XTL BIOPHARMACEUTICALS LTD
Form 6-K
March 26, 2010

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, 2010

Commission File Number: 000-51310

XTL Biopharmaceuticals Ltd.

(Translation of registrant's name into English)

Kiryat Weizmann Science Park
3 Hasapir Street, Building 3, PO Box 370
Rehovot 76100, 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 26, 2010 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 Presents Its Translated From Hebrew Financial Statements For The Year Ended On December 31, 2009

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

1. Chapter A – Description of the Company's Business for the year ending December 31, 2009.
2. Chapter B – Board of Directors' Report on the Corporation's Business Position As of December 31, 2009.
3. Chapter C – Consolidated Financial Statements for the year ending December 31, 2009.
4. Chapter D – Further Particulars of Corporation.
5. Chapter E – Separate financial information for 2009 being presented pursuant to Regulation 9.C. of the Securities Regulations (Immediate and Periodic Reports).

XTL Biopharmaceuticals Ltd.
("the Company")

Annual Report for the year ending December 31, 2009

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As of the date of this report, the Company has no development activity. The Company has no customers or revenues from sales and its continued operation is contingent on closing the Bio-GAL transaction and raising funds in the context of this transaction or on raising funds from appropriate alternative sources.

The investment in the Company's securities involves risks that are characteristic of an investment in a biotechnology or pharmaceutical company that is in seed stages. As of the date of this report, the Company has no development activity, no sales and there is no certainty that the Company will be able to complete the development of the products that it intends to develop and market on a commercial basis. The risk factors that are liable to affect the Company are: (a) the Company has not yet commenced the development of the product that it wishes to develop and there is no certainty that the Company will be able to complete its development and that the product, once developed, will be judged efficient and safe to use. In addition, there is no certainty that the Company will be able to develop the product within the predetermined timeline. Non compliance with timelines will cause the Company additional expenditure and may possibly prevent the completion of the product's development the Company wishes to develop; (b) there is no certainty that the Company's future products, when developed, will have demands that justify their commercial production and marketing. Furthermore, the Company cannot be sure as to the demand for its future products, the product prices offered by it and the cost of production of said products; (c) there can be no assurance that patent registration applications filed by the Company will yield patent licenses. If these applications do not yield patent licenses, the Company's internally generated products will not have intellectual property rights, which will enable others to manufacture the Company's products and compete with its future products; (d) a third party might challenge the means undertaken by the Company to protect its intellectual property (IP). Should the Company be unsuccessful in protecting its IP, it will jeopardize its ability to effectively compete in this market and will have an adverse effect on its business; (e) the Company's future possible development activity is based on obtaining an exclusive license from Yeda Research and Development Company Ltd. and on the Company's compliance with the terms of the license agreement; (f) the pharmaceutical market is characterized by fast and constant developments. The Company's operating results depend on its ability to develop on a timely basis new generations of products. There is no certainty that the Company's R&D activity will yield results and that it will be able to sustain R&D activity at the level required for competing successfully with rival products. It is possible that after the finalization of the regulation of the Company's future products, third parties will succeed in developing alternative products that introduce a technological innovation that will circumvent the Company's future patented rights. In such event, third parties may be able to develop rival products for the Company's future products while not breaching the future patented rights, which in turn will increase competition of the Company's future products and reduce the Company's market potential and return; (g) the Company's activity is subject to compliance with certain standards in the countries where it intends to operate (including European, U.S., Israeli and other standards) and thus will be affected by regulatory changes. A change in the regulatory environment relating to the marketing of drugs, including a change and/or the Company's and its manufacturers' failure to comply with said standards, is liable to impose various limitations on the Company's activity, including the grant of future product approvals; (h) the marketing of the Company's future products (if any) is subject to obtaining regulatory approvals. This process may be considerably time consuming, which will cause a delay in marketing the Company's future prospective products and will incur additional charges in connection with obtaining approvals for marketing the Company's future products (if any) on a commercial basis. In addition, there is no certainty that the Company will receive the necessary marketing approvals. Without obtaining the necessary approvals, the Company will not be able to market any future products; (i) the financial resources at the Company's disposal are inadequate for funding operational costs and for completing the R&D activity of any future planned product. The Company's financing needs may vary significantly from time to time, this due to the possible results of experimental and clinical trials that will be undertaken, competition, technological developments in the field and costs arising from additional requirements of the various regulatory authorities. If and to the extent that the Company does not engage in selling or sublicensing its future products in consideration for substantial future proceeds, it will be forced to raise additional funds for completing its plans. There is no way of assuring that the Company will indeed be able to raise additional financing resources, if and to the extent that those are needed. The absence of adequate financing resources will discontinue the Company's operations (see also Note 1d to the financial statements); (j) the

Company does not generate any income from the sale of products, it has no development activity and there is no certainty that it will be able to generate such sources of income; (k) the Company is expected to become exposed to competition both due to the development of new treatment techniques and due to the penetration of new competitors into the market. For more details of the risk factors that are liable to affect the Company, see chapter 2a to this report.

CHAPTER A -
Description of the Company's Business for the year ending December 31, 2009

1. Description of the General Development of the Company's Business

1.1 General

The Company was established in Israel as a private company pursuant to the Companies Ordinance, 1999 ("the Companies Ordinance") on March 9, 1993 under the name Xenograft Technologies Ltd. On July 3, 1995, the Company changed its name to XTL Biopharmaceuticals Ltd. The Company's objectives are to engage in any legal activity. Currently, the Company is engaged in the development, acquisition, sale, sub-license and business ventures in the medical realm and in therapeutics for the treatment of unmet medical needs as well as improvement of existing medical treatment.

In September 2000, the Company's shares were listed on the London Stock Exchange and the Company raised approximately $ 50 million by a public offering of shares. Since then and until October 2007, the Company's shares were listed on the London Stock Exchange. In August 2004, the Company raised approximately $ 17.8 million in another offering on the London Stock Exchange.

In July 2005, immediately after the third amendment to the Securities Law, 1968 ("the Law") and the addition of the first stock exchange in London as a stock exchange of dual listing, the Company also listed its shares on the Tel-Aviv Stock Exchange Ltd. ("the Stock Exchange") and since then its shares are listed on the Stock Exchange. Accordingly, since that date, the Company was reporting according to foreign law (by virtue of chapter e3 to the Law). (for further information see the Company's immediate report from July 7, 2005 (reference No. 2005-02-025750).

