of all blood cancers. As of the date of this report, in the U.S. alone there are 74,800 Multiple myeloma patients. Every year, about 20,520 new cases are diagnosed ¹⁴. This number increases in direct proportion with the average life expectancy around the world. Accordingly, approximately 10,610 patients died from Multiple Myeloma in the U.S. in 2011. 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 ¹⁵. In addition, it should be noted that Multiple Myeloma is extremely common among men, and within this group, men of African descent have twice the chance of contracting the disease over Caucasian men.

As of the date of this report, 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 specific to cancer cells that are known to have milder adverse events than chemotherapy such as Thalidomide ® ("**Thalidomide**") and Revlimid, both manufactured by Celgene Corporation and Velcade ®, developed by Millennium Pharmaceuticals ("**Velcade**"). 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.

¹⁴ The data is taken from the Facts 2012 report published by the Leukemia & Lymphoma Society.

¹⁵ The data is taken from the website of AMEN, the Israeli Association of Myeloma Patients (http://www.amen.org.il/site_files/index.he.1024.html).

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 tumors 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 Group intends to develop for Recombinant EPO in the treatment of patients with multiple myeloma will try to provide a certain response to this need, i.e.: an efficacious drug that does not cause significant side effects.

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8.2.2

Schizophrenia

Schizophrenia is a syndrome of psychiatric illnesses that are characterized by psychosis and cognitive, perceptual, emotional and behavioral deficiencies which are liable to impair human functions at various levels. According to the U.S. National Institute of Mental Health ("NIMH")¹⁶, schizophrenia is one of the most prevalent mental disorders and about 1.1% of the adult population in the U.S. suffers from schizophrenia during their lifetime. The disease usually erupts before the age of 25 and is partly related to the side effects of antipsychotic drugs. The disease's main symptoms consist of unrealistic delusions, sight and hearing disorders and more rarely visual hallucinations. The symptoms also affect thought patterns and cause bizarre speech patterns. These symptoms lead to different degrees of dysfunctions and distress. Therefore, schizophrenia patients are often in need of assistance in their daily routine such as housing, occupation, society etc.

Schizophrenia is a chronic illness that requires lifelong medicinal treatment. While most available drugs are efficacious in alleviating the "positive" symptoms (which are evident and will not appear in non-schizophrenics such as hallucinations and delusions), even the best available drug is only partially efficacious in treating several of the disease's more disturbing symptoms known as the "negative" symptoms (the absence of symptoms that are commonly evident among schizophrenics, relating to the abnormal behavior and emotions such as lack of feelings or expressions of feelings, withdrawal from family life and from society, lack of energy, lack of motivation, loss of pleasure or interest in life, poor hygiene, numbness to the point of catatonia etc.) as well as cognitive symptoms.

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<http://nimh.nih.gov/health/topics/schizophrenia/index/shtml>.

As of the date of this report, since the factors that cause schizophrenia are yet unknown, the market does not offer the appropriate drugs that can prevent the disease. The currently available drugs for treating the symptoms of the disease generally involve severe side effects.

Antipsychotic drugs consist of Chlorpromazine, Perphenazine, Thioridazine, Haloperidol, Lithium and others, used to treat schizophrenia, dementia and manic depression. These drugs are considered typical antipsychotic drugs.

In addition to the use of typical antipsychotic drugs, in recent years patients have been treated using atypical antipsychotic drugs (Clozapine, Risperidone, Quetiapine etc.) which are considered critical to helping millions of schizophrenics around the world regain their lives and without which those patients would have spent their entire lives in psychiatric institutions.

Decision Resources estimated the size of the schizophrenia treatment market in the U.S., France, Germany, Italy, Spain, the UK and Japan in 2010 at approximately US\$ 6.4 billion ¹⁷. The schizophrenia treatment market is expected to experience significant changes in the coming years due to the loss of exclusivity on some of the leading drugs as patents expire and generic versions are marketed on the one hand and new drugs currently in different stages of development are approved for commercialization on the other.

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<http://decisionresources.com/Products-and-Services/Reports?t=pcorc0711>.

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Although the schizophrenia treatment market is saturated and despite the loss of exclusivity of patents for a large part of the leading drugs, the need for more efficacious antipsychotic medications with fewer or diminished side effects continues to motivate the development of drugs. Moreover, there growing importance is accorded to treating the negative and cognitive symptoms of schizophrenia in view of the enhanced efficacy of existing drugs for treating these symptoms.

8.2.3 Legislative limitations and special constraints applicable to the area of operations

For information about legislative limitations and constraints to which the Group is subject, see item 17 below.

8.2.4 Drug development processes

The drug development process is multi-phased, and includes the following phases: the preclinical phase, Phase 1, Phase 2 and Phase 3 (for more information, see item 3.2 above).

In light of the Group's intentions to develop a new indication for the Recombinant EPO, which is a drug approved for another use, as previously mentioned, and based on the fact that the Preclinical Phase and Phase 1 clinical trials are ones that examine the drug's toxicity and safety, respectively, the Group believes that it will be granted an exemption from carrying out these stages and that the drug development process will begin with Phase 2.

Furthermore, since the completion of the Phase 2a trial on the SAM-101 at the Shalvata Mental Health Center in Israel was successful, the Group intends to continue developing the SAM-101 and estimates that the development may commence from the Phase 2b clinical trial.

The Group's assessment regarding the drug development phases and obtaining an exemption for the Preclinical and Phase 1 clinical trials represents forward-looking information. This information is not definite and is based on information available to the Group as of the date of this report. The actual results may be significantly different from the results derived from this information, since there is no certainty regarding the exemption from carrying out any phase and/or regarding the results of the drug trials to be conducted by the Group.

8.2.5

Critical success factors in the areas of operations

In order to successfully develop a pharmaceutical product, the knowledge and technologies required to facilitate the development of efficient products are needed, as are long-term investments, in the form of financial funding and quality personnel that specialize in the area of operation, clinical planning and development as well as commercialization ability once development has been completed and marketing approval obtained. In addition, ownership of intangible assets (intellectual property) is required that would enable the development and enhancement of the designated product.

The Group has (via its subsidiary as mentioned above) a license for exclusive use of a patent for use of the Recombinant EPO to treat Multiple Myeloma. This, as previously mentioned, is based on the study conducted by Prof. Moshe Mittelman, an internationally renowned hematologist who serves as the Director of Internal Medicine at Ichilov Hospital and as Medical Director in the Group, and an exclusive license for the SAM-101 drug to treat mental illnesses.

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8.2.6 Entry barriers in the areas of operations

The main entry barrier to the drug development market is the lengthy, multiple year process of development, which is a regulated, thorough and cumulative process, i.e.: failure in any development phase will prevent advancement to the next phase. This type of process that takes many years obviously requires allocation of significant financial resources to finance continued development expenses.

As previously mentioned, ensuring intellectual property ownership is of prime importance, since without ownership, certain substances and products cannot be developed and used, thereby preventing progress in development. In addition, guaranteed ownership of intellectual property rights is required to benefit from the results of development on the one hand, and to ensure that the development is not found in another patent, on the other. Without patent protection, anyone could benefit from the results of the research and development without having had to pay the expenses incurred by the original developer, and in the case of the Group, paid for. Similarly, if development deviates into another patent, there will be an option of blocking all commercial activity by the developer. In order to guarantee commercialization freedom of development products, the relevant licenses needed for product development must be ensured. Furthermore, and in addition to the aforementioned, skilled, professional personnel who are experts in the field are required.

8.2.7 Alternatives to the products underlying the areas of operation and changes therein

8.2.7.1 Alternatives to the Recombinant EPO

As of the date of this report, the Recombinant EPO drug that the Group intends to develop faces no competition for this stage of the disease, based on the fact that the Recombinant EPO drug is designed to treat Multiple Myeloma patients in advanced stages of the disease who were already treated with all current standard therapies.

These patients, as previously mentioned, are being treated at this stage with palliative drugs and therapies only (to alleviate pain, etc.). In addition, to the best of the Company's knowledge, as of the date of this report, there is no drug that is being sold or drug in development that works on the immune system like Recombinant EPO.

Despite the aforementioned, it is possible that the Recombinant EPO drug will be found to be effective in the future for patients who are not terminally ill, when combined with other currently available drugs. If said assessment comes to fruition, the Recombinant EPO drug may be used as a substitute and/or supplementary drug to other drugs that are currently available on the market and/or drugs that are currently in development. Multiple Myeloma patients who are in the non-terminal stages currently have in the market drugs that have been approved for use, which may make it entry into this market difficult. It should be noted that the development of the new indication for a drug provides an advantage over a drug that was developed from the beginning, in light of the Group's assessment that one or more phases in drug development, particularly Phase 1, would be redundant, since these phases have already been previously carried out during testing of the same product for its original indication but in this case as well, development of a new indication is expected to be lengthy.

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It should be noted that in recent years¹⁸, treatment of Multiple Myeloma patients in the various stages has been composed of chemotherapy combined with autologous stem cell transplantations or a combination of Thalidomide, dexamethasone (a type of steroid) and Velcade, based on the patient's condition. If said transplantation is carried out, the patients receive initial treatment of high dosages of preliminary chemotherapy. This treatment is largely administered to patients who are under the age of 65. If the patient is above the age of 65, and his physical condition prevents an autologous stem cell transplantation from being carried out, the standard treatment involves a combination of two or more drugs including Thalidomide, steroids, Velcade, Revlimid and mild chemotherapy.

The aforementioned therapies lead to a median survival time of approximately 30 months in close to 83% of patients who underwent autologous stem cell transplantation (and who were under the age of 65) and a survival time of approximately 24 months in almost 90% of patients (and who were under the age of 65).

It is clarified that the currently available therapies and drugs used to treat Multiple Myeloma patients have side effects such as neuropathy – peripheral neuropathy, which occasionally might be irreversible and require discontinuation of the therapy for extended periods of time.

The aforementioned regarding treatment of multiple myeloma patients and patient survival time was taken from the ¹⁸article by Prof. Ben-Ami Sela, director of the Pathology Chemistry Institute, Sheba Medical Center, Tel-Hashomer that was published on the website www.tevalife.com.

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Another drug currently administered to patients is one known as Velcade (scientific name – Bortezomib) which was approved in 2003 by the FDA and that extends the survivability time of patients with the disease, with 33% of all patients attaining an overall survival time of approximately 5 years, with the survival time among all patients on the drug being 33 months. The drug Recombinant EPO that is being developed by the Group may be one that can be administered in combination with this drug.

In addition to the aforementioned, it should be noted that as of the date of this report, several additional drugs are in various phases of clinical trials, and if approved, if and when approved, may constitute an alternative to the recombinant EPO being developed by the Group.

8.2.7.2

Alternatives to the SAM-101

As of the date of this report, there are alternative therapies for the Company's drug, classified into two types: (1) psychosocial therapy which consists mainly of clinic care, full or part-time hospitalization, occupational therapists, psychologists etc; (2) medicinal therapy which consists of administering antipsychotic drugs such as Chlorpromazine, Perphenazine, Thioridazine, Haloperidol and Lithium as well as atypical antipsychotic drugs such as Clozapine, Risperidone, Quetiapine etc.

It should also be noted that as of the date of this report, there are certain additional drugs that are in various stages of clinical trials which, if and once approved, might provide an alternative to SAM-101.

