XTL BIOPHARMACEUTICALS LTD
Form 6-K
March 25, 2013

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, 2013

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)

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 x 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 x

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 24, 2013 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 – Immediate Report

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. Description of the Company's Business for the year ending December 31, 2012.

2. Board of Directors' Report on the Status of the Company for the Year Ending December 31, 2012.

3. Consolidated Financial Statements as of December 31, 2012 (+ Purchase Price Allocation - Proteologics and EPO Impairment Study)

4. Separate Financial Information in accordance with Article 9c of the Israeli Securities Regulations (Periodical and Immediate Reports).

5. Pro Forma Consolidated Financial Statements as of December 31, 2012, in accordance with Regulation 9a of the Israeli Securities Regulations (Periodical and Immediate Reports) – 1970.

6. Additional Company Information.

7. Report on the Effectiveness of Internal Control Over the Auditing of Financial Statements and Disclosures.

XTL Biopharmaceuticals Ltd.

("The Company")

Periodic Report as of 31 December 2012

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Chapter One – 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	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.

	Self (autologous) transplant – the patient receives stem cells from his/her own bone marrow or from his/her peripheral blood.
Neuropathy / Peripheral Neuropathy	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.
T-Lymphocytes	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.
Anticancer Effect	Anticancer effect is any phenomenon that causes cancer cells to stop reproducing, that eliminates them or 'freezes' their growth and spreading.
Schizophrenia	A severe chronic (psychotic) mental illness that is one of the most prevalent mental diseases. It affects most of the mental and social functions, state of mind, perception and thought as well as cognitive functions.
Antipsychotic Drugs	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.

Psychotic Disorder	An extreme mental state of partial or complete loss with reality. Psychosis is characterized as behavior perceived as strange or irregular and incomprehensible that might sometimes arouse feelings of anxiety and social rejection.
Bipolar Disorder	A mental illness that causes dramatic mood swings and sparks manic-depressive episodes.
Minocycline	A broad-spectrum tetracycline antibiotic that has been used for over 20 years and today is mainly used to treat acne. Minocycline is a small molecule with a molecular weight of 495 that is highly lipophilic and can therefore easily traverse the blood-brain barrier.

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.
EMEA	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 EMEA[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.
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.

[1] According to the information appearing at the organization website: http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm

Cardiovascular	Cardio – related to the heart; vascular – blood vessels
Cardiovascular Event	Event such as a heart attack, stroke and death (in the context of hypertension and cardiopulmonary diseases)
USA National Institute of Health	American federal agency that is part of the U.S. Department of Health and Human Services and the primary federal agency for conducting and supporting clinical studies. The NIH website lists all significant clinical trials being conducted around the world.
Blood Pressure	The pressure applied by blood on arterial walls. This pressure undergoes changes due to the contraction and expansion of the heart.
Millimeter of Mercury (mmHG)	Measurement unit of pressure – pressure applied by one column of mercury 1mm high on a basis of 1 square cm.
Systolic Blood Pressure	Maximum blood pressure created in arteries when the heart is contracting ("systole")
Diastolic Blood Pressure	Blood pressure in the arteries at its lowest pressure that occurs when the heart is refilling with blood ("diastole") one moment before it contracts
Sympathetic Nervous System	One of the two parts of the autonomous nervous system responsible for subconscious actions, including control over peripheral resistance, regular heartbeat, intestinal movement, sweating, saliva secretion, etc.
Clinical trials	Clinical trials on human beings
Controlled trials	Clinical trials in which the effect of treatment in both groups of participants is examined. Subjects in one group are given the treatment being studied and in the other group – no treatment or another treatment whose effects are known, so that the effect of the treatment can be assessed by comparing the subjects' reactions in both group.
Randomized, Controlled Trials	Controlled clinical trials in which the placement into groups is random (much like a coin toss). The trial method contains placement objectivity.
Double Blind, Randomized Controlled Clinical trials	Randomized controlled clinical trials in which treatment is administered so that neither the doctor nor the subject are aware of which group the subject belongs. This is the highest level of a trial in achievement of objectivity in clinical trial planning.
Pivotal Study	Trial whose design and scope is such that its results will be accepted by the scientific community as the primary response to a question such as whether a certain treatment is effective.

Peripheral Resistance	The property of blood vessels (or tubes in general) to impede flow. As a result, pressure must be increased to increase the flow. If peripheral vascular resistance rises, the heart generates higher blood pressure to maintain the same level of blood flow throughout the vessels, thereby creating hypertension.
Ejection Fraction	Index of the heart's ability to pump blood into the arteries in each beat from its section known as the "left ventricle". Just before the beat, one of the heart's chambers, the left ventricle, is filled with blood and immediately afterwards, it contracts. Ejection Fraction is the percentage in drop in volume in the left ventricle after each beat.
(Congestive Heart Failure) CHF	Disease in which the heart is unable to withstand the work load imposed on it and pump a sufficient amount of blood to all parts of the body due to congestion of blood in the veins and the excess accumulation of fluid in the body's tissues.