In September 2005, the Company filed with the Securities & Exchange Commission in the U.S. ("the SEC") a request to list the Company's American Depositary Shares ("ADR") for trade on the NASDAQ under a list that is currently known as the NASDAQ Global Market (see reference: 2005-02-050971). Since then and until April 17, 2009, the Company's ADRs were traded on the NASDAQ (for further information see the Company's immediate report from April 17, 2009 (reference No. 2005-02-088053).

In March 2006, the Company completed a fund raising in a private placement of $29 million, in consideration of an allocation of approximately 4.7 million ADRs and approximately 4.7 million options (for acquiring 4.7 million shares or 2.3 million ADRs of the Company).

In November 2007, the Company completed a fund raising of $9.8 million in a private placement in consideration of an allocation of 14.5 million ordinary shares of the Company, p.v. NIS 0.1 each (bearing in mind the share consolidation in June 2009). (See Note 16 of the Company's consolidated financial statements).

In July, 2009, the Company shares were delisted from the Nasdaq due to the drop in the Company's market value to below $25 million. Shortly thereafter, the ADRs were quoted on the Pink Sheets - an inter-dealer electronic quotation and trading system in the over-the-counter (OTC) securities market. Accordingly, as of that date, the Company has been reporting according to Chapter F of the Israeli Securities Law, and in parallel, according to the reporting duty prescribed in the U.S. Securities Exchange Act-1934, with respect to a foreign Private Issuer whose securities are held by the public. Since delisting of the ADR from trade, the Company is no longer subject to the provisions of the Nasdaq. (For further details - see the Company's immediate report of July 12, 2009 (reference no. 2009-01-167058)).

The Company owns 100% of the issued and paid-up capital of a US company, XTL Biopharmaceuticals Inc. ("XTL Inc."), which was incorporated in 1999 under the laws of the State of Delaware.

XTL Inc. was engaged in the development of therapeutics and business in the medical realm. XTL Inc. has a wholly-owned subsidiary, XTL Development Inc. ("XTL Development"), which was incorporated in 2007 under the laws of the State of Delaware and was engaged in the development of therapeutics for the treatment of diabetic neuropathic pain. As of the date of this report, both XTL Inc. and XTL Development are inactive.

As mentioned above, the Company was engaged in the development of therapeutics for the treatment of hepatitis C and B. During 2007, the Company discontinued the development programs and trials in these therapeutics and according to an agreement entered with Yeda Research and Development Company Ltd. (the commercial arm of the Weizmann Institute) all rights reverted to Yeda. (For further information see the Company's reports (reference no. 2007-02-418286 and 2007-02-351218).

In 2005, the Company acquired from VivoQuest Inc. (hereinafter - "VivoQuest"), the exclusive worldwide and perpetual rights to VivoQuest's intangible assets, covering a compound library including certain compounds ("DOS") for the treatment of hepatitis C and other assets. (For further information about the DOS, see Immediate Report published by the Company - (reference no. 2005-02-062344). In the course of 2008, the Company out-licensed the use of the DOS technology to Presidio Pharmaceuticals Inc. (For further information see Item 10.2 below and also the Immediate Report published by the Company on March 20, 2009 (reference no. 2008-02-079572)).

In the course of 2007, the Company signed an agreement with DOV Pharmaceutical Inc. (hereinafter - "DOV") to in-license the worldwide rights for Bicifadine. (For further information see the Immediate Report published by the Company on January 16, 2007 (reference no. 2007-02-012607)).

On November 18, 2008, the Company announced that the Phase 2b clinical trial of Bicifadine for diabetic neuropathic pain did not meet its endpoints and, therefore, the trial failed. As a result, the Company discontinued development of the Bicifadine for diabetic neuropathic pain, (see reference no. 2008-02-321801), it dismissed most of its employees and, in coordination with DOV, ceased maintenance of the patents relating to the Bicifadine. In addition, in December 2008, the Company implemented a restructuring plan aimed at developing its business ("the Plan"). The Plan included, inter alia, dismissal of most of the Company's employees, promoting investments, co-operation and acquisition of holdings primarily in companies engaged in applied research in the life sciences, and in drug research and development (biotechnology and pharmaceuticals). (For further information see the Company's report of December 9, 2008 (reference no. 2008-02-348525)). On March 8, 2009 XTL Development formally ended its engagement with DOV in regard to the Bicifadine, whereby all the rights, development data and materials relating to the drug's IP were returned to them.

As of the date of this periodic report, the Company has certain milestone rights in a drug development program for the treatment of hepatitis C based on the DOS acquired in 2005 from Vivoquest, and sub-licensed to Presidio Pharmaceuticals Inc. ("Presidio") in 2008, in consideration of cash payments and further royalties based on milestones for developing the drug amount to $59 million. (For further details concerning the agreement and milestones - see Item 10.2 below).

The Company's Board meeting held on February 11, 2009 approved the election of Mr. David Grossman and Mr. Boaz Shweiger as directors in the Company and the election of Mr. David Grossman as Co-Chief Executive Officer of the Company. (For further information see the Company's report of February 11, 2009 (reference no. 2009-02-035094)).

At the Extraordinary General Meeting held on March 18, 2009, Mr. Marc Allouche, Mr. David Grossman, Mr. Boaz Shweiger and Mr. Amit Yonay were elected to serve as directors of the Company. Mr. Jaron Diament and Ms. Dafna Cohen were elected to serve as external directors of the Company until March 18, 2012. Furthermore, it was decided to consolidate the authorized share capital of the Company and to change the ADR ratio traded in the U.S. (For further information see the Company's report of March 18, 2009 (reference no. 2009-02-061281)).

1.2 Financial Data

As of the date of this report, the Company is not engaged in any development activity. The following data was extracted from the Company's financial statements:

Summary of the Consolidated Statements on the financial position – in thousands of US$

	Year Ended December 31	
	2009	2008
	US$ Thousands	
Total Assets	715	3,402
Total Liabilities	708	1,928
Equity	7	1,474

Consolidated Statements of Comprehensive Income (Loss) - in thousands of US dollars

	Year Ended December 31	
	2009	2008
	US$ Thousands	
Revenues	-	5,940
Gross profit	-	4,099
Research and development costs	-	11,722
General and administration costs	*) (2,429)	3,937
Impairment of intangible asset	-	7,500
Other gains (losses), net	139	288
Profit (loss) of operations	2,568	(18,772)

* includes reversal of expenses due to forfeiture of performance-based options of the former Chairman and former CEO of the Company, see also Note 16B to the financial statements.

For further details, see Part Two of this report.