8.2.8 Structure of the competition in the area of operations and changes therein

8.2.8.1 General

The Group's competition in the field includes a wide range of companies around the world, starting with small pharmaceuticals up to the mega multinationals. Multinational marketing of a drug requires access to marketing channels around the world, thus generally forcing small companies to collaborate with large companies in the field. On the one hand, this is a limiting factor for small companies. On the other hand, these giant companies are constantly searching for new drugs in order to broaden the range of drugs they market or in order to increase the amount of developed drugs (drug development pipeline). The need of giant multinationals for new drugs in certain periods makes these companies willing to invest vast sums of money to acquire drug development and marketing rights, which is an opportunity for drug developing companies.

The Group has a preliminary plan to conduct a Phase 2 trial of the Recombinant EPO that includes the enrollment of approximately 50 patients ¹⁹. If a situation arises in which a large number of drugs are in development while the Group is conducting the trial, this might make patient enrollment for Phase 2 and Phase 3 of the trial difficult.

¹⁹ This assessment is based on numbers of patients required in clinical studies on other drugs designed to treat multiple myeloma and cancer in general. No comprehensive statistical planning has yet been carried out and the Group still has not convened a discussion on the clinical plan with the regulatory authorities, the FDA and others – and the number of patients that will be ultimately be required may differ from this estimate.

The need for a large number of patients in the advanced phases of the clinical trials poses a significant obstacle in drug development that might affect the chances and timetable involved to complete development of the Group's Recombinant EPO drug. This problem can frequently be solved by adopting a development strategy that includes, inter alia: accurate definition of the type of patients who will participate in the trial (based on the severity of the disease, type of therapies previously received, other drugs they received concomitant with the investigational drug, etc.); optimal choice of sites to conduct the clinical trials (e.g. some of the trials will be conducted in countries in which certain therapeutic alternatives are not yet being offered to patients or study sites known for their ability to enroll patients into trials with relative speed, etc.); use of organizations that specialize in clinical study management²⁰; interest shown by study doctors who will participate in the study on the drug and how it operates; provision of financial incentive to the study fund of the departments participating in the trial (incentive indirectly serves to improve the conditions of the patients' hospitalization) in order to make sure that they prefer directing patients to clinical trial of the Group's drug over other clinical trials. The Group intends to adopt these types of strategies to ensure a rapid patient enrollment rate and compliance with the scheduled timeframe, although there is no guarantee that this will happen.

²⁰These companies are known as Clinical Research Organizations ("CROs").

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8.2.8.2

Competition in the cancer market

The cancer drug market is extremely large. National medical institutions in the U.S. estimated that the overall cost of treating cancer in 2005 was US\$ 209.9 billion ²¹. In 2008, sales of all cancer drugs totaled US\$ 48 billion ²² and this number was expected to grow to US\$ 80 billion in 2010. In 2003, a new anticancer drug was approved for use and marketing known as Velcade, which is used to treat Multiple Myeloma.

In 2008, sales of drugs used to treat Multiple Myeloma in the U.S., France, Germany, Italy, Spain, England and Japan totaled US\$ 2.1 billion (and are expected to rise to US\$ 5.3 billion in 2018 ²³). According to their recent financial statements, actual sales of Velcade in 2011 by Jhonson & Johnson (which markets Velcade outside the U.S.) amounted to US\$ 1.27 billion ²⁴. Also, based on the financial statements of the pharmaceutical Celgene (which markets Revlimid), Revlimid sales in 2011 amounted to \$3.21 billion ²⁵. Velcade sales by the Japanese pharmaceutical Takeda (which markets velcade in the US) in 2010 amounted to \$0.59 billion ²⁶.

²¹ <http://dceg.cancer.gov/files/genomicscourse/meropol-011007.pdf>.

²² According to IMS Health - <http://www.reuters.com/article/idUSN1453543620080515>.

²³ <http://decisionresources.com/News-and-Events/Press-Releases/Multiple-Myeloma-032210>

²⁴ <http://files.shareholder.com/downloads/JNJ/1746723755x0x552947/211DF99C-D473-47DA-B3AF-8EE1A05361D6/2011-A>
(page 32)

²⁵ <http://ir.celgene.com/phoenix.zhtml?c=111960&p=irol-newsArticle&ID=1653011&highlight=>

²⁶ http://www.takeda.com/pdf/usr/default/ar2011e_42865_3.pdf (page 55)

Listed below is a table displaying the advantages and disadvantages of the Company's main competing drugs and therapies as of the date of the report:

Company	Type of therapy / name of drug	Comparative properties		Average	Side effects	Efficiency / survival time
		Route of administration of treatment	Drug intake frequency	monthly cost of treatment in USD		
Celgene Corporation	Thalidomide®	Oral Tablets	One pill per day, dosage occasionally needs to be adjusted based on adverse events	Approx. 1,000	Resulting in congenital defects, peripheral neuropathy (nerve damage), fatigue, constipation, blood clots tendency (including increased risk of deep vein thrombosis), etc.	Single preparation (approximately 30% of patients respond). Combined with another drug, -approximately 50%-60% of patients respond. The drug results in a mild remission of the disease. Response might last a year
Celgene Corporation	Revlimid®	Oral Tablets	Generally, one tablet per day for 21 days followed by a one-week break	Approx. 9,000	Serious injury to bone marrow (sensitivity to infection and suppression of creation of blood platelets (thrombocytes, i.e. risk of life-threatening bleeding), blood clots tendency and embolisms, liver damage, serious damage to bone marrow, damage to digestive system accompanied by nausea, acute diarrhea, etc.	Not tested in comparison to Thalidomide (but is considered better) When combined with another drug, - approximately 50%-60% of patients respond. Response can last up to a year

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Millennium Pharma-ceuticals	Velcade®	Intravenous injection	Two injections per week for two weeks followed by a 10-day break; for a minimal period of 7-8 cycles	Approx. 10,000	Acute Peripheral neuropathy (nerve damage) to the point of impaired function, digestive disorders and nausea, on rare occasions, liver damage, etc.	Triggers a response in 30% in single treatment and when combined with another drug, in approximately 50%-60%. Response lasts a year. In patients in the advanced stages of the disease, the drug extended life by an average of 12 weeks
	Chemo-therapy	Infusion or tablets			Suppression of the immune system and bone marrow, hair loss, nausea and vomiting, damage to all cells in the body	20%-30% of patients respond, response lasts less than a year
	Bone Marrow Transplant	Intravenous			Extremely aggressive treatment and suitable only for people who are relative healthy (under the age of 65)	Approximately 60%-70% of patients respond to therapy for a period of approx. two-three years

It should be clarified that given the fact that the patients with the disease are treated with a combination of drugs and therapies, as detailed in the table above, they become resistant to the treatment administered to them so that at a certain stage, the treatment combination is no longer beneficial and/or negatively affects (side effects) the patient's condition. As a result, the patient's caregivers tend to change the composition of the treatment and drugs administered to each patient, based on their condition in each stage.

For information about other drugs and therapies that are in competition with the Group's drugs, see item 8.2.7 above.

8.2.8.3

Competition in the schizophrenia market

As discussed above, Decision Resources, the research company, estimated the size of the schizophrenia treatment industries in the U.S., France, Germany, Italy, Spain, the UK and Japan in 2010 at approximately US\$ 6.4 billion ²⁷.

²⁷<http://decisionresources.com/Products-and-Services/Reports?r=pcorcg0711>.

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The schizophrenia treatment market is liable to experience significant changes in the coming years due to the loss of exclusivity on some of the leading drugs as patents expire and generic versions are marketed on the one hand and new drugs currently in different stages of development are approved for commercialization on the other.

Although the schizophrenia treatment market is saturated and despite the loss of exclusivity of patents for a large part of the leading drugs, the need for more efficient antipsychotic medications with fewer or diminished side effects continues to motivate the development of drugs. Moreover, there growing importance is accorded to treating the negative and cognitive symptoms of schizophrenia in view of the enhanced efficiency of existing drugs for treating these symptoms.

Below is data about the sales volumes of several leading schizophrenia drugs based on the financial statements of the selling companies:

In 2011, the worldwide sales of Zyprexa (Olanzapine) by Eli Lilly totaled approximately US\$ 4.6 billion. The global sales of Abilify (Aripiprazole) by Bristol Meyers in 2011 totaled approximately US\$ 2.8 billion. The total sales of Seroquel/XR (Quetiapine) by AstraZeneca in 2011 amounted to approximately US\$ 5.8 billion. It should be noted that these drugs are not only given to schizophrenics but also to other mental patients. Furthermore, as described above, in the coming years, certain patents granted for some of the leading drugs will expire and new generic drugs will be introduced into the market.

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8.2.8.4

Methods of dealing with the competition

In order to successfully cope with the anticipated competition, the Group must position its drug by emphasizing its advantages over the competition. According to the Group, the anticipated advantages of the Recombinant EPO, 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 Group believes that the fact that the Recombinant EPO'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 Group's estimation, an advantage in the Multiple Myeloma therapy market.

The Group also estimates that the expected benefits of the SAM-101 are based on the assumption that in addition to being highly effective in treating schizophrenia, it will also minimize the weight gain tendency, which is a major reason why many schizophrenics abstain from taking medications.

In addition, among the main factors affecting the ability of a new product to penetrate the drug market and its competitiveness are clinical advantages that the product provides and the ability to protect its intellectual property rights. In light of the fact that the Group has licenses for the exclusive use of the patent for the Recombinant EPO to treat patients with Multiple Myeloma and for the SAM-101 to treat schizophrenia, the Group believes that its drugs contains the right properties to withstand expected competition.

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Several years will pass until the Group's products reach the market but until they reach this stage, the chances are that one of the giant pharmaceutical companies in the field will try to seek collaboration with the Group in the drugs' development and/or marketing.

The Group's assessments regarding product compatibility and possible penetration into the drug market represent forward-looking information. This information is not definitive and based on the Company's currently available information as of the date of this report. Actual results may be significantly different from the results derived from this information, since there is no certainty regarding results of the clinical trial that the Group will conduct on the drugs.

9. Customers

9.1 As of the date of this report, the Company has not yet begun marketing and distribution of its products and therefore has no customers.

9.2 The potential customers of the Company's products are international or local pharmaceutical companies and/or international and/or local distributors.

10. Marketing and distribution

10.1 As of the date of this report, the Company has not yet begun marketing and distributing its products.

10.2 The marketing and distribution strategy reviewed by the Company primarily involves strategic partnerships with international or local pharmaceutical companies and/or international and/or local distributors.

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11.

Fixed assets and facilities

The Company's offices are located in Herzliya, in accordance with a rental agreement from 4 August 2010. The basic rental 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 upon introducing an alternative tenant in its place, pursuant to approval of the landlord. Monthly rental costs and management fees in accordance with the agreement, starting from October 2010, offset by co-payment of the subtenants who subleased 30% of the property (for a one-year period) total NIS 20 thousand (US\$ 5.3 thousand).