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

2.1 General

a. The Company was incorporated in Israel on 9 March 1993 as a private company in accordance with the Israeli Companies Law, 1999 ("**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.

b. 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 ("**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.

c. 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 potential 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.

On 22 August 2012, Presidio requested to terminate its agreement with the Company that is valid since 24 August 2012. Following the announcement to terminate said agreement, all DOS technology (including all patents maintained by Presidio) was returned to the company 90 days after the date of said notice, in accordance with the provisions of the agreement. As of the date of the report, the Company plans to review the renewal of activity in the Hepatitis C sector and/or locate strategic partners to continue the development and marketing of drugs to treat Hepatitis C based on DOS technology returned to it from Presidio.

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d. In July 2009, the Company's shares were delisted from trade on the NASDAQ due to a claim by the NASDAQ Compliance 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 Israeli 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.

On 1 June 2012, the Company submitted a request to re-list its ADRs on NASDAQ, subject to compliance with all of the criteria required that was examined by the NASDAQ admissions committee, including criteria of minimal price for ADR (in accordance with various listing criteria). On September 24, 2012, the Company's Board of Directors approved the change in quantity of shares to ADR so that 20 ordinary shares of the Company will comprise one ADR, in order to support the Company's compliance with the conditions for listing the ADR for trade on NASDAQ. The determining date for change in the ADR ratio was 4 October 2012. As of the report date, the relisting process has yet to be completed as previously mentioned and the Company is in the midst of discussions with the NASDAQ Compliance committee to complete the process.

Despite the aforementioned, as of the date of this report, the Company is registered 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-Mellon (BONY) costs, and other various costs that were estimated, at the time of this report, at US$ 120,000 a year.

e. 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 as stipulated in this article) 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.

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

f. On 19 March 2009, the Company entered into an agreement with Bio Gal Ltd. (Hereinafter "**Bio Gal**") to purchase assets, rights to the patent to use Recombinant Erythropoietin to extend the lives of terminal Multiple Myeloma patients as well as improve the quality of their lives. 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 outstanding 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.

g. On 27 February 2011, the Company published a prospectus (Hereinafter "**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 Tel-Aviv Stock Exchange Ltd. (Hereinafter: "**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.

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, as stipulated below: (a) 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.

(c) 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.

h. 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. On 30 November 2011, the Company reported that it had closed an agreement for obtaining an exclusive global license to MinoGuard's entire technology. For more information about the exclusive licensing agreement, see Article 18.11.2 below.

i. 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 EPO 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).

j. On 2 November 2011 , the Company entered a contractual arrangement in a memorandum of understanding to an agreement in which it will acquire NiCure technology, 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 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

of directors. For more information about the Company's contractual arrangement, see Article 8.11.3 below. As of the date of approval of the financial statements, the transaction has not been completed and the Company is considering this project fit to its business plan.

k. On 14 March 2012, the Company entered a strategic collaboration framework agreement with Clalit Health Services – Clalit Research Institute Ltd. (Hereinafter: "**The Institute"**) and Mor Research Applications Ltd. in which the Institute would grant the Company the right to receive content based on data originating in the Institute's database regarding technology originating in the inventions and patents of Clalit Health Service physicians, in projects whose content will be agreed upon between the Company and the Institute and Mor in advance and in writing. For more information about the agreement, see Article 8.11.1 below.

l. On 12 April 2012, the Company entered a contractual arrangement with Kitov Pharmaceuticals Ltd. (Hereinafter: "**Kitov**") in a non-binding letter of intent in which the Company plans to purchase the entire share capital of Kitov in consideration for allocation of the Company's shares as well as milestone payments through the Kitov product development process. On 6 March 2013, and after the report date, the Company announced that negotiations it conducted with Kitov did not come to fruition and the parties decided to end the process.

m. On 10 June 2012, the Company received notice from the TASE updating that beginning on 17 June 2012, the Company's securities would be listed on the TA-Yeter 50 and the TA-BlueTech 50 indices.

n. On 13 June 2012, the Company entered a contractual arrangement in an agreement on principles with InterCure Ltd. (Hereinafter: "**InterCure**") in which, subject to implementation of a debt arrangement in accordance with Article 350 of the Israeli Companies Law 5759-1999 (Hereinafter: "**The Arrangement**"), the transaction has not yet been completed in which InterCure would convert all of its debts into ordinary shares of InterCure in accordance with a distribution that will be agreed upon between it and all of its creditors (including employees), the Company will acquire control over InterCure in consideration of an accumulated investment of $2.7 million, some in cash and some in allocation of Company shares. As part of the suspending condition for implementation of the agreement, InterCure undertook that on the date of completion of the transaction, it will be without debts and/or financial undertakings, net and without any contingent liabilities, with the exception of the sum of up to $150,000 liability net.

On 25 July 2012, the transaction was completed following compliance with all of the suspending terms and the Company acquired 16,839,532 ordinary shares with no n.v. of InterCure in consideration for the allocation, by way of private allocation of 7,165,662 ordinary shares of NIS 0.1 n.v. per Company share whose value on the date of the signing of the Agreement, in accordance with the value of the Company share on the TASE totaled $2.2 million, and that represents $1.75 million for InterCure pre-money, but after conversion of InterCure debts as previously mentioned (Hereinafter: "**Adjusted Value for InterCure**"). The fair value of Company shares on the date of completion of the transaction totaled $2,469 thousand. In addition, the Company transferred to InterCure a sum of $150,000 in cash based on the adjusted value for InterCure. With execution of the said allocation, the Company held 50.79% of the issued and outstanding share capital of InterCure.