2. The Company's Agreement with Bio-Gal Ltd.

In March 2009, the Company entered into an asset purchase agreement with Bio-Gal Ltd. (hereinafter - "Bio-Gal"), a private company, for the rights to a use patent on Recombinant Erythropoietin for the prolongation of multiple myeloma (type of blood cancer) patients' survival and improvement of their quality of life. (For further information see the Company's immediate report of March 19, 2009 (reference no. 2009-01-061491)). On September 30, 2009, the Company and Bio-Gal Ltd. signed an extension of the closing date of the transaction to November 30, 2009 (see reference no. 2009-01-244809). On November 30, 2009, the parties signed a further extension date of the transaction until February 28, 2010, which was extended once again up to April 30, 2010, to enable its completion (see reference no. 2009-01-305211).

On December 31, 2009 the Board approved the Company's engagement under an agreement to acquire 100% of the shares of Xtepo Ltd. ("Xtepo"), a new Israeli company established by Bio-Gal's shareholders for purposes of the transaction and which Bio-Gal shall transfer to the use patent for Recombinant Erythropoietin ("EPO").. Furthermore, the amount of USD $1.5 million was to be invested by private investors (through the exercise of options granted to them).

For the purposes of the acquisition, the Company will issue approximately 133 million ordinary shares of the Company to Xtepo's shareholders, against obtaining 100% of their shares in Xtepo by way of issuing ordinary shares of the Company in an extraordinary private placement to Xtepo's shareholders, in accordance with the Securities Regulations (Private Offering Securities in a Listed Company - 2000) (hereinafter: “Share Swap Agreement). The said Share Swap Agreement was approved at an Extraordinary General Meeting of Shareholders on March 2, 2010, such that after completing the share swap, Xtepo's shareholders will hold (together with their holdings of the Company's shares prior to the share swap) approximately 70.64% of the Company's issued and outstanding share capital, while the balance, in the amount of 29.36%, will be held by the Company's shareholders.

Below is a diagram showing the Group's structure after the Share Swap Agreement.

* As of the date of this report, this company is inactive.

It should be noted that the Share Swap Agreement stipulates, inter alia, that its execution is conditional on a number of prerequisites, which the primary ones are: a) publishing an allocation report offering an extraordinary private placement for the allocation of the shares; b) obtaining the approval of the Company's Extraordinary Meeting of Shareholders for the Share Swap Agreement; c) exercising the options by Xtepo's investors, such that on the transaction date, Xtepo will have approximately $1.5 million available at hand; d) the Israel Tax Authority's approval; e) the Tel Aviv Stock Exchange approval to register the allocated shares for Xtepo's shareholders; f) any other approval that may be required for executing the Share Swap Agreement according to law (hereinafter collectively: "the Prerequisites").

For further information on the Share Swap Agreement, see the Company's immediate report of January 15, 2010 (reference no. 2009-01-355719).

As of the date of this report, a considerable part of the Prerequisites referred to above have been fulfilled, including the approval of the Company's shareholders (obtained on March 2, 2010). The Company did not receive the Tax Authority's approval for the share swap and transfer of the intangible assets. According to the Management and its advisers, the transaction is expected to be completed in the second quarter of 2010.

1 Together with their holdings prior to the closing of the Share Swap transaction

The Company's projections on obtaining the Tax Authority's approval and other Prerequisites as outlined above is forward-looking information based solely on the evaluation of Management and its advisers. The foregoing might not be realized as the Management's evaluations are not certain.

Should the transaction and the fund raising involved not be achieved in the upcoming weeks, there are substantial doubts as to the Company's ability to continue operating as a going concern. The auditors, in the Company's financial statements, have drawn attention to the Company's financial position and its inability to pursue its activities without completing the transaction and/or raising funds from other external sources. (See Note 1.D of the financial statements).

Notwithstanding the aforesaid, and on the assumption that the Company does obtain the necessary approvals for complying with the Prerequisites and closing the transaction, the Company will act, whether by itself or through Xtepo (the Company, its subsidiaries including Xtepo, and a second tier company, shall hereinafter be referred to as "the Group"), in order to commercialize a new indication for the use of the EPO drug in the treatment of patients suffering from multiple myeloma, as detailed below:

3. The Group’s activity and description of its business development

3.1 Terminology

For the sake of convenience, the meaning of the terms used in this section will be as follows:

Multiple myeloma	Multiple myeloma is a hematological cancer accounting for about 10% of all hematological cancers and about 1% of all malignant diseases. This disease is characterized by uncontrolled proliferation of plasma cells, a type of white blood cells, in the bone marrow, thus leading to the formation of malignant cell foci causing damage and partial bone destruction This disease has a multi-focal (multiple) nature, reflected by formation of multiple malignant cell foci. The malignant cells and the proteins secreted by them are responsible for a series of clinical manifestations and complications, including damage to the bones, accompanied by pain and fractures, damage to the bone marrow and anemia, susceptibility to infections, weakening of the immune system, nervous system impairment, renal insufficiency, coagulation defects, etc. Multiple myeloma is an incurable disease, with mean life expectancy of the patients being about 3-5 years.

Plasma cells	A group of cells constituting about 2-5% of all white blood cells in the human body. Plasma cells produce immunoglobulins, which are immune system proteins serving as antibodies.
Erythropoietin- EPO	A hormone produced by the kidneys, the known function of which is stimulation of red blood cell production in the bone marrow.
Recombinant Erythropoietin (Recombinant EPO)	A genetically – engineered hormone usually designed for treatment of various types of anemia, mainly anemia affecting patients suffering from renal insufficiency (and treated with hemodialysis), as well as patients with various types of malignant diseases accompanied by anemia.
Autologous stem cells	Stem cells are undifferentiated cells, out of which the three types of blood cells are formed. Most stem cells reside in the bone marrow; however, some of them- called peripheral blood stem cells (PBSC)- are collected from the bloodstream. Autologous transplantation – the patient receives stem cells from his own bone marrow or peripheral blood.
Neuropathy/ Peripheral neuropathy	Functional impairment of the nerves responsible for transmitting sensation from the tips of the hands and feet. In mild cases, peripheral neuropathy may cause tingling in hands and feet, while in severe cases, it may cause pain and pricking sensation in all parts of the body, up to difficulties in limb function and movement.
T- Lymphocytes	White blood cells, which are an important component of the immune system. These cells act in various ways, and are responsible for assisting the body in its fight against infections, malignant cells, etc.
Anti- cancer effect	Anti- cancer effect is any effect causing the cancer cells to stop dividing and multiplying, destroying the cells or “freezing” their growth and spread.
Helsinki committee	A committee acting in accordance with People’s Health Regulations (Clinical trials in human subjects), 1980, responsible for approving and supervising clinical trials - for more information, see paragraph 2.10.1 below.
IRB	Institutional Review Board – A committee equivalent to the Helsinki committee in the US and other world countries.
FDA	Food and Drug Administration – The US authority responsible for control and regulation of drug development and registration in the US.
EMEA	European Medicines Agency – The European authority responsible for control and regulation of drug development and registration in European Union countries. EMEA currently includes about 30 member - countries.2