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12. **Research and development**

Listed below is a table of clinical trials that the Company intends to conduct:

Trial title	Development stage of the trial (*)	Purpose of the clinical trial	Study site	Scheduled number of trial subjects	Number of subjects as of the date of the report	Trial nature and status	Performance timetable	Projected cost (estimate)	Aggregat between Decem
Recombinant EPO ²⁸ for treating Multiple Myeloma	2	Primary endpoint: extension of life Secondary endpoint: improved quality of life and improvement in various blood parameters	Not yet decided	About 50	0	Not yet submitted to the authorities and/or Helsinki Committee	The trial is expected to begin in the first quarter of 2013	US\$ 1-1.5 million	Prelimin 2 study the exis proteins blood o mainten and han Compar registrat process countri regulato A total thousan

²⁸ In accordance with the Company's preliminary plan that was accepted within the confines of the Bio-Gal transaction.

Trial title	Development stage of the trial (*)	Purpose of the clinical trial	Study site	Scheduled number of trial subjects	Number of subjects as of the date of the report	Trial nature and status	Performance timetable	Projected cost (estimate)	Aggregated between December
SAM-101 for treating schizophrenia 29	2	Testing various dosages of Minocycline in combination with antipsychotic drugs in schizophrenia patients. No endpoints have been determined yet	Not yet decided	Not yet decided	0	Not yet filed	The Group is in planning stages of the clinical trial which is scheduled to commence in 2013	About US\$ 2-2.5 million	The MinoGuard transaction includes the exclusive license to use the SAM-101 was consummated in November 2012 and thereafter development costs have been incurred (see more information in Note 15a of the Company's consolidated financial statement)

(*) For extensive information, see item 8.2.3 above. It should be noted that no approval has yet been received for conducting the trial from Phase 2.

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Based on the data received in the MinoGuard transaction.

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Assuming that the clinical trials detailed above achieve the desired results, the Company faces several business options: (1) conducting a Phase 2b and/or Phase 3 clinical trial; (2) entering into a collaboration agreement with a large pharmaceutical company to continue the drugs' development; or (3) granting a license to a large pharmaceutical company to continue development and commercialization of the drugs. The considerations for choosing among the above options will depend on the Company's financial ability and on the suggestions made by other business partners.

As of the date of this report, the Company and its medical consultants believe that a Phase 3 clinical trial of the EPO drug is expected to last between 3-4 years, with an estimated cost of US\$ 10-30 million. This is based, inter alia, on data obtained from the Company's regulatory consultants and on a review of the history of clinical trials in companies in the industry.

As for the SAM-101 drug, it is impossible at this stage to assess the development cost of a Phase 3 clinical trial or any other stage that is more advanced than Phase 2 since the Phase 2 clinical plan and its exact targets have yet to be defined.

The Group's assessments regarding the projected expenses for Phase 2 and primarily Phase 3 clinical trials represent forward-looking information. This information is not definitive and based on the Company's currently available information as of the date of this report. Actual results might be significantly different from the results derived from this information since the expected number of patients for the Phase 3 trial, the duration of the trials and the complexity of the trials are uncertain and depend primarily on variables external to the Company such as: decisions made by the FDA and other health institutions, clinical trial results of other companies in the industry and other regulatory issues. The costs incurred in conducting the trials might therefore significantly change.

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13.

Intangible assets

13.1 On November 30, 2011, the Company entered into an agreement with MinoGuard for acquiring an exclusive license to use MinoGuard's leading drug, SAM-101, which is based on a combination of existing antipsychotic drugs and a known medicinal compound for treating mental illnesses, focusing on schizophrenia. See more details about the license agreement in item 18.1 below.

13.2 In December 2009 ³⁰, the Company, via XTEPO, entered into an agreement with Bio-Gal to acquire the license to use the patented Recombinant EPO in the treatment of advanced stage Multiple Myeloma patients and improve the quality of their lives. For additional information about the license agreement, see item 18.4 below.

13.3 In March 2008, the Group entered into an agreement to out-license the development rights acquired from VivoQuest to Presidio. For further details regarding the agreement - see item 18.5 below.

13.4 In August 2005, the Group entered into an agreement to acquire rights and assets from VivoQuest. Pursuant to the agreement, the Group acquired the usage rights to the development of a novel pre-clinical library of compounds for the treatment of Hepatitis C ("**DOS**"), laboratory equipment and the lease rights to a laboratory used by VivoQuest. In accordance with the agreement, and as of the date of this report, the Group has usage and development rights only concerning which it is obligated to pay up to US\$ 34 million on the basis of milestones, of which an amount of US\$ 25 million will be paid by the Group subject to regulatory approval and the actual sales of products. It should be noted that, according to the agreement, the Group has been granted the choice of settling the said amounts either in cash or through the allocation of shares.

³⁰ Following the amendment of the terms of the contractual arrangement from 18 March 2009 with Bio-Gal.

13.5 The Company has an exclusive license of the patents and patent applications of the Recombinant EPO and SAM-101 drugs, as detailed in the table below:

Patent name	Countries		Priority date	Application No.	Patent No.	Status	Expiration date (**)
	in which application was filed	in which application was filed					
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, the UK, Ireland, Italy, the Netherlands, Spain, Switzerland and Sweden.

(**) Subject to meeting all the required annual payments.

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Patent name	Countries in which application was filed	Priority date	Application No.	Patent No.	Status	Expiration date (*)
Combined therapies of antipsychotic drugs and tetracyclines in the treatment of psychiatric disorders	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	
	1-PCT	18.10.2007	PCT/IL2007/ 001251	-	Expired	
	USA	18.10.2007	12/446444	-	Examination	18.10.2027

(*) Assuming that a patent is registered based on the PCT.

14. Human capital

As of the date of this report, the Group has three full-time employees/service providers in the administration and finance departments (two of whom are executives) and three service providers/consultants who provide the Company administrative, medical and financial services (one of whom is an executive). For information about the terms of employment of officers, see Regulation 21 in Chapter D of this report.

15. Financing

As of the date of this report, the Company has no loans or any liability with the exception of the current liabilities to suppliers, other service providers, employees and directors.

16.

Taxation

16.1

The tax rates applicable to the Group under law

Tax rates

The Company's revenues in Israel are subject to corporate tax at the regular tax rate. In accordance with the provisions of the Law to Amend the Income Tax Ordinance from August 2005, a gradual lowering of the corporate tax rate was established. As a result of this amendment, the corporate tax rates beginning in the 2008 tax year and thereafter are: 2008 – 27%, 2009 – 26%, 2010 – 25%.

On 14 July 2009, the Knesset ratified the Economic Efficiency Law (Legislative Amendments for Implementation of the Economic Plan for 2009 and 2010) ("**Amendment 2009**") that established, inter alia, a gradual reduction in the corporate tax rate, from the corporate tax rate beginning in 2010 and thereafter as follows: 2011 – 24%; 2012 – 23%; 2013 – 22%; 2014 – 21%; 2015 – 20% and 2016 and thereafter – 18%.

On 6 December 2011, the Law for Changing the Tax Burden (Legislative Amendments), 2011 ("**Amendment 2011**") was published in the Israeli Records and prescribed that the outline of reducing the corporate tax rate stipulated in Amendment 2009 as described above will be eliminated and the corporate tax rate will be increased to 25% starting from 2012 and thereafter. Amendment 2011 has no material effect on the consolidated financial statements as of 31 December 2011 since the Group has operating losses for tax purposes in respect of which the Group does not record deferred taxes due to the uncertainty of their utilization in the foreseeable future.

For additional information about the Group's tax liabilities, See Note 21 to the financial statements as of 31 December 2011.

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16.2 On 15 July 2010, the Company signed a pre-ruling arrangement with the Israeli income tax authorities regarding the share swap agreement in accordance with Articles 103 and 104 of the Israeli Income Tax Ordinance. As a result of the agreement, the Company became subject to various restrictions and some of the Company's aggregate losses for tax purposes were cancelled.

Listed below is a summary of the main terms of the agreement:

16.2.1 The Company's accumulated business and capital losses for tax purposes were reduced and set at NIS 80 million (approximately US\$ 22 million) and NIS 0.7 million (approximately US\$ 0.19 million ³¹), respectively. The contents of this article do not derogate from the authority of the tax assessing officer to determine that the amount of accumulated losses is lower than the aforementioned sums.

16.2.2 The losses incurred by the Company prior to the share swap agreement, following the reduction in item 1 above, will not be deductible against any income originating from XTEPO (the transferred company) and will not be deductible against a capital gain from the sale of XTEPO shares.

16.2.3 XTEPO's shareholders will not be permitted to sell their rights in the Company for two years from the end of the year in which the transaction was completed ("**the blocking period**"), subject to legislative changes.

16.2.4 The Company and XTEPO undertook to maintain the main economic activity that they had on the eve of the transaction during the blocking period.

16.2.5 The Company will not be permitted to sell its holdings in XTEPO for the entire blocking period.

31 Based on the exchange rate as of 30 September 2010 which was US\$ 1 = NIS 3.665.

It should be noted that the provisions of Articles 103 and 104 of the Israeli Income Tax Ordinance that discuss restructuring and mergers impose statutory restrictions and various conditions on entities participating in the restructuring / merger and, inter alia, limit the dilution of holdings both by means of prospectus as well as private placements. The summary of the main restrictions mentioned above does not purport to be a review of the provisions of Articles 103 and 104 of the Income Tax Ordinance and does not replace the need to read said Articles in their entirety.

Furthermore, on 1 February 2012, the Israeli tax authorities issued a position circular regarding the restrictions prescribed in Articles 103 and 104 to the Income Tax Ordinance which grants an exemption from certain restrictions in said Articles during the blocking period, among others in cases of allocation of rights to "new" shareholders in private raising rounds.

As of 31 December 2011, the Company has incurred accumulated business losses for tax purposes of US\$ 24 million (approximately NIS 90 million) in Israel and accumulated capital losses of US\$ 0.18 million (approximately NIS 0.7 million) that are carried forward to future years. For more information, see Note 21c to the Company's financial statements as of 31 December 2011.

In addition, the Company's management believes that the utilization of losses for tax purposes of the U.S. subsidiaries as of 31 December 2011, totaling approximately US\$ 20 million, is limited and therefore the tax losses might be significantly lowered in accordance with local laws that deal with changes in control in a company following the consummation of the Bio-Gal transaction. As mentioned in the annual financial statements for 2011, the Company does not record deferred taxes in respect of losses for tax purposes since their utilization in the foreseeable future is not certain.

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17. **Limitations arising from legislation, regulations and special constraints on the area of operation**

17.1

The Helsinki Committee

A prerequisite for the Group's ability to conduct trials is obtaining prior approval from parties certified to approve clinical trials on human subjects in every country in which the Group wishes to conduct the said trial. The trials must comply with the principles in the Helsinki Declaration and must have obtained ethics committee approval in every medical institution in which the trial is being conducted. The doctor and/or the committee of doctors with whom the Group will cooperate will submit the trial protocol to the medical institution's ethics committee. After the discussion during which the committee will determine whether the trial protocol complies with the rules of ethics, and if the protocol is approved, the scheduled trial can begin. Any change in the trial protocol requires an update and a resubmission for ethics committee approval.

Helsinki Committee approval – as previously mentioned, a prerequisite for approval of use of pharmaceutical products by the western health agencies, including the Israeli Ministry of Health, and it allows proof of safety and efficiency of pharmaceutical products through clinical trials. In order to conduct clinical trials in Israel that involve human subjects, permission must be obtained in accordance with the study plan (protocol) ("**the permit**") from the committee (known as the Helsinki Committee), which operates by the virtue of the Public Health Regulations (Clinical Trials on Human Subjects), 1980 ("**the Public Health Regulations**").