In addition, the Company and Medica Fund, which invested in InterCure shares, in addition to the Company a sum of approximately $460,000, granted to InterCure convertible loan of $500,000 (the Company's share stood at $330,000) for a period of up to ten months with an interest rate of 15%. The Company and the Medica Fund have the right to convert the loan to 11,546,507 additional shares of InterCure (the Company's share is 7,620,695 shares) that will be capitalized, upon conversion of the loan and assuming full dilution, as of the date of completion of the transaction, approximately 24.47% of the issued and outstanding share capital of InterCure (the Company's share in the convertible loan will be 16.15% of the issued and paid-up capital of InterCure). On 6 August 2012, Medica Fund converted the loan it granted InterCure into shares. On 3 March 2013, the Company's Board of Directors granted an extension of an additional 6 months to repay the loan (Hereinafter: "**Date of Repayment''**) subject to that if InterCure receives money from any source (without operating income) up to the date of repayment, InterCure will be required to pay off the balance of the loan, or any part of it, in payments that will not be less than $50,000 per payment.

The Company's holding rate in the issued and paid-up share capital of InterCure as of the report date totaled 45.41%. At the same time, if the Company converts the loan it granted InterCure into shares, its holding in InterCure will be 54.72%. If all warrants granted to employees and directors in InterCure are exercised, and assuming that said conversion of shares will stand the Company's holding percentage in InterCure at 52.77%. For more information about InterCure, see Article 2.33 below.

It should be noted that on 28 October 2012, InterCure allocated 20,185,184 performance-contingent warrants that can be exercised into 20,185,184 ordinary shares with no n.v to Giboov Ltd. (Hereinafter: "Giboov"). If all of the performance-contingent warrants granted to the directors and employees are exercised, and that have not yet expired or forfeited, the Company's holding percentage in InterCure will be 36.76% of the issued and oustanding share capital of InterCure. As of the date of the signing of the financial statements, said warrants had not yet reached maturity.

o. On 21 November 2012, the Company acquired from Teva Pharmaceutical Industries Ltd. (Hereinafter: "**Teva**"), in an outside transaction, 4,620,356 ordinary shares of NIS 1 n.v. per share of Proteologics Ltd. (Hereinafter: "**Proteologics**"), which comprises Teva's full holdings in Proteologics and approximately 31.35% of the issued and outstanding share capital of Proteologics (as of the date of acquisition; approximately 31.24% as of 31 December 2012), in consideration of approximately NIS 6.5 million (approximately $1.7 million).

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Proteologics is a public company whose shares are listed on the TASE and that specializes in the discovery and development of drugs that operate on various components of the Ubiquitin system that was discovered by Dr. Avram Hershko and Dr. Aaron Ciechanover, 2004 Nobel Prize laureates in chemistry for this discovery. For more information about Proteologics, see Article 2.3.4 below.

2.2 Listed below is a flowchart of the Company's holding structure as of this report date

2.3 Information about the Company's Holdings

2.3.1 As of the report date, the American companies, XTL Biopharmaceuticals Inc. and XTL Development Inc. are not operational.

2.3.2 **XTEPO Ltd.** – XTEPO is a private company incorporated and registered in Israel on 9 November 2009, in accordance with the Israeli Companies Law 5759-1999 (Hereinafter: "**The Companies Law**") for the purpose of a share swap agreement with Bio Gal Company as stipulated in Article 2.1 above.

2.3.3 **InterCure Ltd.**- InterCure incorporated in Israel on 20 November 1994 as a private company in accordance with the Israeli Companies Ordinance [New Version] 5743-1983 ("**The Companies Ordinance**"). On 26 July 2007, the company became a public company as defined in the Israeli Companies Law 5759-1999. Since its inception, InterCure has been specializing in the development of unique technologies and devices for non-medicinal and non-invasive treatment of chronic illnesses including hypertension, heart failure, sleep difficulties and stress. InterCure therapeutic devices are based on patent-protected technologies for respiratory modulation that reduces hyperactivity of the sympathetic nervous system.

Over the past decade, InterCure has been preparing the groundwork required for large-scale commercialization of technologies and devices that it developed that include, inter alia, clinical trials, regulatory approvals in major markets, mass production and quality control systems, marketing systems and sales to consumers and physicians, branding and advertisements, distribution channels and business partnerships.

As of the date of the report, and following proof of the clinical efficacy and after having obtained FDA[3] approval, InterCure sold approximately 200,000 devices under the brand RESPeRATE® (Hereinafter: **"The Device**" or "**The Product**"), in its various versions, to the first target market that it defined –non-medicinal and non-invasive treatment of hypertension in chronic patients who are unable to stabilize with drugs and/or who suffer from adverse events from drug therapy and/or who have not yet begun drug therapy. Most of the devices to treat hypertension were sold to the end-users (patients) at a price of $300-400 per unit[4].