2 According to the information present in the website of EMEA:
http://www.emea.europa.eu/htms/aboutus/emeaoverview.htm

Serious Adverse Events (SEA) or Serious Adverse Drug Reaction	Any disturbing medical event, at any dose, which is either life threatening or fatal, or requiring hospitalization or extension of current hospitalization, or causing permanent disability or permanent functional impairment.
Activity	Laboratory or clinical results indicating clinical efficacy of the drug.
Efficacy	Proof of clinical effect of a drug in a human clinical trial.
Orphan drug	A special pathway for approval and marketing of medicinal agents by the FDA. This pathway is designed to fulfill the need for the development of drugs for unique populations, as well as for the treatment of relatively rare and incurable diseases (in the US – diseases affecting 200,000 patients (maximal number), in the European Union - diseases with an incidence of up to 5 per 10,000 people). Recognition of a certain drug as an orphan drug grants the manufacturer regulatory marketing exclusivity for a period of 7 years in the US and 10 years in the European Union.
Ethical drug	A patented drug; only its developer is authorized to manufacture and sell it.

3.2 General

Xtepo Ltd. (hereafter: “Xtepo” or "the Subsidiary") is a private company incorporated and registered in Israel since November 9, 2009, according to the Corporations Law 1999 (hereafter Corporations Law).
Together with fulfillment of all the prerequisites for executing the transaction, as detailed in paragraph 18 of this report, Xtepo will receive an exclusive license for using the patent for the treatment of multiple myeloma patients with recombinant EPO, based on a series of studies including, among others, an empirical observation in patients treated with recombinant EPO by Prof. Moshe Mittelman. Prof. Moshe Mittelman is an internationally recognized hematologist, who proved by empirical observations that treatment with recombinant EPO may prolong survival in multiple myeloma patients, along with a significant quality of life improvement, and with reduced side effects, as compared to the currently available medications. Please see paragraph 10.1 below for details of the license agreement.

3.3 The Group’s drugs

EPO

Recombinant EPO (hereafter: “The EPO drug”) is a drug currently used for the treatment of anemia caused by renal insufficiency and various types of cancer, in view of the fact that chemotherapy may exacerbate and accelerate the development and progression of anemia in cancer patients.

3.4 Drug development procedure – General description

Drug development is a complex procedure usually including the following major phases3; in order to move from one phase to the next one, it is necessary to fulfill the criteria defined by the health authority for every phase, as follows:

(a) Pre-clinical phase – This phase includes animal studies designed to demonstrate efficacy of the drug in animal models of the disease for which the drug is indicated. The pre-clinical phase also includes experiments, performed under stringent conditions, designed to examine whether the drug exerts toxic side effects, and to evaluate its various features in animals. In addition, the pre-clinical phase includes development of Good Manufacturing Practice methods (GMP- a set of manufacturing requirements with which the drug has to comply in order to be approved for future administration to the patients).

(b) Phase I – This is the first clinical phase of drug development, during which a preliminary examination is performed in human subjects, with the aim of evaluating the safety and the maximal safe dosage of the drug. Tests of drug distribution and duration of its retention in the bloodstream may also be performed during this phase; these tests enable evaluation of the bioavailability of the drug and other parameters. Phase I studies may be carried out in either healthy volunteers or in patients.

(c) Phase II – This phase involves preliminary examination of drug efficacy in patients. In addition, one of the aims of this phase is to determine the optimal therapeutic dose of the drug. Its safety evaluations are ongoing simultaneously. In many cases, several Phase II studies are performed: Phase IIa study, the objective of which is proof of concept, and a more extensive Phase IIb study, including a larger number of patients and study centers, as compared to Phase IIa study.

(d) Phase III – The most important phase of multinational, multicenter, randomized, placebo- controlled and double-blind studies. This phase involves a larger number of subjects (hundreds and even thousands), and is carried out in a large number of medical centers worldwide, using a single dosage. The objective of this phase is to prove the safety and efficacy of the drug in a large number of patients in order to enable a more accurate simulation (compared to earlier phases) of its use by physicians in clinical practice. Following successful completion of this phase, applications for approval of drug registration may be submitted to the relevant health authorities.

3 Description of the phases is general; changes may sometimes occur with respect to various drugs. For example, in certain cases, phases I and II or II and III may be combined.

It must be emphasized that performance of clinical trials in human subjects during each phase, Phase I, II and III, requires preliminary approval by the Helsinki committee /IRB and by the regulatory authorities of the countries involved in the clinical trials. It must be noted that obtaining successful results in the early phases is absolutely required for the transition from one phase to the next one.

Following successful completion of all the above phases (including completion of Phase III), The Group will be able to submit an application for approval of registration of the drug by the relevant health authority, e.g. US FDA.

As demonstrated above, drug development is a long process requiring significant funding in view of the prolonged duration of the trials, approval processes and analysis of information and results obtained from the studies, the completion of which will enable The Group to submit an application for approval of registration of the drug by the FDA or any equivalent regulatory authority in another country. Clinical development, including performance of clinical trials, is frequently assisted by expert subcontractors, qualified for working under stringent professional standards required by the regulatory authorities.

4. The Group's field of activity

The Group will be involved in one field of activity, in accordance with the license agreement for exclusive use of the EPO drug patent, with the aim of commercializing a new indication for the above drug, which is treatment of multiple myeloma patients, based on the studies performed by Prof. Moshe Mittelman.
In addition, the Group will take action to receive a status of an orphan drug for the EPO drug in order to obtain marketing exclusivity for a limited period and reduced regulatory constraints during the development process.

The company's assessments with respect to receiving a status of an orphan drug include a forward- looking statement. This statement is uncertain, and is based on the information available to the company at the time of preparing this outline. It should be emphasized that it is possible that an orphan drug status will not be granted to the EPO drug, and it will be entitled to neither an accelerated regulatory pathway nor to limited marketing exclusivity period.

Second part – Other information

5. Financial information with respect to the Group's field of activity

Due to the fact that, as of the date of this report, not all the prerequisites had been fulfilled for closing the transaction outlined in Item 2 above, and since Xtepo was established for purposes of the transaction (close to the date of this report) Xtepo does not have financial statements. (For financial information on the Company - see Item 1.2 above as well as Chapter B of this report.)