The permit is issued subject to submitting the application for approval by a licensed doctor who will be the principal investigator in charge of the trial, to the investigator participating in the clinical trial on human subjects having the skills and experience in their field to conduct the trial and to the trial complying with the conditions below:

- (a) The anticipated advantages for the participant in the trial and for the company justify the risk and discomfort involved in the trial;
- (b) The clinical and scientific information currently available justifies conducting the requested clinical trial;
- (c) The clinical trial is scientifically planned to facilitate a response to the question being studied, and is described in a clear, detailed and precise manner in the trial protocol;
The risk to the trial participant is minimized due to the use of proper study methods, and use, whenever possible, of
- (d) procedures that have already been carried out on human beings or on animals. In addition, trial participants will be closely monitored during the trial and in the follow-up;
- (e) Trial participants will be selected based on the inclusion and exclusion criteria in accordance with the trial protocol;
- (f) An informed consent form for the trial is to include all necessary information as described in the procedure;
- (g) The trial protocol includes provisions on protection of participants' privacy and the confidentiality of the collected information;
 - (h) The trial protocol includes a mechanism for trial follow-ups;
 - (i) Suitable insurance coverage of participants taken out by the trial sponsor;
- (j) The sponsor and the principal investigator are capable of allocating the resources required to properly conduct the trial, including skilled personnel and required equipment;
- (k) The nature of the commercial contractual arrangement with the investigator and with the study site does not prejudice any proper conduct of the trial;
If all or some of the participants in the trial are potentially subject to undue pressure or influence regarding
- (l) participation in the trial – appropriate measures will be adopted to prevent or minimize said undue pressure or influence.

17.2

FDA and EMEA approval

The products the Group intends to develop and market are pharmaceutical products. As such, their manufacturing, sale and marketing are contingent on obtaining a license in every country in which the Group wishes to market the said products. To obtain the said approval, the Group must comply with the licensing requirements, including safety conditions and quality assurance standards required in each of the countries.

The requirements to obtain approval to sell the Group's drugs varies from country to country, as does the time needed for the various authorities to conduct tests in each country to obtain the license and costs involved. The lack of a license in a certain country for the Group's products will prevent their sale and accordingly, might harm the Group's revenues. Main markets the Group is targeting include the United States and the European Union.

The Group intends to complete product development, obtain FDA and EMEA approval for the drugs' marketing and sale. It will be clarified that every approval is separate and independent. Said approval will be required in the future for any modification of the products, which will obtain approval or for expanding their current applications.

Once FDA or EMEA approval has been obtained, the Group will be able to market the products only for the indications listed in the approval. The FDA and EMEA can conduct tests and investigations to ensure the Group's compliance with the legal and licensing requirements. In addition, the Group can work to monitor and keep track of its compliance with the FDA requirements via a quality control system and by significantly reducing the possibility of failure, and even report them in advance, if detected. Non-compliance with the said requirements can lead to sanctions against the Group, including publication of a public warning regarding the product (black box warning), imposition of penalties and civilian compensations, refusal to approve new products for the Company or to remove licensing from the current product.

It should be noted that today, the FDA is considered the most stringent agency and its approval is a significant sign, indicating the receipt of an approval granted by the other regulatory agencies.

17.3 U.S. Health Care Reform (Obama Reform)

To the best of the Company's knowledge, the U.S. Health Care Reform will have no effect on the Company's financial activity.

18. Significant agreements

18.1 Acquisition agreement with MinoGuard

On 24 March 2011, the Company entered into a term sheet to acquire the activity of MinoGuard Ltd. ("**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. On 30 November 2011, the Company completed the agreement for obtaining an exclusive global license to MinoGuard's entire technology as follows:

a) The Company will act conduct clinical trials, develop, register, market, distribute and sell the drugs arising from the developed technology, regardless of a specific disease ("**the license**").

In return for the license, the Company will pay MinoGuard cumulative fees in connection with meeting certain R&D milestones and with the drug's approval in a total of approximately US\$ 2.5 million. In addition to the payment of milestones as above, the Company will pay MinoGuard royalties at a rate of 3.5% of the sales of b) products deriving from the license and/or 7.5%-20% of the net consideration to the Company in case a sublicense is granted to a third party, depending on the drug's clinical trial phase when such sublicense is granted. It should be noted that the Company has the right, at its sole discretion, to repay the fees detailed herein in cash or by allocating securities to MinoGuard.

In addition to said fees, if the Company does not commence the Phase 2 clinical trial by 30 June 2013 (whereby, as stated in the agreement, obtaining approval for commencing the clinical trial or continuing the clinical trials that had been or will be conducted by MinoGuard and/or its researchers will be viewed as commencing Phase 2 trial in this c) context), the Company will pay MinoGuard an annual fee for the license at US\$ 45 thousand to be paid on said date and augment (assuming the trial has not been launched) by US\$ 90 thousand annually until a maximum of US\$ 675 thousand in the eighth year of the license period.

The consideration for the license was determined following negotiations held between the Company and MinoGuard and is expected to be paid out of the Company's own resources and from royalties from sales, to the extent that the development milestones are achieved and/or that the relevant commercialization approvals are obtained.

In the Company's estimate, and based on the Phase 2 clinical trial budget set forth in the agreement, the cost of investing in the technology's development in accordance with the necessary procedures until completing the Phase 2 clinical trial as of the date of this report is estimated at US\$ 2.5 million.

It should be noted that the technology transferred to the Company according to the license is patent protected until 2027. It should be noted that if the Company does not commence the Phase 2 clinical trial detailed above within a period of 9.5 years from the date of the agreement, the license will expire.

Furthermore, the technology's development stage has not yet been completed and there is no guarantee that all the different R&D milestones and product approval targets will be met, that all the necessary approvals will be obtained from the relevant authorities or that the drug will achieve the commercialization stage.

For more information regarding the license agreement, see the Company's report from 30 November 2011.

18.2

Term sheet for the acquisition of "NiCure" technology

On 2 November 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 a due diligence study, 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 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 20 years.

For more information regarding the acquisition of the "NiCure" technology, see the Company's report from 3 November 2011. As of the date of this report, the transaction was not closed.

18.3

Option agreement for exclusive license

On 1 September 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, 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 US\$ 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 US\$ 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 US\$ 2 million is 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 elected not to exercise the right to acquire the technology and that right expired on 30 November 2011.

18.4

License agreement with Bio-Gal

On 31 December 2009, the Group, through XTEPO, entered a contractual arrangement with Bio-Gal in an agreement to receive an exclusive license for a patent (as this term is defined below), that was signed between Bio-Gal and Yeda and Mor Research Applications Ltd. ("**Mor**") (Yeda and Mor collectively - "**the license owners**") in 2002 ("**the original licensing agreement**"), for exclusive use of the registered patent of the license owners for the Recombinant EPO drug 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 ("**the patent**"). It should be noted that the assignment of the original licensing agreement to the Company involved obtaining the consent of the license owners, who gave it, and then XTEPO, which was established for the purpose of said agreement, stepped into the shoes of Bio-Gal as license owner in every respect.

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 U.S. 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. It is important to note, though, that the Company's EPO drug received an Orphan Drug status in May 2011.

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:

- 1) Annual licensing fee of one percent (1%) of net sales of the EPO drug by the Group and/or its subcontractors (who might operate under a sub license).

- A one-time payment if one of the following are met (see also subsection 3 below that updates the terms of this item): (1) sale of 50% or more of XTEPO shares to a third party; (2) merger between XTEPO and a third party; (3)
- 2) sale or transfer of XTEPO's strategic assets ("**the exercise**") totaling US\$ 250,000 or 2.5% of XTEPO's gross gains from the exercise (whichever is lower).

Despite the aforementioned, the parties to the agreement decided that the said payments will be deferred to the date

- 3) of successful completion of Phase 2 of the clinical trial for which the Group will pay Yeda a one-time sum of US\$ 350,000, whichever of the following comes earlier:

- (a) Capital raising of at least US\$ 2 million by the Company or by XTEPO following successful completion of Phase 2 clinical trial.
- (b) Six months from the date of successful completion of Phase 2 clinical trial.

On 3 August 2011, the Bio-Gal transaction was consummated after all the prerequisites had been met, including obtaining a ruling from the Israeli tax authorities regarding the Israeli tax exemption of the share swap agreement pursuant to Articles 103 and 104 to the Israeli Income Tax Ordinance.

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18.5

Sublicense agreement with Presidio

On 19 March 2008, the Group entered into a contractual arrangement for granting a sublicense of the DOS technology to Presidio, a company incorporated in Delaware that specializes in drug development and marketing ("**the agreement**"). On 4 August 2008, the Group signed an amendment to the agreement ("**the amendment**") in which Presidio assumes responsibility for all development, commercialization and patent cost responsibilities, including all resulting costs, regarding the DOS technology, in exchange for an initial payment of US\$ 5.94 million and a future payment of up to US\$ 59 million based on milestones such as submitting an application for registration of an investigational new drug ("**IND**") with the FDA, submitting an application for commercialization and marketing of the drug with the FDA or any parallel authority and payment of royalties of between 1% - 10%, based on Presidio's revenues. In addition, the Group is entitled to receive a varying percentage of receipts paid to Presidio if the latter grants a DOS sublicense to a third party.

The Company carries out various controls to monitor the DOS development progress by Presidio that include, inter alia, receiving updates from Presidio and monitoring FDA publications regarding clinical trials. From time to time and as needed, the Company will contact Presidio for additional updates in accordance with the agreement between the Company and Presidio.

To the best of the Company's knowledge, based on the reports provided by Presidio's management, as of the date of the report, Presidio has yet to begin carrying out any clinical trial based on the DOS technology.

19.

Legal proceedings

As of the date of this report, the Group is not facing and is not conducting any legal proceedings of any kind.

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20.

Targets and business strategy

The Group intends to develop its drugs by conducting clinical trials, including Phase 2 clinical trials, while creating value for the Group and for the drugs that it owns: the Recombinant EPO drug used to treat patients with Multiple Myeloma and the SAM-101 drug for treating patients with mental disorders, particularly schizophrenia. The Company is planning to examine other technologies for their incorporation in the Company's activities.

Listed below is a table summarizing the Company's strategy expected targets for 2012-2014:

	2012	2013	2014
Recombinant EPO	Obtaining approval for clinical trial	Clinical trial	Clinical trial
SAM-101	Study and clinical trial planning	Obtaining approval for clinical trial	Clinical trial

The Company's management and its regulatory advisors estimate that obtaining an approval for initiating the Recombinant EPO clinical trial is expected to be received by the end of 2012 and continue for a period of two-and-a-half years.³²

It should be noted that in addition to the aforementioned, the Group is striving to identify, examine and acquire additional technologies including, inter alia, the development of a new indication for drugs that have been approved for marketing for the treatment of currently incurable diseases and/or improvement of existing therapies. In addition, the Group plans on developing collaborations with large pharmaceutical companies to market its drugs and other collaborations to develop its clinical abilities, inter alia, through a scientific advisory committee that will be set up, to create collaborations with major research institutions and retain its position in the capital markets.

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The estimated trial period is a Company projection based on the patient enrollment rate in other companies conducting clinical trials on Multiple Myeloma treatments in compliance with FDA standards.