In addition, InterCure has several initial clinical trials and professional medical publications that indicate the efficacy of the technology it developed in non-medicinal and non-invasive treatment in heart failure patients. In addition, InterCure has evidence of the efficacy of the device in alleviating stress and in facilitating sleep. For more information about InterCure's area of operation, see Article 3.2 below.

InterCure has two subsidiaries: InterCure Inc. ("InterCure Inc") a private company founded on 11 February 2000 in accordance with the laws of the State of Delaware USA that has offices in Manhattan New York, USA and InterCure UK Limited ("InterCure UK"), a private company founded on 12 May 2008 in the United Kingdom and as of the report date, is not an active company.

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=7215

[4] The devices were sold directly by InterCure and its subsidiary in the United States, and through various distribution channels as stipulated in Article 9.6 below. As such, the average price that the Company receives for the device is lower than the price to the consumer. The price of $300-400 per consumer occasionally includes indirect taxes (such as VAT and sales tax) in accordance with the sale in various countries. In addition, the Company occasionally conducts sales promotion campaigns that cause a decline in the average price of a device during the sale period.

2.3.4 **Protelogics Ltd** – Protelogics was incorporated in Israel on 19 May 1999 as a private company limited in shares formerly known as Lismon (Israel) Ltd. In May 2000, the Company changed its name to its current name Proteologics Ltd. Since March 2010, Protelogic shares have been listed on the Tel-Aviv Stock Exchange Ltd.

As of the report date, Proteologics specializes in research and development of new drugs for a range of illnesses based on the Ubiqutin system. Proteologics has the knowledge and expertise of the Ubiqutin system and is channeling its efforts towards discovering new drugs that operate on various components of this system, particularly cancer and inflammatory diseases.

The Ubiquitin system was first discovered in 1978 by Professor Avram Hershko and Professor Aaron Ciechanover, of the Faculty of Medicine in the Technion, and Professor Ernie Rose, who won the 2004 Nobel Prize in Chemistry for this research. Disruptions in the body's Ubiquitin system might result in a long series of diseases, including metabolic disorders, nerves disorders, malignant diseases, inflammatory diseases, viral diseases, etc.

Protelogics' research and development method involves selecting target proteins in the Ubiqutin system, whose integration in their actions causes the formation of a certain disease and the ability to be a target for the drug. Once the target protein has been selected, Proteologics works to develop a drug that neutralizes or inhibits or activates said target proteins, improving or curing said disease. Proteologics believes that the knowledge it has accrued regarding the Ubiquitin system, including the knowledge, unique tools and experience in discovering lead molecules that can be used in drug development may help it detect and develop new drugs for an array of diseases.

For more information about Proteologics, including information about its area of operation, executive officers, etc. see the periodic report for 2012 that was published by the company on 10 March 2013.

It should be noted that the Company considers its holding in Proteologics as an asset only and its products and management are not considered part of the Company's activities.

3 Areas of Activity

As of the report date, the Company operates (The Company, subsidiary XTEPO and InterCure, hereinafter jointly: "**The Group**") in two main areas of activity: (a) Planning, development and research in order to develop and commercialize its technologies (Hereinafter: "**Drug Development Field"**); (b) Development and marketing of unique technologies and devices for non-medicinal and non-invasive treatment of chronic diseases including hypertension, heart failure, sleep difficulties and stress (Hereinafter: "**Medical Device Field"**). For more information about the Group's activities in the medical device field, that was carried out through InterCure, see Article 3.2 below.

3.1 Listed below is information about the Group's activities in the field of drug development:

3.1.1 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 transaction 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 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. 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.

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3.1.2 Drug development process - general description

Drug development is a complex process that generally includes the following primary stages[5]. Each stage must comply with the health agencies' criteria before the next stage can begin, as follows:

a) 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 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).

b) 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 asses 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.

c) 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.

[5] Description of the stages is general and changes are occasionally possible, including in different drugs. for example, in some cases, Phases 1 and 2 or 2 and 3 may be unified

d) 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.

3.2 As previously mentioned, InterCure operates in the field of medical products and developed unique technologies and tools for non-medicinal and non-invasive treatment of chronic diseases including hypertension, heart failure, difficulty sleeping and stress. InterCure's therapeutic devices are based on patent-protected technology for respiratory modulation that reduces hyperactivity of the sympathetic nervous system. Listed below is information about the Group's activities that are being carried out through InterCure in the field of medical devices:

3.2.1 InterCure Products and Services

As of the report date, InterCure is manufacturing (through subcontractors) and markets the following products and services:

3.2.1.1 RESPeRATE – basic version of the device.

3.2.1.2 RESPeRATE Duo – basic version of the device that allows two users to save the information about the exercise data in the device in separate computer memories.

3.2.1.3 RESPeRATE Ultra – version of the device that includes an ability to instruct new users on how to efficiently use the device, smaller device size and larger user screen than in the basic version.

3.2.1.4 RESPeRATE Ultra Duo – version of the device that allows two users to save information about the exercise data in the RESPeRATE Ultra model in separate computer memories.