6. General environment and effect of external factors on the Group's activity

The market of anti- cancer drugs in general, and the market of drugs for the treatment of multiple myeloma in particular, for which the Group's drug is intended, is characterized by an increasing need for new developments in the field of treatment of various cancer types. In spite of the general progress in the field of pharmaceuticals, and the impressive achievements observed in this field during the last years, up to the date of this outline, there are still numerous diseases, including various cancers, for which the currently available medication treatments are insufficient due to either limited activity range or insufficient efficacy, as well as due to severe adverse events. The increasing mean population age, paralleled by increasing number of cancer patients in general, and multiple myeloma patients in particular, emphasizes the ever increasing need for new therapeutic agents aimed at treatment of these diseases.

There is no drug, even the most efficient one in reducing disease symptoms, which can be efficient in all the patients. In many cases, for certain populations of patients, there is no efficient drug for treating their disease or the stage of their disease. Furthermore, in many cases, a certain drug may be efficient for a certain period of time, followed by cessation of its positive effect. In addition, many drugs cause severe side effects, thus sometimes preventing the patients from taking the drugs.

The target market of the Group's drug is unique (for further details, see paragraph 7.2 below), and according to the opinions of the Group's experts, the capacity of any drug to bite into a market share depends on its short- term and long- term efficacy, as well as its side effects, including absolute effects and effects relative to those caused by the competing drugs.

In view of the fact that the Group is developing a new indication for the EPO drug, which is an established and approved drug for the treatment of anemia, the Group expects to receive exemptions from performing pre- clinical and Phase I clinical studies. At present, the Group has a preliminary design for initiating a Phase II clinical study in multiple myeloma patients. It should be noted that in view of the fact that the above design was provided to the company as part of the license agreement for patent use, and considering the long time period that had elapsed since the date of study design preparation, it is conceivable that the Group will be required to introduce changes into the design and to submit them for additional approval by the health authorities prior to study initiation.

Prof. Mittelman's studies indicate that treatment of multiple myeloma patients with the EPO drug leads to significant suppression of disease symptoms, improves their immune system function, stabilizes their health status, prolongs their survival and induces a marked improvement in their quality of life, without causing severe side effects. These features make this drug superior in most of its therapeutic aspects. Provided that these features are apparent in additional clinical studies, as required by the regulatory authorities for drug registration, the Group may foresee that the drug will conquer a large market share in the market of drugs designed for the treatment of multiple myeloma, including treatment of patients with advanced/ terminal disease not responding well enough to the currently available therapies. In addition, the Group foresees another market share for the above drug, based on combinations of the EPO drug with the currently available therapies. If these predictions turn out to be true, the drug will have an estimated market share of millions of USD per year. However, it must be emphasized that clinical research is associated with numerous elements of uncertainty. Therefore, the possibility that the Group will not succeed in continuous demonstration of the safety and efficacy of the drug, or that the actual drug efficacy will be lower than expected, cannot be excluded. In addition, possible development of competing drugs by Exstipo's competitors cannot be excluded.

The above Group's estimates with respect to the potential capacity of the Group's drug to conquer a large market share in the market of drugs designed for the treatment of multiple myeloma include a forward looking statement. This statement is uncertain, and is based on the information available to the company at the time of preparing this outline. It should be emphasized that the actual results of the advanced clinical trial phases may be significantly different from the estimates implied by this statement, thus there is no certainty regarding further successful development of the EPO drug by the Group.

Third Part – Description of the Group’s Business Activities in its field

7. General information on the field of activity

The following is a detailed description of the Group’s business activities, on the assumption that the transaction outlined in Item 2 above will be completed, including trends, events and developments in the macro- economic environment of the Group, which significantly affect, or may significantly affect the Group’s business activities, as follows:

7.1 Introduction

7.1.1 Prof. Mittelman's research study

Analysis of the clinical findings observed by Prof. Mittelman in multiple myeloma patients revealed that treatment with recombinant EPO has prolonged the survival of some patients beyond that predicted for them, based on their condition, without this treatment. The results and conclusions drawn from the above observations were further tested in murine models of multiple myeloma, demonstrating that recombinant EPO has anti- cancer activity, based on its effect on the activation of T- lymphocytes.

These observations have led to the assumption that recombinant EPO affects the immune system regardless of malignant tumors. Another study performed by Prof. Mittelman's research team revealed that patients with advanced multiple myeloma demonstrate prominent changes in various immune system parameters, and that treatment of these patients with recombinant EPO results in improvement of the immune system status in terms of its various components, as well as its function, which may significantly contribute to the prolonged survival of these patients.

7.2 Structure of the Group's field of activity and the changes occurring within it

Multiple Myeloma (MM)

Multiple myeloma is a hematological cancer characterized by uncontrolled proliferation of plasma cells in the bone marrow, thus leading to the formation of malignant cell foci causing damage and partial bone destruction. This disease has a multi-focal (multiple) nature, reflected by formation of multiple malignant cell foci. The malignant cells and the proteins secreted by them are responsible for a series of clinical manifestations and complications, including damage to the bones, accompanied by pain and fractures, damage to the bone marrow and anemia, susceptibility to infections, weakening of the immune system, nervous system impairment, renal insufficiency, coagulation defects, etc. Multiple myeloma is an incurable disease, with mean life expectancy of the patients being about 3-5 years.

In the US alone, the total number of new cancer cases diagnosed in 2005 was about 1.4 million (about 0.4% of the population), with the number of deaths due to cancer approaching 0.6 million (about 0.2% of the population)4. Out of the overall known cancer types, the most common types are colon cancer (about 100,000 new patients), lung cancer (about 170,000 new patients), breast cancer in women (about 210,000 new patients) and prostate cancer in men (about 230,000 new patients). In the US alone, the number of patients diagnosed with any type of cancer is estimated to be several millions.

4 The data were taken from the NCI (National Cancer Institute) website http://seer.cancer.gov.csr/1975_2002/results_merged/sect_01_overview.pdf

Multiple myeloma is a common hematological cancer accounting for about 10% of all hematological cancers, with 60,000 multiple myeloma patients currently living in the US alone. 16,000 new cases are diagnosed in the US annually, and this number is increasing with the increasing average life expectancy worldwide. In general, multiple myeloma is considered to be a disease of advanced age, with typical onset at the age of 65- 70 years, although cases of multiple myeloma diagnosed in people in their fifties are not rare. In addition, multiple myeloma accounts for about 1% of overall cancer cases of all types, and for about 2% of all deaths due to cancer5. It should be noted that multiple myeloma is more common in men, and the risk of developing the disease is twofold higher in men of African origin, as compared to white men.