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The Group's assessments regarding its targets and business strategy represent forward-looking information. This information is uncertain and based on the Company's currently available information as of the date of this report. Actual results might be significantly different than the estimates derived from this information, since the clinical development of drugs is essentially a process that contains numerous uncertainties and as such, inter alia, there is no certainty that the timetable for development and obtaining initial clinical results from the drugs will come to fruition in the way expected by the Group's management.

21. **Expected developments in the coming year**

The Company intends to act in the course of the coming year to obtain FDA approvals for initiating the Phase 2 clinical trial on the Recombinant EPO drug which consists, inter alia, of obtaining regulatory approvals and conducting preliminary studies for collecting various parameters of clinical data on patients that will help define the focal point of the trial with the aim of proving the advantages of the Recombinant EPO in the treatment of patients with Multiple Myeloma. The Company also intends to investigate data and plan the clinical trial of the SAM-101 drug.

As stated in item 20 above, the Company is planning to explore other technologies in the course of its business in order to integrate them in the Company and expand the variety of its technological solutions.

For information about the clinical trials that the Company intends on conducting, see item 12 above. Without derogating from the generality of the aforementioned, the Company does not rule out any possibility of filing applications to obtain grants from the Chief Scientist in accordance with the Israeli Law for the Encouragement of Industrial Research and Development, 1984, as will be determined by the Company's board of directors pursuant to the recommendations of the Company's management.

The Group's estimates regarding the developments in the ensuing year, including projected expenses, represent forward-looking information. This information is uncertain and based on the Company's currently available information as of the date of this report. Actual results might be significantly different from the results derived from this information, since there is no guarantee regarding the future and the results of clinical trials that the Group is planning to conduct.

22. **Discussion of risk factors**

Listed below is information about the risk factors that might have crucial effect on the Group's operations and business results.

22.1 **Industry risks**

22.1.1 **Exposure to effects of regulation**

The Group, like any business involved in the medical field, is subject to approvals, licenses and regulation on the part of government and international organizations related to environmental quality, toxins, medicine, etc. If any amendments are made in the provisions of the law that are related to the Group's activities, this might result in heavy expenses to the Company and even discontinuation of the development of its drugs.

22.1.2 **Dependency on external financing**

The Group, like any business in the biotechnology industry, depends on external financing since it essentially does not have all of the revenues whereas development expenses incurred in development of its drugs are high. At a certain stage, the Group's financing sources will run out and the Group will not be able to continue financing the drug development activity as previously mentioned. See Note 1b of the Company's financial statements.

22.1.3 **Dependency on professional, skilled personnel**

As a biotechnology company, the Group is required to employ skilled personnel who can perform the tasks with consummate professionalism and skill in order to achieve maximum results with maximum supervision.

22.1.4

Dependency on trial volunteers

As an organization in the clinical biotechnology industry that performs trials, the Group requires healthy and sick volunteers to carry out its trials. A frequent difficulty when conducting clinical trials involves the enrollment of volunteer patients due to fierce competition over these patients (particularly when patients are in the advanced stages of their disease) and occasionally due to patients' use of other drugs – which may disqualify them from participating in the trials.

22.1.5

Exposure to lawsuits

In light of the Group's operations in the clinical trials industry, it is exposed to legal proceedings related to potential adverse events of its drugs. Adverse events of drugs are a known phenomenon, particularly during the development stages. The Group cannot guarantee that no adverse event will be discovered in relation to its drugs, thus creating the possibility that such discovery is to render the Group vulnerable to various lawsuits.

22.1.6

Competition

The Group is exposed to the possibility that competing companies will develop a similar drug to the one developed by it – for additional information about the competition and the products competing with the Group's products, see item 8.2.7 above.

In addition, it should be noted that the Recombinant EPO related patent is scheduled to expire in 2019 and the drug will become generic. Despite the aforementioned, in May 2011, the Company's EPO drug obtained an Orphan Drug status from the FDA, which allows the manufacturer, among others, regulatory exclusivity in marketing the drug for a period of seven years in the U.S. from the date of receiving the marketing approval (see details in item 2.1 above).

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It should further be noted that the patent for using Erythropoietin to treat anemia will shortly expire and there is a risk that in certain countries, the Recombinant EPO will be given in off-label-use. The Group, however, believes that this risk is limited since the Recombinant EPO is a drug that includes the Black Box warning that may deter doctors from prescribing it for off-label-use, and subsequently, from taking the drug not according to its indications.

22.2

Risks which are unique to the Group

22.2.1

Development failure

As a company operating in the biotechnology industry, the Group essentially relies on the future potential embodied in the development of its drugs since as of the date of this report, the Company has no income. If the Group's expectations regarding the development of its drugs fail to be realized into products with marketing feasibility, the continued existence of the Group as an independent organization will be in doubt. Since the field in question is drug development, there is no certainty that the Group's drug trials will succeed. As previously mentioned, if these trials fail, the Group's entire existence will be in question. It should be emphasized that any clinical study contains numerous elements of uncertainty and the possibility that the Group will fail in its attempt to prove and demonstrate the efficacy and safety of its drugs or if those drugs turn out to be less efficient than expected cannot be ruled out. In addition, the possibility of the development of other drugs by the competitors that will compete with the Group's drugs and capture a significant share of its market share cannot be ruled out as well.

22.2.2

Relative dependency on key figure

The Group is moderately dependent on Prof. Moshe Mittelman who serves as the Company's medical director³³ and who developed the indication of the Recombinant EPO on which his study is based. If for some reason Prof. Mittelman fails to support scientific / clinical aspects and/or if he no longer serves in his position, then the Group will suffer some damage. If Prof. Mittelman discontinues his work with the Group, some time may pass until the Group finds a replacement for Prof. Mittelman. It should be emphasized that regarding any aspect related to performance or continued performance of the clinical trials on the Recombinant EPO, the Group believes that Prof. Mittelman's leaving will not cause a significant delay in the Group's clinical activities as specified above.

22.2.3

Intellectual property protection

The Group, being a company in the biotechnology industry, largely relies on the possibility of protecting and preserving its intellectual property. Infringement of its intellectual property rights through violation of the patents given to the company can seriously harm the Group's operations. Without protection of the Group's intellectual property, there is nothing stopping any other party from using the Group's developments without having had to incur heavy development expenses. In addition, protecting the patent given to the Group might not withstand legal proceeding that will validate the claims included in it.

³³It should be noted that Prof. Mittelman has been serving as medical director in the Company since 4 August 2010.

22.2.4

Marketing and sales

The Group lacks any manufacturing, marketing and sales facilities. If its drugs do reach the stage at which the Group can commercialize the drugs, it will need to collaborate with another organization or try to create manufacturing, marketing and sales systems to realize the drugs' inherent marketing potential.

Below is a table of risk factors that might affect the Group's operations and business results as well as the Group's assessment with regard to the degree to which these risk factors might affect the Group's operations in general:

Type of risk	Brief description	Degree of impact on the Group's operations		
		High	Moderate	Low
Industry risks	Compliance with laws and regulations	√		
	Dependency on external financing	√		
	Dependency on professional, skilled personnel		√	
	Dependency on locating trial participants	√		
	Adverse events are liable to occur during use of the drugs and definitely during use of the drugs in development– which can lead to lawsuits		√	
	Development of rival drugs	√		
	Patent expiration in 2019 and failure to obtain Orphan Drug approval in Europe and in Japan	√		
Risks unique to the Group	Numerous elements of uncertainty – unsatisfactory results, delay or failure of the Group's drugs – no guarantee of trial success or lack of adverse events	√		
	Dependency on a key figure – Prof. Moshe Mittelman who serves as the Company's medical director			√

Type of risk	Brief description	Degree of impact on the Group's operations High Moderate Low
	Due to the strong dependency on patents and protection of intellectual property, there is a possibility of infringement of existing patents	√
	In the future, when the Group's drugs move ahead to the manufacturing stage, the Group will be dependent on manufacturers since it is unable to mass produce the drugs	√

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Chapter B

XTL BIOPHARMACEUTICALS LTD.

DIRECTORS' REPORT ON THE COMPANY'S STATE OF AFFAIRS

AS OF DECEMBER 31, 2011

The board of directors of XTL Biopharmaceuticals Ltd. ("**the Company**") hereby presents the Company directors' report for 2011.

The data presented in this report relate to the Company and its subsidiaries on a consolidated basis ("**the Group**"), unless explicitly stated otherwise.

PART 1 - THE BOARD OF DIRECTORS' EXPLANATIONS FOR THE STATE OF THE CORPORATION'S BUSINESS

1.1 Significant events during the year

On February 27, 2011, the Company published a supplement prospectus according to which the Company offered up to 13,210,000 Ordinary shares of NIS 0.1 par value and up to 6,605,000 registered warrants (series 1) to purchase up to 6,605,000 Ordinary shares at an exercise price equal to NIS 0.7 per share, linked to the dollar in any trading day on the Tel-Aviv Stock Exchange ("**TASE**") from the date of registration for trade to November 27, 2011 and up to 19,815,000 registered warrants (series 2) to purchase up to 19,815,000 Ordinary shares at an exercise price equal to NIS 1.0 per share, linked to the dollar in any trading day on the TASE from the date of registration for trade to February 27, 2013. Further details are given in the Company's report from February 27, 2011.

On March 7, 2011, and pursuant to the Israeli prospectus that the Company published, as above, the Company published a supplementary announcement in which, among others, it updated the number of securities which it had offered under the prospectus as follows: the new number of securities was determined to be up to 10,700,000 Ordinary shares of NIS 0.1 par value and up to 5,350,000 registered warrants (series 1) to purchase up to 5,350,000 Ordinary shares in any trading day on the TASE from the date of registration for trade to November 27, 2011 and up to 16,050,000 registered warrants (series 2) to purchase up to 16,050,000 Ordinary shares.

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On March 7, 2011, the Company published an immediate report about the results of the tender according to the above supplementary announcement ("**the tender**") as detailed below:

58 orders to purchase 79,004 units with total monetary value of NIS 10,553,017 were accepted in the tender.

The surplus demand in the issuance was more than 185% and the price per unit as fixed in the tender was NIS 132.25.

19 orders to purchase 19,953 units with price per unit higher than the price per unit determined in the tender were responded in full.

2 orders to purchase 30,600 units with price per unit determined in the tender were partially responded such that each of these orderers received about 74.66% of its order.

37 orders to purchase 28,451 units with price per unit lower than the price per unit determined in the tender were not responded.

The number of units ordered at the price per unit or at a higher price was greater than total offered units thus causing oversubscription. Accordingly, the Company used its right to allocate additional units as detailed in item 2.2.6.2 to the Israeli prospectus and item 1.4 to the above supplementary announcement ("**the additional allocation**"). According to the additional allocation, the Company allocated 6,420 units to orderers who booked orders at the determined price per unit such that 95.64% of their order was responded.

Total (gross) immediate proceeds that the Company received for the securities offered to the public under the supplementary announcement, including the additional allocation, amounted to NIS 6,509,345.

On March 22, 2011, 4,666,667 warrants (unregistered) which had been issued in 2006 under a private placement to American investors expired.

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 in return for royalties on sales and milestone payments throughout the clinical

development process, without making any other payments.

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MinoGuard was founded in 2007 in order to commercialize combination therapies for treating psychotic diseases, focusing on schizophrenia. The approval of the agreement between the parties was 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.

On November 30, 2011, the Company closed the MinoGuard transaction according to which an exclusive license to MinoGuard's entire technology, including the SAM-101 drug. 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.