3.2.1.5 RESPeRATE Ultra Deluxe – version of the device with an illuminated display easy to use in the dark (bedroom environment).

3.2.1.6 RESPeRATE Rx – version f the device sold under a phsician's prescription in the United Kingdom

3.2.1.7 Accessories to the device, such as a carry case and speakers

3.2.1.8 Extended warranty period for the devices, which provide 36 month warranty period instead of an initial 12-month warranty period around the world, with the exception of Europe, in which the initial warranty period is 24 months in accordance with the law.

3.2.1.9 Support plan and personal training in the US through email and telephone, for a fee that improves the effectiveness of the InterCure products and regular customer support.

In addition, InterCure offers its customers from time to time peripheral equipment (the revenue from which is not material as of the date of publication of this report), such as a blood pressure meters and books on hypertension, which it buys from third parties, as well as value added service online for the community of users who are interested in non-medicinal treatment of hypertension (user forums, eNewsletters, etc.). InterCure does not charge for online services at this stage.

InterCure even provides technical support services to customers, including through call centers, for its products in the US, UK and Israel. These services are provided free of charge and people who are not customers can call and ask questions about the device.

For more information about InterCure products and services, see Article 9 below.

4 **Investment in the Company's Capital and Shares Transactions**

4.1 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 warrants on 7 March 2011 through a 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.

4.2 On 18 March 2012, the Company's Board of Directors approved a private offering to institutional and private investors (foreign and Israeli) in consideration for $2.4 million (approximately NIS 9.1 million). As part of the private offering, the Company allocated 11,560,362 ordinary shares of the Company with NIS 0.1 n.v. per share, 3,853,454 warrants (Series A) and 1,926,727 warrants (Series B), that reflect a share price of NIS 0.789[6].

The warrants (Series A) can be exercised into shares from the date of their allocation (18 March 2012) and until 17 September 2012, so that every warrant will be exercised into one ordinary share of NIS 0.1 n.v. per share against exercise surcharge of NIS 1.046, linked to the US dollar. In the period, 560,000 warrants (Series A) were exercised into 560,000 ordinary shares of the Company of NIS 0.1 n.v. per share in consideration for $155,000. On 17 September 2012, the balance of warrants (Series A) totaling 3,293,454 warrants expired. The warrants (Series B) can be exercised into shares from the date of their allocation (18 March 2012) and until 17 March 2015 so that each warrant will be exercised into one ordinary share of NIS 0.1 n.v. per share against exercise price of NIS 1.124 per share, linked to the US dollar.

4.3 On 25 July 2012, the Company finalized its contractual arrangement in an agreement with InterCure in which the Company acquired control of InterCure in consideration for an aggregate investment of approximately $2.7 million, part in cash and part in allocation of Company shares. The Company acquired 16,839,532 ordinary shares with no n.v. of InterCure in consideration of the allocation by means of private allocation of 7,165,662 ordinary shares of NIS 0.1 n.v. per share of the Company, whose value on the date of the signing of the agreement is based on the value of a Company share on the TASE, totaling $2.2 million and that represents a value of $1.75 million for InterCure pre-money, after conversion of InterCure debts as previously stipulated. The Company's price per share derived from the value of the allocated shares divided by the share portions received by the Company is NIS 1.194. The fair value of Company shares on the date of completion of the transaction was $2,469 thousand. For more information about the acquisition of InterCure, see Article 2.1 above.

[6] Based on a conversion rate of NIS 3.769 per $US 1 that is the representative rate of the US dollar from 16 March 2012.

The table presents the investments made in the Company by investors only:

Date of Allocation	Number of Offerees	The Consideration	Company value post money derived from allocation (if relevant)
18 March 2012	6	$2.4 million (approximately NIS 9.1 million)	Approximately NIS 156 million
25 July 2012	1	$2.2 million dollars	Approximately NIS 285 million

For details about option allocations to employees and service providers, see Note 20 to the consolidated financial statements.

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 Israeli Companies Law 5759-1999.

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

Below is financial information about the Group's area of activity (in Thousands of Dollars)

	Drug Development			Medical Device		
	2012	2011	2010	2012	2011	2010
Revenue (from third parties)	-	-	-	938	-	-
Costs	(1,359)	(1,224)	(1,256)	(1,555)	-	-
Loss from Regular Activity	(1,359)	(1,224)	(1,256)	(617)	-	-
Loss from regular activity attributed to Parent Company owners	(1,359)	(1,224)	(1,256)	(282)	-	-
Loss from regular activities attributed to minority interest	-	-	-	(335)	-	-
Assets attributed to field of activity	7,310	4,073	3,797	3,776	-	-
Liabilities attributed to field of activity	757	629	963	905	-	-

For information and explanations about the results of Company activities and the changes that occurred during the period, see Company Board of Directors explanations about the status of Company affairs attached as Chapter B of this report.

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

Listed below are the trends, events and developments in the Group's macro economic environment that have affected or that might materially affect the Group's activity results in its area of activity:

7.1 Drug Development

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 market of the Group's drug 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 2011 at approximately US$ 7.4 billion**.** [7]Due to the partial success of the 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.