Drugs competing with the Group's drug

At present, numerous medications and treatments are available for multiple myeloma patients at various disease stages. Sometimes combination therapy is given, including chemotherapy, radiotherapy, medication therapy and bone marrow transplantation. It should be noted that the most common treatment given to multiple myeloma patients is chemotherapy, which destroys cancer cells, but also causes damage to normal cells in the patients' body, mainly active cells e.g. mucous membrane cells, connective tissue cells, as well as blood cells, including cells of the immune system, cells of the reproductive organs, etc. The damage caused to normal cells leads to the development of side effects including nausea, hair loss, severe pain, etc. In addition, biological drugs are available, which are more specific to cancer cells and known to cause less side effects, as compared to chemotherapeutic agents. Examples of such drugs are Thalidomide® marketed by Celgene Corporation (hereafter: Thalidomide) and Velcade® developed by Millennium Pharmaceuticals (hereafter: Velcade). These biological drugs are very expensive and have to be administered, at least in part, by injection.

In the Western world, drugs available on the market of anti- cancer drugs in general, and on the market of anti-myeloma drugs in particular, are usually approved for a strictly specific indication. For example, a drug indicated for treatment of multiple myeloma may only be given to patients complying with the precise definition of patients eligible for such treatment, based on the disease stage, previous treatments, etc. This situation leads to an anti- cancer drug market comprised of multiple patient populations. One of the challenges inherent in anti- cancer drug development is definition of the filed for which the drug is intended, since there are numerous types of cancer, each with several disease stages, and any approved drug is designed to be used during a specific stage of a specific cancer. There are many patient populations suffering from diseases for which no appropriate treatments are available.

5 The data were taken from the website of Multiple Myeloma Association
http://www.amen.org.il/site_files/index.he.1024.html

Furthermore, the efficacy of currently available drugs is limited. For each of the available drugs, there is a considerable percentage of non- responders. In addition, in many patients considered to be responders, the response to the drug is merely partial, and drug combination is required in order to achieve the desired clinical outcome. Malignant tumors are sometimes so aggressive, that a mean prolongation of survival by several months, or sometimes a slight improvement in quality of life, is sufficient to define the drug as effective.

In view of the above, there is a clinical need for drugs designed for the treatment of multiple myeloma, which would be efficient on one hand, and would have a minimal number of side effects on the other. The new indication for the EPO drug, which the Group intends to develop, i.e. treatment of multiple myeloma patients, attempts to fulfill this need. That is: an effective drug not causing significant side effects.

7.3 Restrictions, legislation and special constraints in the field of activity

About Restrictions, legislation and special constraints in the field of activity of the Group, see section 9 below.

7.4 Drug development processes

The process of drug development is a multi- phase process, composed of the following phases: pre- clinical phase, Phase I, Phase II and Phase III clinical studies (see paragraph 1.4 above for further details).

In view of the Group’s intention to develop a new indication for the EPO drug, which is already approved for another indication, and in view of the fact that the pre- clinical phase and Phase I clinical studies are aimed at evaluating drug toxicity and safety, respectively, the Group’s experts believe that it will receive an exemption from performing the above clinical studies, and that the drug development process will begin with a Phase II clinical study.

The above Group's estimates with respect to the phases of drug development and the exemption from performing the pre- clinical phase and Phase I clinical studies include a forward looking statement. This statement is uncertain, and is based on the information available to the company at the time of preparing this outline. It should be emphasized that the actual results may be significantly different from the estimates implied by this statement, thus there is no certainty with respect to receiving an exemption from performing a certain phase and/or with respect to the results of the drug trials performed by the Group.

7.5 Critical success determinants in this field of activity

Successful development of a medical product requires basic knowledge and technology enabling the development of effective products, long- term investments of both financial funds and high quality personnel experienced in the specific field of activity, as well as capacities of commercialization following the completion of development and approval for marketing. In addition, ownership of intellectual property is required in order to enable further development and upgrading of the future product.

The Group (via the Subsidiary as mentioned above) will have an exclusive patent license for using the EPO drug for the treatment of multiple myeloma, based on the research performed by Prof. Moshe Mittelman, an internationally recognized hematologist, Director of Internal Medicine Department at Ichilov Hospital, who is also the Principal Investigator at the Group.

7.6 Barriers at the entrance to the field of activity

The major barrier at the entrance to the field of drug development is the fact that drug development is a long- term process, a sequential, accurate and cumulative procedure lasting for several years. That is, lack of success at any stage of the development process precludes moving forward to the next stage. Needless to say, such a long process requires allocation of significant financial resources in order to cover the ongoing development costs.

As mentioned above, ensuring ownership of intellectual property is of crucial importance, since no use and development of certain materials and products will be possible without it, thus precluding any progress in development. In addition, ensuring ownership of intellectual property is required in order to benefit from the product developed, and to ensure that the developed product is not protected by another patent. Without patent protection, anyone would be able to benefit from the research and development products without covering any costs, as the original developer, Bio-Gal in this case, has covered them. Similarly, if the development extends into the field of another patent, the patent owner will be able to block any commercial activity of the developer. In order to ensure commercialization freedom for the development products, the relevant licenses have to be obtained for product development. In addition to the above, qualified and professional personnel, experienced in the relevant field, is required.

7.7 Alternatives to the development product and changes occurring in them

At present, there are no drugs competing with the EPO drug, which the Group intends to develop, in view of the fact that the EPO drug is designed for treating multiple myeloma patients already treated with all the currently available treatment options. At this disease stage, terminal patients are treated with analgesics only.

In spite of the above, the Group's EPO drug may be found effective for non- terminal patients in the future, if given in combination with other currently available drugs. If the above prediction turns out to be true, the EPO drug may become useful as an alternative and/or adjuvant therapy to drugs available on the market and/or drugs under development. However, approved drugs are available for non- terminal multiple myeloma patients, which may cause difficulties in penetration into this market. It must be noted that development of a new indication for an existing drug is superior to development of a new product, in view of the Group's estimate that certain drug development phases will actually become obsolete (mainly Phase I clinical trial, which has already been performed for the original indication). However, development of the new indication is expected to be a long lasting process.

It must be noted that during the last years6, the preferred treatment given to multiple myeloma patients, at various disease stages, is composed of chemotherapy combined with autologous stem cell transplantation, or a combination of Thalidomide, dexamethasone (a type of steroid) and Velcade, depending on the patient's condition. If stem cell transplantation is performed, the patients receive initial high- dose chemotherapy (relevant for patients younger than 65 years of age).