To the best of the Company's knowledge, MinoGuard has successfully completed a Phase 2a prospective, randomized, double-blind, placebo-controlled clinical trial conducted on about 70 schizophrenics. The trial met its endpoints showing that the technology 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 in patients.

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 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 securities to MinoGuard, at its sole discretion.

The licensed technology transferred to the Company is protected by patent through 2027 (subject to approval of the PCT application). 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.

On April 21, 2011, the Company 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 credits on research and development expenses and waiver of FDA filing fees.

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 (which is in the planning and preparation towards phase 2 clinical trial).

On June 1, 2011, the Company announced on convening the annual general meeting of the Company's shareholders whose agenda would be the following proposed resolutions:

a. To discuss the Company directors' report and financial statements as of December 31, 2009 and 2010.

b. To reappoint an auditor - to reapprove Kesselman & Kesselman as the Company's auditors for 2010 and 2011 and to authorize the Company's Board to determine their fee.

c. To reappoint directors - to reappoint, on an individual basis, Amit Yonay, Marc Allouche and David Grossman as directors in the Company until the next annual meeting.

d. To amend the Company's articles of association - to add regulations dealing with indemnification and liability insurance of officers in the Company that are designated to adapt the provisions of the Company's articles of association to certain liabilities prescribed by the Law for Improving Enforcement in the Israeli Securities Authority.

e. To amend the indemnification letters that the Company had given in the past to officers in the Company (as well as to directors) that are non-executive directors.

f. To insure officers (recurring transaction) - to approve a three-year period "recurring transaction" from September 1, 2011 to August 31, 2014 to the Company's engagement in the ordinary course of business in future insurance policies that cover the liability of directors and officers, as they will exist from time to time, as well as directors and officers that are or that may be considered as controlling shareholders in the Company.

On July 12, 2011, the annual general meeting of the Company's shareholders was convened and the issues discussed above were approved.

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 NIS 0.1 par value each at an exercise price equal to 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 maximum 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.

On July 21, 2011, a shareholder exercised 15,544 warrants (series 1) into 15,544 Ordinary shares of NIS 0.1 par value each for the total exercise price of approximately \$ 3 thousand.

On August 29, 2011, the Company's Board approved the adoption of an employee stock option scheme 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.

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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.

On November 2, 2011, the Company entered into a term sheet by which it will acquire the NiCure technology ("**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 as the drug mentioned above was approved for the treatment of reducing hypertension and is being provided to patients for already 20 years.

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

1.2 The financial position, operating results, liquidity and financing resources

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.

1.2.1

The financial position

Balance sheet highlights (U.S. dollars in thousands)

Line item	December 31, 2011		December 31, 2010			
	Amount	% of total balance sheet	Amount	% of total balance sheet		
	\$000		\$000			
Total balance sheet	4,073	100	3,797	100	%	
Equity	3,444	85	2,834	75	%	
Current assets	1,584	39	1,222	32	%	
Property, plant and equipment	32	1	35	1	%	
Intangible assets	2,457	60	2,540	67	%	
Current liabilities	629	15	963	25	%	

Equity

The Company's equity as of December 31, 2011 was approximately \$ 3,444 thousand, an increase of approximately \$ 610 thousand from December 31, 2010, representing 85% of total balance sheet compared to 75% of total balance sheet as of December 31, 2010. The increase in equity is primarily a result of effecting the issuance of March 7, 2011 under a public prospectus on the Tel-Aviv Stock Exchange with total immediate net proceeds of approximately \$ 1.75 million (see 1.1 above), less the loss for the period.

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Assets

Total current assets as of December 31, 2011 was approximately \$ 1,584 thousand, an increase of approximately \$ 362 thousand, compared to approximately \$ 1,222 thousand as of December 31, 2010. The change is primarily a result of increase in the items cash and short-term deposits as explained below.

The Group's carrying amount of cash and short-term deposits as of December 31, 2011 was approximately \$ 1,495 thousand, an increase of approximately \$ 429 thousand, compared to the balance of cash and short-term deposits of approximately \$ 1,066 thousand as of December 31, 2010. The increase is primarily a result of cash received under fundraising, as above, less negative cash flows from operating activities in the reporting period.

The carrying amount of accounts receivables in the statement of financial position as of December 31, 2011 totaled approximately \$ 68 thousand, compared to approximately \$ 110 thousand as of December 31, 2010. The decrease is primarily a result of decrease in the line item prepaid expenses in connection with the Company's Israeli prospectus which was published on February 27, 2011 (see also 1.1 above) as well as decrease in the line item Government authorities.

Property, plant and equipment as of December 31, 2011 totaled approximately \$ 32 thousand, compared to \$ 35 thousand as of December 31, 2010 - with no material change.

The carrying amount of intangible assets as of December 31, 2011 was approximately \$ 2,457 thousand, and comprises mainly the license to use the recombinant rHuEPO drug for multiple myeloma which was acquired in the Bio-Gal transaction from August 3, 2010 including costs involved in the transaction of approximately \$ 187 thousand which were capitalized upon closing. The carrying amount as of December 31, 2010 was \$ 2,540 thousand and included the balance of an intangible asset - the right to examine a medical technology in the field of the immune system in the total of \$ 120 thousand. The decrease in the carrying amount as of December 31, 2011 is primarily a result of the current amortization of the exclusive right to examine a medical technology, as above, during the period of exclusivity (15 months) which has ended in November 2011.

Liabilities

The carrying amount of current liabilities as of December 31, 2011 totaled approximately \$ 629 thousand, compared to approximately \$ 963 thousand as of December 31, 2010. The decrease is primarily a result of payment of outstanding suppliers and other payables including amounts due in preceding periods which, under the payment terms, were paid in the reporting period, among others, for professional services in connection with the preparation of the Company's Israeli prospectus which was completed on March 7, 2011.

1.2.2 The results of the business activity**Condensed statements of comprehensive income (loss) (U.S. dollars in thousands)**

	Year ended December 31,		
	2011	2010	2009
	\$000		
Research and development expenses	158	64	0
General and administrative expenses	1,078	1,222	(2,429)
Other gains, net	12	30	139
Operating income (loss)	(1,224)	(1,256)	2,568
Finance income (expenses), net	17	(1)	(4)
Income (loss) before taxes on income	(1,207)	(1,257)	2,564
Tax benefit	0	0	23
Net income (loss) for the year attributable to equity holders of the Company	(1,207)	(1,257)	2,587

Research and development expenses

Research and development expenses for the years ended December 31, 2011 and 2010 totaled approximately \$ 158 thousand and \$ 64 thousand, respectively. Research and development expenses comprise mainly expenses involved in the preparation to carry out the rHuEPO drug Phase 2 clinical trial designed to treat cancer patients with multiple myeloma comprising, among others, costs in connection with medical regulation, patents registration costs and medical consulting costs. The item research and development expenses also include amortization expenses of the exclusive right to examine a medical technology in the field of the immune system. The increase in research and development expenses in 2011, compared to 2010 substantially derives from medical consulting costs as well as the amortization of the exclusive right to examine a technology in the field of the immune system.

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The Group had no research and development expenses in 2009 because the clinical trial of Bicifadine was terminated in November 2008 after it did not meet its endpoints (see also Note 10c to the financial statements) and due to the fact that the Bio-Gal transaction, in the framework of which the Company acquired the rHuEPO drug, was closed only in August 2010.

General and administrative expenses

General and administrative expenses for the year ended December 31, 2011 totaled approximately \$ 1,078 thousand, compared to approximately \$ 1,222 thousand for the year ended December 31, 2010. The decrease in general and administrative expenses in 2011 compared to 2010 is principally explained by the decrease in professional service expenses, decrease in insurance expenses of directors and officers which reflects the decrease in the annual premium in view of the improvement in Company's parameters, decrease in patent maintenance expenses principally for the rHuEPO drug following registration of patents in all countries where it was filed in 2010, decrease in expenses for share-based payment to employees and service providers which were accounted for by the graded vesting method under which the expenses are declined over the vesting period offset by an increase in salary costs/consulting fees of senior officers which were updated in the second half of 2010 according to agreements and an increase in the rentals which reflect the rent agreement of the Company's permanent offices since August 2010.

The income/decrease in general and administrative expenses for the year ended December 31, 2009 totaled approximately \$ (2,429) thousand which derived from "reverse" of expenses in respect of previous years relating to options of the former chairman and former CEO of the Company because the terms of the options that were contingent on 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, as above, totaled approximately \$ 1,672 thousand, compared to approximately \$ 1,078 thousand and \$ 1,222 thousand in 2011 and 2010. The decrease in general and administrative expenses compared to 2009 mainly arises from the decrease in the Company's operating expenses as part of the reorganization plan performed by the Company since the end of 2008 which included, among others, cut in salary and consulting expenses following downsizing steps in the Company, decrease in office rent expenses and economic streamlining measures.

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Other gains, 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 status 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.

Finance income (expenses), net

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 as a result of effecting the issuance in March 2011 (see also 1.1 above).

Taxes on income

The Company had no tax expenses/income for the years ended December 31, 2011 and 2010. The tax benefit in 2009 totaled approximately \$ 23 thousand and it originated from offsetting tax paid by a U.S. subsidiary in previous years against current losses based on regulations published in the U.S. in November 2009 according to which tax paid in previous years may be credited during a period of up to five years against current losses. The Company had no current tax expenses in 2009 although it presented net income in the period because the net income in the period derived from reverse of expenses from previous years of options (see item on general and administrative expenses above) which are not deductible for tax purposes. Further, the Company did not recognize deferred taxes for carryforward losses and current expenses in the reporting year because revenues and gain are not probable in the foreseeable future due to the nature of the Company as a research and development company.

Comprehensive income (loss)

Comprehensive loss for the years ended December 31, 2011 and 2010 totaled approximately \$ 1,207 thousand and \$ 1,257 thousand, respectively.

The decrease in loss in 2011 compared to 2010 is principally explained by decrease in professional service expenses, decrease in insurance expenses of directors and officers, decrease in patent maintenance expenses, decrease in expenses for share-based payment to employees and service providers offset by an increase in salary costs/consulting fees of senior officers according to their agreements, increase in the rentals of the Company's offices and increase in research and development expenses in connection with the preparations for the rHuEPO drug clinical trial which started only after the Bio-Gal transaction was closed in August 2010.

Comprehensive income for the year ended December 31, 2009 totaled approximately \$ 2,587 thousand. The change in relation to 2011 and 2010 is principally explained by the "reverse" of expenses (decrease of expenses) in a total of approximately \$ 4.1 million which was recorded in 2009 in respect of expenses from previous years of options that were contingent on the performance of the former chairman and the former CEO of the Company following the non-compliance with the option terms and their forfeiture after their departure, which led to offsetting current general and administrative expenses and recording a gain (see also explanation in the item on general and administrative expenses above).

Loss in 2009, after the neutralization of the effect of the "reversal" of the options, as above, totaled approximately \$ 1,514 thousand, compared to a loss of approximately \$ 1,207 thousand and \$ 1,257 thousand in 2011 and 2010, as above. The change arises from reducing current expenses and general streamlining measures expressed by downsizing in keeping with the reorganization plan effected by the Company at the end of 2008, as explained above.