[7] http://decisionresources.com/Products-and-Services/Report?r=pcorcg0713

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 efficiency and safety of the drugs or that the drugs will prove to be less efficacious 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 statements. This information is uncertain and based on the information the Group has as of the date of this report. It is 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 not definite.

7.2 The Medical Device Field

7.2.1 General

In September 2008, a global financial crisis erupted that resulted in a severe credit crisis, to developments and turmoil in markets and to a significant economic slowdown.

7.2.2 Macro Economic Trends

The Group's activity, through InterCure, focuses on the development of innovative technologies and home medical devices as well as the marketing of these devices. The home medical device sector was affected by macro economic trends. Generally recognized is that during any period characterized by economic slowdown, as is projected in the American market, expenses for the purchase of consumer products declines. At the same time, InterCure believes that in the field of medical devices, the impact of declining expenditure due to the economic slowdown in the market is diminished. Concurrently, since in most cases, the Group's products are paid for by the consumer, the economic slowdown in the Group's target markets had a negative material impact on sales.

7.2.3 Aging Population and Increased Public Awareness

Among the adult population in the industrialized world (particularly between the ages of 50-80), there is increasing demand for products that improve health, including home medical devices in areas in which the Group is active. In industrialized nations in which the Group operates, through InterCure, the percentage of adults in the population has been increasing, as has been public awareness of the need to protect health and for more proactive treatment in health-related areas.

7.2.4 Usage Internet And Direct Marketing

In the United States, which leads in direct advertising of pharmaceuticals, about one-third of consumers exposed to direct advertising ask their physician about the medical treatment or drug advertised and in a significant percentage of cases, the physician prescribes to the patient the drug the patient requests.[8] The increased use of online devices may affect demand for InterCure products, which are largely based on commercial activity of online advertising and direct sales to consumers through the internet.

7.2.5 Alternative Medicine Trend

In the United States, and in other industrialized nations, recent years have witnessed a significant increase in the number of people who use alternative medicine. In addition, some physicians believe that alternative medicine is applicable and/or effective[9]. This trend, as long as it continues, may increase demand for InterCure products, which allows for non-medicinal treatment of the disease.

7.2.6. Reimbursement

InterCure believes that there is demand for technology that may reduce the cost of medical treatment, including home medical devices that may reduce cost of treatment hypertension and diseases caused by hypertension. Accordingly, InterCure believes that medical insurers might decide to indemnify the purchases or InterCure products for part or all of the purchase of the device in order to lower the gross expenses in refunding money to policyholders for the purchase of drugs to lower blood pressure and treatments for the disease. Although InterCure does not base its business model on medical reimbursement for the purchase of the product, it is working to convince medical insurers to provide full or partial refund to policyholders who purchase the product. InterCure believes that a reimbursement from the medical insurers, if any, may increase sales.

[8] Food and Drug Administration Surveys of patients, 2004
http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDER/ucm109875.pdf

[9] Astin JA, Marie A, Pelletier KR, Hansen E, & Haskell WL; A Review of the Incorporation of Complementary and Alternative Medicine by Mainstream Physicians; Arch Intern Med, 1998; 158: 2303-2310

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In the US, the reimbursement procedure in insurance companies consists of a few stages. In the first stage, an application is made for the receipt of a CPT code from the American Medical Association (AMA). In the second stage, an application to an ICD-9 code is made to the coordinating committee of the Medicare centers. In the third stage, an application is made to the Statistical Analysis Medical Equipment (SADMERC) regional contractor for the receipt of a new code (HCPCS). After receiving the code with a patient's request to receive a device, the patient's date should be examined in order to verify he fits the criteria enabling him to get reimbursed. If the patient fits the criteria, a device will be supplied to the patient and an invoice will be issued to the insurer.

As of today, InterCure does not have a reimbursement code for its products in the US, and one cannot evaluate at this stage, whether it will receive such code in the future.

In the United Kingdom, InterCure filed an application to establish insurance indemnity as part of the British health basket. On 17 November 2011, InterCure announced that the British Department of Health approved its application for insurance indemnity for the product and as part of the health basket in Britain[10]. As a result, InterCure signed several distribution agreements in Britain, and on 1 February 2012, began selling the product in a manner in which patients in Britain who were required to pay GBP 200 out of pocket to purchase the product could receive the device free of charge or for a nominal fee upon presentation of a signed physician's prescription.

7.2.7 Clinical Studies

Clinical studies on the importance of lowering blood pressure and/or the link between hypertension and other diseases and/or publications regarding InterCure products, including on their effectiveness, and the link between them and other areas of medicine, may affect the scope of demand for InterCure products. Clinical studies that were published in recent years defined a new category of "pre-hypertension" (People whose blood pressure exceeds 130/85 mmHG) by the National Institute of Health in the US. The definition of hypertension in a manner that will include hypertension above 130/85 mmHG, if any, may increase the number of people who will treat their hypertension and accordingly, increase demand for products designed to lower blood pressure, including InterCure products.