For patients older than 65 years of age, the physical condition of which does not enable autologous stem cell transplantation, the standard chemotherapy is a combination of two anti- cancer drugs (not specifically indicated for multiple myeloma treatment), sometimes including Thalidomide.

The above treatments result in overall survival of about 30 months in 83% of the patients undergoing autologous stem cell transplantation (below age 65), and in overall survival of about 24 months in 90% of the patients (above age 65).

It must be clarified that the treatments and medications currently used to treat multiple myeloma are associated with severe side effects, e.g. neuropathy – peripheral neuropathy, which may sometimes be irreversible, requiring treatment discontinuation for prolonged periods of time.

The drug currently given to terminal patients is Velcade (Bortezomib), approved by the FDA in 2003. This treatment results in prolongation of survival, with 33% of the patients achieving the survival period of 5 years; the mean survival period observed in patients treated with this drug is about 33 months. The EPO drug developed by the Group may become an alternative to this drug.

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6 The above information with respect to the treatment of multiple myeloma patients and their survival periods was taken from the paper by Prof. Ben-Ami Sela, Director of the Institute of Pathological Chemistry, Sheba Medical Center, Tel Hashomer, published online: www.tevalife.com

7.8 Structure of the competition in the field of activity and changes occurring in it

7.8.1 General

The competitors in this field of activity are a broad range of companies worldwide, including small bio-pharmaceutical companies, up to huge international companies. International marketing of a drug requires access to worldwide marketing channels, which usually forces small companies to cooperate with large companies in the field. On one hand, this is a limiting factor for small companies and on the other- these huge companies are always searching for new drugs in order to enrich the range of products marketed by them, or their "drug development pipeline". During certain periods, the need for new drugs leads the huge multi- national companies to make very high investments in order to purchase rights for drug development and marketing, which may provide an opportunity for companies developing drugs.

The Group has a preliminary design for a Phase II clinical trial, including enrolment of about 50 patients7. Development of numerous drugs at the time of the Group's trial may impose difficulties on patient enrolment for Phase II and III clinical trials. The need for a significant number of patients during the advanced phases of clinical trials may become a considerable obstacle in drug development, which may affect the chances and the schedule of the Group's EPO drug development. In many cases, this problem may be solved by using a development strategy including, among others: correct definition of study subjects (by disease severity grade, by types of previous treatments received, by types of concomitant medications received together with the study drug, etc.); optimal selection of study centers (for example, performing some trials in countries where other treatment alternatives are not yet offered to the patients, or choosing study centers famous for their relatively rapid enrolment capacity, etc.); use of companies specializing in performance of clinical studies8; interest of the investigators participating in the study with respect to the drug and its mechanism of action; providing financial contribution to the research funds of departments participating in the study (this incentive is indirectly designed to improve hospitalization conditions for the patients) in order to ensure referral of patients to the Group's clinical trial, rather than referral to other clinical trials. The Group intends to use such strategies in order to ensure rapid patient enrolment and compliance with the predetermined schedule, although this cannot be guaranteed.

7.8.2 Competition in the cancer market

The market of anti- cancer drugs is a huge market. In 2003, the overall volume of sales of anti- cancer drugs had reached 28 billion USD, out of which about 15 billion USD were attributed to drugs against multiple myeloma, while the remaining sum included supportive care drugs (e.g. drugs for regeneration of the immune and blood systems damaged by chemotherapy, anti- emetic drugs, etc.). During 2003- 2004, Velcade, a new anti- cancer drug indicated for the treatment of multiple myeloma, was approved and introduced into the market. For details on other drugs competing with the Group's drug, see paragraph 7.2 above.

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7 This assumption is based on the number of patients required for clinical trials with other drugs designed for the treatment of multiple myeloma and cancer in general. No comprehensive statistical design has yet been planned, and Xtepo had not yet discussed the clinical design with the regulatory authorities, the FDA and others, thus the actual number of patients required may differ from the above assumption.

8 These companies are known as CRO – Clinical Research Organization

7.8.3 Ways of coping with competition

In order to successfully cope with the expected competition, the Group must position its drug on the market while emphasizing its superiority over the competing drugs. According to the Group's estimates, the expected advantages of its drug, subject to approval, are based on the assumption that it will prolong survival, and improve the patients' quality of life with minimal side effects. According to the Group's estimates, the fact that its drug may be effective when given in combination with other available drugs, or after treatment with other drugs, will reinforce its position and provide the company with a marketing advantage. Thus, provided that the drug is approved, these advantages are expected to grant the company significant superiority, which will ensure a great advantage in the market of multiple myeloma treatments, based on the right marketing efforts.

In addition, the clinical advantages of the product and the ability to protect the intellectual property are crucial factors influencing the ability to introduce a new product into the market and to cope with competition. In view of the fact that the company has an exclusive patent license to use recombinant EPO for the treatment of multiple myeloma patients, the company believes that the drug has the right qualities suitable for coping with the expected competition.

Several years are required for the Group's product to reach the market. However, until that stage is reached, one of the huge companies in this field may wish to cooperate with the Group in the development and/ or marketing of the EPO drug.

The Group's estimates with respect to adjustment of the product and its introduction into the market include a forward looking statement. This statement is uncertain, and is based on the information available to the company at the time of preparing this outline. The actual results may be significantly different from the estimates implied by this statement, thus there is no certainty with respect to the results of the drug trials performed by the Group.

8. Intangible assets

8.1 In December, 20099, the Group, through Xtepo, entered into an agreement with Bio- Gal Limited (hereafter: Bio – Gal) to acquire a patent license for using recombinant EPO to treat terminal multiple myeloma patients and to improve their quality of life. For further details on the license agreement, see paragraph 10.1 below.

9 After the amendment of the agreement with Bio-Gal of March 18, 2009

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

In March 2008 and as amended in August 2008, the Group entered into an agreement to out-license the development rights acquired from Vivoquest to Presidio Pharmaceuticals, Inc. ("Presidio"). For further details regarding the agreement - see Item 10.2 below.