Basic and diluted loss per share for the years ended December 31, 2011 and 2010 amounted to approximately \$ 0.006 and \$ 0.011 per share, respectively.

The decrease in basic and diluted loss per share in 2011, compared to 2010 derives mainly from the increase in the number of shares as a result of the issuance of shares under the Bio-Gal transaction from August 3, 2010 and the issuance of shares under the Israeli public prospectus from March 7, 2011.

The change in comprehensive loss in 2011 and 2010 is immaterial and, accordingly, it does not materially affect the decrease in loss per share in those years.

Basic and diluted earnings per share for the year ended December 31, 2009 amounted to approximately \$ 0.044 per share which derived from the income that the Company recorded in this year due to reverse of expenses in respect of previous years relating to options of the former chairman and former CEO of the Company, as above.

1.2.3

Cash flows

Cash flows used in *operating activities* in the years ended December 31, 2011 and 2010 totaled approximately \$ 1,312 thousand and \$ 735 thousand, respectively. The increase in the cash flows from operating activities in 2011 compared to 2010 derives principally from the payment of debt to suppliers, service providers and other payables in respect of the current period and previous periods according to the payment terms, among others, for the professional services in connection with the preparation of the Company's Israeli prospectus which was completed on March 7, 2011.

Cash flows used in operating activities in the year ended December 31, 2009 totaled approximately \$ 2,488 thousand. The decrease in the cash flows used in operating activities in 2011 and 2010 compared to 2009 is mainly a result of the Group's efficiency measures as part of the reorganization plan effected by the Company at the end of 2008 which continued also in 2009 as well as the fact that the Company had limited activity until the date of closing the Bio-Gal transaction on August 3, 2010 (see also explanation in the item on general and administrative expenses above).

Cash flows used in *investing activities* in the years ended December 31, 2011 and 2010 totaled approximately \$ 1,372 thousand and \$ 103 thousand, respectively.

The increase in the cash flows used in investing activities in 2011, compared to 2010, is primarily a result of investing the cash received from the issuance of March 7, 2011, as above, in short-term deposits. In 2010, the cash flows from investing activities were mainly used for the payment of costs involved in the Bio-Gal transaction. Cash flows used in investing activities in the year ended December 31, 2009 totaled approximately \$ 24 thousand and they were also mainly used for costs involved in the Bio-Gal transaction which have incurred during that period.

Cash flows provided by *financing activities* in the years ended December 31, 2011 and 2010 totaled approximately \$ 1,744 thousand and \$ 1,480 thousand, respectively and they mainly stem from cash inflow on the issuance under the Israeli public prospectus from March 7, 2011, as above, and for the cash received in the issuance of shares under the Bio-Gal transaction, respectively.

The Company had no financing activities in 2009.

1.2.4

Financing resources

The Group has no revenues from operations at this stage and it funds its operations from its own capital and from current credit from suppliers and service providers. As of December 31, 2011, the Company's balance of cash and cash equivalents and short-term deposits amounted to approximately \$ 1,516 thousand. Further, after the reporting period, in March 2012, 4,795,000 warrants (series 2) were exercised into 4,795,000 Ordinary share of the Company of NIS 0.1 par value each for the total proceeds of approximately NIS 5.0 million (approximately \$ 1.35 million). Moreover, in March 2012, the Company completed a private placement for the total of approximately NIS 9.1 million (approximately \$ 2.4 million), under which 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) were issued.

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).

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2. PART 2 - EXPOSURE TO MARKET RISKS AND THEIR MANAGEMENT

2.1 Exposure to market risks and their management

- a. The person responsible for managing market risks in the Group is Ronen Twito, the Company's CFO.

Description of the market risks to which the Group is exposed - the Group's activities expose it to a variety of market risks including the changes in the exchange rates of the NIS in relation to the dollar, because the Company's functional currency is the dollar and substantially all of its expenses are denominated in dollar.

The policy of the Group in managing market risks - the Group accepted the Board's resolution from March 9, 2011 which was reapproved on March 29, 2011, that the Company would hold its cash in dollars, except the amount to settle NIS-denominated liabilities until the end of 2011. On August 29, 2011, the Company's Board authorized the Company's management to hold NIS at the required amount for the repayment of NIS-denominated liabilities from time to time and as timely suitable, through June 30, 2012. On March 29, 2012, the Company's Board determined that the Company's management is authorized, from time to time, to hold NIS at the required amount for the repayment of NIS-denominated liabilities for a consecutive period of nine to twelve months at any time.

d. Supervision of risk management policy - the Group identifies and assesses the principal risks facing it. The financial risks management is performed by the Group subject to the policy approved by the Group's Board.

2.1.1

Exchange rate risk

Substantially all of the Company's expenses are denominated in dollars against which the Company holds its available liquid resources in or linked to dollars. Nevertheless, some of the Company's expenses are denominated in NIS, which create exposure to the changes in the exchange rate of the NIS in relation to the dollar. The Company acts to minimize the currency risk by holding part of its liquid resources in NIS up to the amount of Company's management anticipation of the NIS liabilities.

As a hedge against economic exposure, which does not significantly contradict the accounting exposure, the Company holds substantially all of its current assets in or linked to dollar.

2.1.2 Risks arising from changes in the economic environment and the global financial crisis

In recent years, the world has experienced several events both in the political-security realm and in the economic realm which have trembled the international markets in general and the Israeli market in particular. The noteworthy of these events in the political-security realm are the violent turmoil in neighbor countries which in part have led to dramatic changes in regimes as well as escalated world tension against Iran on the background of its nuclear program.

As for the economic crisis which already lasts for several years, during the recent year, the European economic condition was deteriorated as reflected, among others, by lowering the credit rating of several countries in the euro-block by international rating agencies including France, Spain, Italy, Ireland, Greece, Portugal, Belgium, Cyprus and Slovenia. These credit downgrading have led to resignation of prime ministers in part of the countries because they were asked to extensive budget cuts.

Also, during the year, one of the rating companies lowered the credit rating of the U.S.

The Company's management estimates that since the Group's investment policy is to invest only in bank deposits in currencies that are used for its current needs (dollar, which is the Group's functional currency and NIS - based on its needs and the Board's decision), it is not directly exposed to changes in the market prices of quoted securities. Also, since the Group is in development stages and has no revenues from operations at this stage and its expenses budget relies on several suppliers and service providers the events described above have relatively low impact on its results, compared to selling products companies. Nevertheless, since the Group funds its operation mainly from its own capital, as above, the events described above have a significant effect on the Group's ability to raise funds in the future in order to finance its plans and activity (see Note 1b to the financial statements).

2.2

Report of linkage basis

Linkage basis of balance sheet items as of December 31, 2011:

	U.S.\$ \$000	NIS	Other currencies	Non- monetary	Total
Assets:					
Cash and cash equivalents	8	114	1	-	123
Short-term deposits	1,000	372	-	-	1,372
Accounts receivable	-	25	-	43	68
Restricted deposits	-	21	-	-	21
	1,008	532	1	43	1,584
Liabilities:					
Trade payables	75	12	1	-	88
Other accounts payable	325	216	-	-	541
	400	228	1	-	629
Monetary assets less monetary liabilities	608	304	0	43	955

Linkage basis of balance sheet items as of December 31, 2010:

	U.S.\$ \$000	NIS	Other currencies	Non- monetary	Total
Assets:					
Cash and cash equivalents	853	210	3	-	1,066
Accounts receivable	-	53	-	57	110
Restricted deposits	25	21	-	-	46
	878	284	3	57	1,222
Liabilities:					
Trade payables	161	39	3	-	203
Other accounts payable	407	353	-	-	760
	568	392	3	-	963

Monetary assets less monetary liabilities	310	(108)	0	57	259
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2.3**Sensitivity evaluation****Reporting on the exposure to financial risks:****Sensitivity to changes in the exchange rate of the dollar in relation to the NIS:**

	Gain (loss) from changes			Gain (loss) from changes	
	+10%	+5%	31.12.2011	-5%	-10%
	\$000				
Cash and cash equivalents	11	6	114	(6)	(11)
Short-term deposits	37	19	372	(19)	(37)
Accounts receivable	3	1	25	(1)	(3)
Short-term restricted deposits	2	1	21	(1)	(2)
Trade payables	(1)	(1)	(12)	1	1
Other accounts payable	(22)	(11)	(216)	11	22
Exposure in the linkage balance sheet	30	15	304	(15)	(30)

3.**PART 3 - CORPORATE GOVERNANCE ASPECTS****3.1****Policy of granting contributions**

As of the reporting date, the Company did not determine the policy on granting contributions and during the reporting period the Company did not make contributions.

3.2**Company's internal auditor**

The Company's internal auditor is Mr. Daniel Shapira, who owns a CPA firm specializing in rendering internal auditing services to companies traded in Israel and overseas. The firm has 19 years of experience in performing **3.2.1** internal audit of public companies with experience in wide range of businesses. The auditor is not an employee of the Company but he renders internal audit services as an external entity. The tenure of the internal auditor started on December 26, 2000.

3.2.2 To the Company's best knowledge, the internal auditor complies with the guidance of article 146(b) to the Companies Law, 1999 and with the guidance set in articles 3(a) and 8 to the Internal Auditing Law, 1992.

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3.2.3 According to the internal auditor's announcement, the professional regulations pursuant to which the auditor conducts the audit are as the accepted professional standards of the Israeli Internal Auditing Law, 1992.

3.2.4 The internal auditor's supervisor in the organization is the chairman of the audit committee.

To the Company's Board best knowledge, the scope, the nature and the continuity of the internal auditor's activities and his plan of work are reasonable under the circumstances and sufficient to achieve the aims of
3.2.5 internal auditing in the Company. As stated in article 9 to the Israeli Internal Auditing Law, 1992, the internal auditor was given free access, including ongoing and direct, where appropriate, to the Company's information system and its financial data.

In 2011, the internal auditor performed an audit in the issue of the Group's cash management and the implementation of relevant procedures as well as in the issue of the Company's signatory rights policy. The
3.2.6 working plan was determined, among others, based on a survey of the risks assessment conducted by the internal auditor and consulting with the Company's audit committee.

3.2.7 The audit committee and/or Board approve the issues in the working plan every year.

3.2.8 The working plan allows the internal auditor discretion to deviate from it. According to the practice at the Company, the auditor has to report on the reasoned deviations from the working plan.

The overall audit budget for 2011: considering the size of the Company and the current scope of its operation and
3.2.9 taking into account the approved annual working plan, as above, the audit budget was placed at the scope of about 100 hours.

Professional standards: the internal auditor, based on his announcement, prepares the internal audit in accordance with the accepted professional standards as stated in article 146(b) to the Israeli Companies Law, 1999 and in conformity with article 8 to the Israeli Internal Auditing Law ("**the Internal Auditing Law**")
3.2.10 including, among others, quality standards and performance standards. Pursuant to a professional guidance of the Institute of Internal Auditors in Israel, the internal auditor maintains quality assurance plan including self internal examination.

3.2.11 In the Board's opinion, the auditing work was conducted in accordance with accepted professional standards for internal auditing.

The Board and its audit committee authorized the appointment of the internal auditor while taking into account
3.2.12 his professional qualifications, experience in the practice of auditing and his familiarity with the Company's business.