7.2.8. Developments in Medical Treatment (Devices and Drugs) and Development and Manufacturing of Competing Products

InterCure activity may be affected by the development, manufacturing and marketing of products using other technologies that compete with its own technologies and products. In addition, the introduction to use of new procedures for medical treatment, as well as new drugs to treat hypertension that have no adverse events might harm demand for InterCure products.

[10] British Department of Health approval refers to England and Wales. Scotland and North Ireland are separate authorities that, to the best of Company knowledge, update their health basket in accordance at a later stage and without need for additional applications by the Company.

To the best of InterCure's knowledge, as of the date of this report, there is no non-medicinal non-invasive medical device to lower blood pressure with proven effectiveness in clinical trials that has been approved for marketing by the FDA but new technologies might be developed in the future that will lower blood pressure. It should be noted that the Company's technology is unique and patent-protected, which limits the development of competing technologies.

In the third quarter of 2010, InterCure learned that the Lloyds Pharmacy chain in Britain ("**The Chain**"), which distributed InterCure devices, developed in conjunction with Harvard Medical Devices Ltd. ("**The Manufacturing Company**") and began advertising a competing device that claims non-medicinal treatment of hypertension at a lower price that the one developed by InterCure ("**The Competing Device**"). A review conducted by InterCure, to the best of its knowledge, revealed that the Competing Device, does not modulate respiration in an interactive manner during the exercise (mode of action is patent-protected by InterCure and has been proven effective in the lowering of blood pressure). At the same time, a review conducted by InterCure's advisors reveals that the Competing Product includes elements that were copied from its products, a possible copyright infringement. InterCure has adopted several measures and its possibilities, including legal and regulatory actions. To the best of InterCure's knowledge, sale of the Competing Device began in the first quarter of 2011 under Lloyds Pharmacy's private brand and under the brand Kinetics, which belongs to the Manufacturing Company. At this stage, InterCure cannot assess whether and how sales of the Competing device will affect its sales in Britain.

For information regarding to InterCure's intellectual property, see section 9.3. for additional information regarding competition to InterCure's technology see section 9.8.

InterCure cannot influence the entry of new competition into the market or on the continue developments of existing competition. As such, it plans to continue investing in the development of new products and protecting the intellectual property rights in order to protect its competitive status.

7.2.9. Company Product Approval Policies by Regulatory Authorities

InterCure activity is affected by regulatory authority policies in various countries regarding approval of product marketing and control. InterCure has regulatory approval to market its products in the US, the EU, Israel[11] and other countries. For more information about the relevant regulatory authorities and necessary approvals, see Article 9.20.

[11] Approval of medical devices is in the renewal stage following expiration of the previous approval on 31 January 2013. InterCure and its regulatory advisors believe that said approval is expected to be received in the next several months.

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7.2.10 Israeli Identity

The sale of InterCure products in various countries outside of Israel might be affected by the international standing of Israel. In general, Israeli identity serves in certain cases as a sales promotion (in light of recognition of the technological advantages in Israel) and in other cases as a disadvantage which might result in cancellation of transactions (such as within the confines of the Arab boycott, etc.)

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

8 Drug Development

8.1 General Information about Drug Development Activities

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.

8.1.1 General

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 receive 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 findings[12] raised the premise that Recombinant EPO affects the immune system, regardless of the cancerous tumor. 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.

[12] The findings were published by Prof. Mittlemen 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..

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It should be noted that in 2006, a study was published by the Cleveland Clinic and H. Lee Moffitt Cancer and Research Institute[13], which retrospectively examined 257 patients who were administered Recombinant 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 Recombinant EPO treatment of patients with Multiple Myeloma**.**[14]

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 disease.

Following in-vivo studies which demonstrated the efficacy of treating schizophrenics in a rat model with recognized antibiotics[15] in 2004, Prof. Levkovitz and Dr. Mendelovic 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 drug 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 drug 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.

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

[14] The articles published 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.

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

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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 deterioration [16]

Three independent groups of researchers (from the universities of Manchester, England, Japan[17] and Maryland) who have been studying the combination of these drugs have also reached similar conclusions to those of Prof. Levkovitz and Dr. Mendelovic.

8.1.2 Structure of the Drug Development Activity of the Group and Changes Therein

8.1.2.1 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 2013 will reach 1.7 million (approximately 0.5% of the population), with the number of cancer-related deaths totaling 0.6 million (approximately 0.2% of the population) [18]. Of all forms of cancer currently known, the most common forms in the U.S. [19] are intestinal cancer (approximately 102,000 new patients a year), lung cancer (approximately 228,000 new patients), breast cancer in women (approximately 235,000 new patients) and prostate cancer in men (approximately 239,000 new patients).

[16] *Levkovitz Y, Mendlovic S, et al. J. Clinical Psychiatry*

[17] *Miyaoka T et al. Clinical Neuropharmacology 31, October 2008*

[18] The data is taken from the National Cancer Institute - NCI- http://www.cancer.gov/cancertopics/what-is-cancer

[19] Data taken from "Cancer facts & Figures 2013" published by the "American Cancer Society".