9. Restrictions, valid legislation and special constraints relevant to the field of activity

9.1 Helsinki committee

Approval of clinical trials in human subjects by the relevant authorities (in each of the countries where the Group intends to conduct a trial) is a prerequisite for performing clinical trials sponsored by the Group. The trials have to comply with the principles of the Declaration of Helsinki, and be approved by the ethics committee at every institution participating in the trial. The physician and/or physician’s committee, with whom the Group will collaborate, will submit the study protocol to the institutional ethics committee. Following discussion, including examination of the ethical aspects of the study, subject to protocol approval, the trial may be initiated. Any protocol change requires updating and resubmission for approval by the ethics committee.
Approval by Helsinki committee – as discussed above, is a prerequisite for approving the use of medicinal products by Western health authorities, including the Israel Ministry of Health; it enables proof of safety and efficacy of medicinal products by clinical trials. In order to perform clinical trials in Israel, approval of the protocol has to be obtained (hereafter: authorization) from the committee (the above Helsinki committee), acting in accordance with People’s Health Regulations (Clinical trials in human subjects), 1980) (hereafter: People’s Health Regulations).

Authorization is subject to submission of the application for approval by a licensed physician, who will be the investigator responsible for the study; the investigator participating in the human clinical trial will have the skills and the relevant expertise required for conducting the trial under the following conditions:

a) The expected advantages, for the subject and the company, justify the risk and discomfort associated with the trial for the subject;

b) The existing scientific and medical information justify performance of the requested clinical trial;

c) The clinical study design is scientifically valid, enabling it to provide answers to the question under investigation; it is presented in a clear, detailed and accurate manner in the study protocol;

d) The risk for the study subject is minimal, due to the use of correct methods, and use of procedures already performed in humans or tested in animals, as much as possible;

e) The study subjects will be chosen in accordance with inclusion/ exclusion criteria specified in the study protocol;

f) Informed consent form for the study including all the required information, as specified in the procedure;

g) Study design including instructions with respect to patient's privacy protection and confidentiality of the data collected;

h) The study design includes a proper mechanism of study monitoring;

i) The sponsored has ensured proper insurance coverage for the study subjects;

j) The sponsor and the investigator are capable of allocating the resources required for adequate performance of the study, including qualified personnel and the necessary equipment;

k) Adequate performance of the study will not be harmed by the nature of commercial agreement with the investigator and the institution in which the study is performed;

l) If the study subjects, some or all, may be exposed to inadequate pressure or influence in order to convince them to participate in the study – appropriate measures were taken in order to prevent the above pressure or to minimize the above influence.

9.2 Approval by FDA and EMEA

The product to be developed by the Group is a medicinal product. Thus, its production, sale and marketing are dependent on its approval in every country where it is intended for marketing. In order to receive the above approval, the Group has to comply with the approval requirements, including safety and quality control standards, as required in each of the countries.

The requirements for approval of the drug for sale, as well as the duration of the approval process and the costs associated with it, vary from one country to another. Lack of approval of the Group's product in a certain country will preclude its sale, thus reducing the Group's income. The major markets where the Group intends to act are the US and the European Union.

Having completed the product development process, the Group intends to receive approvals by FDA and EMEA for its marketing and sale. It must be clarified that these approvals are separate and independent. Such approval will be required in the future for any product change to be approved or for extension of the existing applications.

Following approval by FDA and EMEA, the Group will be authorized to market the product only for the approved indication. The FDA and EMEA may perform audits and investigations in order to verify that the Group meets the requirements determined by law and regulation. In addition, the Group may act to monitor its compliance with FDA requirements using a system of quality control, thus significantly reducing the chances of failures and enabling warning of failures in advance, if discovered. Failure to comply with the requirements may lead to sanctions against the Group, including publication of a Black box warning with respect to the product, imposition of penalties and civil compensations, refusal to approve new products of the company or cancellation of existing product approval.

It must be noted that at present, FDA is the most stringent authority; therefore FDA approval is a significant indication for approval by other regulatory authorities.

10. Essential agreements

10.1 License agreement with Bio- Gal

On December 31st, 2009, the Group, via Xtepo had engaged with Bio Gal for the transfer of rights for an exclusive patent license (as defined below), which was originally signed between Bio- Gal and Yeda Research and Development Ltd. (hereafter: Yeda) and Mor Research Applications Ltd. (hereafter: Mor) (Yeda and Mor together are “license owners”) in 2002 (hereafter: "original license agreement"), for exclusive use of the registered patent of the EPO drug license owners, in order to develop a new indication intended to prolong the survival and improve the quality of life of multiple myeloma patients (hereafter: "the patent"). It must be noted that the transfer of rights according to the original license agreement was dependent on consent of the license owners, who gave their consent, thus enabling Xtepo to replace Bio- Gal as a valid license owner.

According to the terms of the original license agreement, Bio Gal is committed to conduct the research for further development of the patents owned by the license owners, including full financing of the research, and will be the owner of an exclusive license for the development, use, marketing, distribution and sale of drugs for the treatment of multiple myeloma and other types of cancer, as permitted by the research. According to the license agreement, Bio-Gal will bear all the costs associated with the preparation, completion, maintenance and protection of any patent registered as a result of the research. The exclusive license given to the above company will be effective for 15 years from the day of the first commercial sale of the drug by Bio- Gal, or until expiration of the patent in the countries where the patent is registered (the latest of the events). It should be noted that the patent is registered in the US since 1999, as well as in Europe, Israel, Japan and Hong Kong. In addition, a patent application was submitted in Canada. The patent will expire in 2019 in those countries where it was registered.

In return for the transfer of the above license, and in accordance with modifications introduced into the original license agreement (the last one was introduced in April 2008), the Group will pay to Yeda:

1. Annual license fee of one percent (1%) of the net sales of the Group and its subcontractors.
2. A single payment upon the following conditions: (1) Sale of 50% or more of Xtepo's shares to a third party (2) Merging of Xtepo with a third party (3) Sale or transfer of Xtepo's strategic assets (hereafter: "realization event"), with a value of USD$250,000 or 2.5% of the gross profit of Xtepo from this event (the lowest of the two).
3. In spite of the above, the parties have decided to agree that although performance of the transaction according to this report is a realization event, the appropriate payments will be postponed until the successful completion of Phase II clinical trial, following which the Group, via Xtepo will pay Yeda a single sum of USD $250,000, and additional USD $100,000 in case of raising at least USD $2 million, and subject to successful completion of Phase II clinical trial.

10.2 Out-licensing agreement to Presidio

On March 19, 2008 the Group entered into an agreement to out-license the DOS program to Presidio Pharmaceuticals, Inc. - a company incorporated in the State of Delaware and engaged in drug research and development (hereinafter respectively - "the Agreement" and "Presidio"). On August 4, 2008 the Group signed an amendment to the Agreement ("Amendment to the Agreement") whereby Presidio took it upon itself to carry out all the development and commercialization activities, including all the costs involved therein, in connection with the DOS. In consideration for this, XTL would receive a down payment of USD $5.94 million. and a future payment of up to USD $59 million