The reports of the internal auditor were submitted in writing to the Company's audit committee which has discussed them in August 2011 and February 2012 and decided to accept his key recommendations in each of
3.2.13 the reports. The reports of the internal auditor are submitted to the chairman of the Board and to the chairman of the audit committee. All documents and information requested by the internal auditor are delivered to him, as stated in article 9 to the Internal Auditing Law, and he has free access to information, as stated in this item, including ongoing and direct access to the Company's information system and its financial data.

3.2.14 On March 26, 2012, in a meeting of the audit committee together with the internal auditor it was decided on the auditing issues for 2012 and the dates when such auditing will be performed.

3.2.15 The salary of the internal auditor for the services he rendered in 2011 totaled approximately NIS 22 thousand (approximately \$ 6 thousand).

In the opinion of the Board and under the circumstances, the compensation of the internal auditor is reasonable
3.2.16 and does not impact professional judgment and this, among others, taking into account the Board's impression of the way in which he conducts the internal auditing work at the Company.

3.3

Directors - experts in accounting and financing

^{1.} In the reported period, 12 meetings of the Board were held and 6 meetings of the committee that examines the financial statements/the audit committee.

2. Details about directors with accounting and financial qualifications:

According to a decision of the Company's Board from August 27, 2009, the minimal number of directors with accounting and financial qualifications is two. In its determination the Company's Board relied on the scope of the Company's activity which does not justify more than two directors with accounting and financial qualifications and the nature of its activity in the development of drugs and bio-technology realm. Below are the names of directors with accounting and financial qualifications in the Company:

3.3.1 Amit Yonay - received a BSc in electrical engineering from Binghamton University and an MBA in business administration from Tel-Aviv University. He is an entrepreneur and businessman in the real estate sector in the U.S.

3.3.2 Jaron Diament - received a BA in economics and accounting from Tel-Aviv University. He serves as the CEO of Tagor Capital Ltd. and as an external director of Mega Or Holdings Ltd and as an independent director in Danidav Investments Ltd.

3.3.3 Dafna Cohen - received a BA in economics and political science and an MBA in finance and accounting from Hebrew University, Jerusalem. She serves as a director of Formula Systems (1985) Ltd, director of Inventech Central and director of Europort Ltd.

3.3.4 Marc Allouche - received a BA in economics and a MBA in finance and accounting from Dauphine University, Paris. He is a business advisor, investment banker and an entrepreneur.

As for additional details of their qualifications, education, experience and knowledge, see chapter D regulation 26 to the periodic report.

3.4

Independent directors

The Company did not adopt in its articles a provision regarding the tenure of independent directors.

3.5

The accountant

The Company's accountant is the accounting firm Kesselman & Kesselman (PwC Israel). Total fee to the accountant for 2011 amounted to \$ 55 thousand (around 1210 working hours) for audit and tax services. The fee is determined between the accounting firm and the Company's audit committee.

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Below are details of the total fee to which an accountant is entitled in the reporting year and the previous year for rendering of services to the Group:

	For accounting services relating to audit and tax services		For other services	
	\$000	Hours	\$000	Hours
2011	51	1,122	4	88
2010	60	1,210	12 *)	190

*) Comprises mainly services for the Israeli prospectus that was published in February 2011.

3.6

Salary to officers

On March 26, 2012, the Company's Board held a discussion with the Company's senior officers and examined their employment/service agreements, among others, by reference to the contribution of each of the senior officers in the reporting period.

3.6.1 The following information was presented for each of the Company's senior officers:

a. The employment agreements and conditions of Messer.

1. David Grossman, the Company's CEO
2. Ronen Twito, CFO
3. Prof. Moshe Mittelman , Medical Director
4. Marc Allouche, Director
5. Amit Yonay, Chairman of the Board

At the Board's meeting the employment/service agreements of the Messer. were reviewed in detail, in accordance to the elaboration in chapter D to this report.

b. Description of the activity of the officers during the reporting year and in general (a separate discussion was held for each officer):

- The extent of their activity in relation to the duty and the Company's targets
- Transactions entered into with the involvement of the officer and the officer's contribution to their advancement
- Management activities in the capacity of the officer

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c. Criteria used in examining payments to the Company's officers:

Examining the duty of the officer, accomplishment of different requirements in the capacity of the duty and Company's targets

Examining the overall payment made to the officer over the relevant year by reference to the standard norms for officers with similar duties in comparable companies and/or in companies with comparable market value

Examining the significant changes during the year, if taken place, in the nature of the Company's activity, in the officer's duty, in the level of responsibility and in the efforts required to fulfill the officer's duty

d. A summary of the conclusions and the Board's arguments:

After a separate and detailed discussion with respect to each of the above officers, all Board's members, 1. unanimously, have declared that the payments to the officers are fair and reasonable in general and for the reporting year in particular.

In their considerations, the Board's members have especially indicated the fact that the current year was a significant year for the Company in view of the following achievements: the closing of the MinoGuard transaction through 2. which the Company expanded the technology pipeline it holds, effecting the issuance under the Israeli public prospectus on the TASE and progress in the preparation towards Phase 2 clinical trial in the Company's rHuEPO drug (see Notes 1 and 16a to the financial statements).

Directors' fee

The Company's directors, as well as external directors, are entitled to identical directors' fee which does not deviate from the standard and is determined in accordance with the Companies Regulations (Rules Regarding Remuneration and Expenses for an External Director), 2000 consistent with the Company's ranking and similarly to the maximum compensation under these regulations. The Company pays directors annual remuneration of approximately \$ 10 thousand and attendance remuneration of approximately \$ 0.375 thousand a meeting.

Details of the payments made to senior officers and directors are elaborated in chapter D to the periodic report.

3.7 Disclosure of the financial statements approval process

The Company's Board transferred the overall responsibility to the financial statements to the members of the audit committee as the committee that examines the financial statements. Below are the names and details of the members of the committee that examines the financial statements:

Chairman of the committee - Jaron Diament, external director, expert in accounting and financing.

Dafna Cohen - external director, expert in accounting and financing.

Marc Allouche - director, expert in accounting and financing.

As for details of their qualifications, education, experience and knowledge, see chapter D regulation 26 to the periodic report.

After being nominated, the committee's members gave the Company a declaration pursuant to the provisions of article 3 to the Companies Regulations (Directives and Conditions for Approving Financial Statements), 2010 as to having accounting and financing qualifications in accordance with the Companies Regulations (Conditions and Tests of Director with Accounting and Financing Qualification and Director with Professional Qualification), 2005.

Several days before the meeting of the committee, the Company's draft consolidated financial statements, draft report on the description of the corporation's business, draft directors' report, draft report on separate financial information and draft report on the effectiveness of internal control over financial reporting and disclosure are delivered to the members of the committee.

The meeting of the committee that examines the financial statements which was held on March 26, 2012 was also attended, besides the members of the committee, the Company's CEO, David Grossman, the CFO, Ronen Twito, the Company's legal consultant, Ronen Kantor, Adv., and a representative of the Company's auditors (Kesselman & Kesselman, CPAs), Ido Heller, CPA.

At the meeting of the committee in which the financial statements are discussed, the Company's CEO and CFO review in a detailed manner the key points of the financial statements, the Company's financial results, financial position and cash flows. This presentation comprises an analytical analysis and it gives details of the composition of and movement in material items and a comparison is made to previous periods.

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In the meeting, a discussion is held in the issue of estimates and judgments made in connection with the preparation of the financial statements as well as valuations used in the preparation of the financial statements and internal controls over financial reporting. In the framework of the discussion, the auditors give their reference to the audit procedure and to the data in the financial statements. Also, the Company's CEO and CFO review significant transactions that were carried out and any changes that occurred in the Company during the reporting period compared to corresponding periods presented. In this framework, a discussion is held during which the members of the committee raise questions regarding the financial statements.

In the framework of the discussion, the committee forms its recommendation to the Board, among others, about the estimates and judgments made in connection with the financial statements, internal controls over financial reporting, overall financial statements disclosures and appropriateness, accounting policies adopted and the accounting treatment applied to the Company's material issues, valuations and impairment losses of assets, including the assumptions and estimates used to support the data in the financial statements.

The committee that examines the financial statements transferred its recommendations to approve the financial statements to the Board's members. The members of the Company's Board believe that the recommendations of the committee that examines the financial statements have been transferred reasonably enough before the discussion, considering the scope and complexity of the recommendations. The Company's Board stated that a two-day difference between the meeting of the committee in the issue of the Company's financial statements as of December 31, 2011 and the meeting of the Company's Board in the issue of their approval would be considered a reasonable amount of time.

On March 29, 2012, after it was made clear that the financial statements reflect properly the financial position of the Company and its operating results, the Company's Board approved the financial statements of the Company as of December 31, 2011 in the presence of the following directors: Amit Yonay (chairman), Dafna Cohen, Jaron Diament, Marc Allouche and David Grossman.

4. PART 4 - THE CORPORATION'S FINANCIAL REPORTING

4.1 Significant events after the reporting period

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

4.1.2 On February 13, 2012, the Company announced on convening an annual general meeting of the Company's shareholders whose agenda would be the following proposed resolutions:

4.1.2.1 To reappoint directors - to reappoint, on an individual basis, of Amit Yonay, Mark Allouche and David Grossman as directors in the Company until the next annual meeting.

4.1.2.2 To reappoint external directors - to reappoint, on an individual basis, of Jaron Diament and Dafna Cohen as external directors in the Company for a second term.

4.1.2.3 Approving a conditional bonus award to the Company's CEO - if the Company effects a fund raising during a period of thirty six months from the date of this resolution, the Company will pay the CEO a bonus equal to 1.2% of the above fund raising amount up to a maximal amount of \$ 200 thousand.

4.1.2.4 Subject to the approval of section 4.1.2.2 above, the Company will allocate to each of the external directors, at no consideration, 150,000 unregistered options to purchase 150,000 Ordinary shares of the Company of NIS 0.1 par value each (a total of 300,000 options) at an exercise price equal to NIS 0.58633 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 \$ 79 thousand on the date of the approval of the general meeting of the Company. 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.

On March 19, 2012, the annual general meeting of the Company's shareholders was convened and the issues discussed above were approved.

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 **4.1.3** the Institute provides the Company with the right to receive contents 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.

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.

The Company estimates that access to data through this agreement will enable the Company to evaluate safety and efficacy of data of the technologies under development as well as technologies where development has not yet commenced.

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 Company's shareholders exercised 4,795,000 warrants (series 2) into 4,795,000 Ordinary share **4.1.4** of NIS 0.1 par value each at an exercise price equal to NIS 1.05 per share for the total of approximately \$ 1.3 million (approximately NIS 5.0 million).

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). **4.1.5** 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.

4.2

Critical accounting estimates

The significant accounting estimates were expressed in the following items: intangible assets and share-based payments as well as share appreciation rights. As for critical accounting estimates, see Note 3 to the financial statements.

4.3

Persons authorized to sign

The Company does not have any independent signatories.

March 29, 2012

Date **Amit Yonay, *Chairman of the Board*** **David Grossman, *Director and CEO***

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Chapter C

XTL Biopharmaceuticals Ltd. Consolidated Financial Statements as of December 31, 2011

Our audited and consolidated financial statements for the fiscal year ending December 31, 2011, as well as our accountant's report, are incorporated by reference from Form 20-F filed by XTL Biopharmaceuticals Ltd with the Securities and Exchange Commission on March 29, 2012 at pages F1 - F144.

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Chapter D

Additional Corporate Inform