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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 and in 2013, about 22,350 new cases are diagnosed [20]. This number increases in direct proportion with the average life expectancy around the world. Accordingly, approximately 10,710 patients are expected to die from Multiple Myeloma in the U.S. in 2013. 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 [21]. 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 ells, 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. In addition, two drugs were recently approved to treat multiple myeloma, Kyprolis ®, which was developed by Onyx Pharmaceuticals, Inc. and approved by the FDA in July 2012 and POMALYST ®, which was developed by Celgene and approved by the FDA in February 2013.

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.

[20] The data is taken from "Cancer facts & Figures 2013" published by the "American Cancer Society".

[21] The data is taken from the website of AMEN (Association for Multiple Myeloma) - http://www.amen.org.il/site_files/index.he.1024.html

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Furthermore, the efficacy 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 efficacious.

Based on the aforementioned, there is a clinical need for drugs to treat Multiple Myeloma that will be, on the one hand, efficacious 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.

8.1.2.2 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**") [22], schizophrenia is one of the most prevalent mental disorders and about 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.

[22] http://www.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 as 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.

The research company, Decision Resources estimated the size of the schizophrenia treatment in the U.S., France, Germany, Italy, Spain, the UK and Japan in 2010 at approximately US$ 7.4 billion [23].

The schizophrenia treatment industry experienced significant changes during this period due to the loss of exclusivity on some of the leading drugs as patents expired and the marketing of generic drugs which led, according to Decision Resources, to a decline in sales in the aforementioned countries to approximately $6.5 billion, and against approval of new drugs to be marketed that are currently in various stages of development that might increase the scope of sales in those countries to approximately $7.9 billion in 2021.

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, the 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.

[23] http://decisionresources.com/Products-and-Services/Report?r=pcorcg0713

8.1.3 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 Article 8.10 below.

8.1.4 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 3.1.2 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 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.

8.1.5 Critical Success Factors in the Areas of Operation

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.

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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 ad 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.

8.1.6 Entry barriers in the areas of operation

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.

8.1.7 Alternatives to the products underlying the drug development field of operation and changes therein

8.1.7.1 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. At this stage, these patients are treated, with supportive drugs and treatments (palliative etc.). in addition, to the best of the Company’s knowledge, to the date of this report, there is no known drug or drug under development that works on the immune system as the recombinant EPO does.

Despite the aforementioned, it is possible that the Recombinant EPO drug will be found to be efficacious 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 its 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.

It should be noted that in recent years [24], 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.

[24] The aforementioned regarding treatment of multiple myeloma patients and patient survival time was taken from the article 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 July 2012, the FDA approved for use the drug Carfilzomib (Kyprolis) of Onyx Pharmaceuticals Inc. This drug is considered more effective than Velcade. In Phase II studies, there were incidents in which patients failed to respond to Velcade but responded to Kyprolis[25]. As of the date of these reports, the information available regarding the drug is still limited.

In addition, in February 2013, the FDA approved the drug Pomalidomide, which is considered more effective than thalidomide and Revlimid[26].

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.

8.1.7.2 Alternatives to 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.

[25] Niesvizky R et al: Clin Canter Res 2013; Kortuem KM et al: Blood 2013; 121:893

[26] Traynor K et al: Am J Health Sys Pharm 2013;70:474; Leleu X et al: Blood 2013; 121:1968

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

8.1.8.1 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[27]. 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. 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 management [28]; 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.

[27] 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

[28] These companies are known as CRO - Clinical Research Organization

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8.1.8.2 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 2008 was US$ 201.5 billion [29]. In 2008, sales of all cancer drugs totaled US$ 77.4 billion [24].

In 2011, sales of drugs used to treat Multiple Myeloma in the U.S., France, Germany, Italy, Spain, England and Japan totaled US$ 4.4 billion (and are expected to rise to US$ 7.2 billion in 2021[30]). According to their recent financial statements, actual sales of Velcade in 2011 by Johnson & Johnson (which markets Velcade outside the U.S.) amounted to US$ 1.5 billion [26]. Also, based on the financial statements of the pharmaceutical Celgene (which markets Revlimid), Revlimid sales in 2011 amounted to $3.21 billion [31]. Velcade sales by the Japanese pharmaceutical Takeda (which markets Velcade in the US) in 2010 amounted to $0.73 billion [32]. In July 2012, the FDA approved the drug Kyprolis of Onyx Pharmaceuticals Inc. and its sale in 2012 according to its financial statements for that year, totaled $64 billion [33].

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: [If a reimbursement can be obtained from the insurers or from any other party, this should be noted in the table]

[29] http://www.cancer.org/cancer/cancerbasics/economic-impact-of-cancer

[30] http://decisionresources.com/News-and-Events/Press-Releases/Multiple-Myeloma-100212

[31] http://ir.celgene.com/phoenix.zhtml?c=111960&p=irol-sec

[32] http://www.takeda.com/investor-information/annual/pdf/index/ar2012_en.pdf (page 45)

[33] http://www.sec.gov/Archives/edgar/data/1012140/000104746913001966/a2212722z10-k.htm

		Comparative properties				
Company	**Type of therapy / name of drug**	**Route of administration of treatment**	**Drug intake frequency**	**Average monthly cost of treatment in USD**	**Side effects**	**Efficiency / s**