XTL BIOPHARMACEUTICALS LTD
Form 20-F
April 06, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)
¨ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2008

OR

¨ TRANSITIONAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

¨ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____to _____.

Commission file number: 000-51310

XTL BIOPHARMACEUTICALS LTD.
(Exact name of registrant as specified in its charter)

Israel
(Jurisdiction of incorporation or organization)

Kiryat Weizmann Science Park
3 Hasapir Street, Building 3, PO Box 370
Rehovot 76100, Israel

(Address of principal executive offices)

David Grossman
Co-Chief Executive Officer
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(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

American Depositary Shares, each representing ten Ordinary Shares, par value NIS 0.02	The NASDAQ Capital Market
(Title of Class)	(Name of each exchange on which registered)

Securities registered or to be registered pursuant to Section 12(g) of the Act: None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

21,444,383 American Depositary Shares 292,805,326 Ordinary Shares

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

Yes o No ý

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

Yes o No ý

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

Yes ý No o

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

Large accelerated filer £ Accelerated filer ý Non-accelerated filer £

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

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

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

Item 17 o Item 18 £

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

Yes o No ý

XTL BIOPHARMACEUTICALS LTD.
ANNUAL REPORT ON FORM 20-F

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

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "expect," "anticipate," "intend," "plan," "believe," "seek," "estimate," and similar expressions are intended to identify such forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under "Item 3. Key Information–Risk Factors," "Item 4.- Information on the Company," "Item 5. Operating and Financial Review and Prospects," and elsewhere in this report, as well as factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

PART I

Unless the context requires otherwise, references in this report to “XTL,” “we,” “us” and “our” refer to XTL Biopharmaceuticals Ltd. and our wholly-owned subsidiaries, XTL Biopharmaceuticals, Inc. and XTL Development, Inc. We have prepared our consolidated financial statements in United States, or US, dollars and in accordance with US generally accepted accounting principles, or US GAAP. All references herein to "dollars" or "$" are to US dollars, and all references to "Shekels" or "NIS" are to New Israeli Shekels.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable

ITEM 3. KEY INFORMATION

Selected Financial Data

The table below presents selected statement of operations and balance sheet data for the fiscal years ended and as of December 31, 2008, 2007, 2006, 2005 and 2004. We have derived the selected financial data for the fiscal years ended December 31, 2008, 2007, and 2006, and as of December 31, 2008 and 2007, from our audited consolidated financial statements, included elsewhere in this report and prepared in accordance with US GAAP. We have derived the selected financial data for fiscal years ended December 31, 2005 and 2004 and as of December 31, 2006, 2005 and 2004, from audited financial statements not appearing in this report, which have been prepared in accordance with US GAAP. You should read the selected financial data in conjunction with “Item 5. Operating and Financial Review and Prospects,” “Item 8. Financial Information” and “Item 18. Financial Statements.”

	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except share and per share amounts)				
Statements of Operations Data:					
Revenues					
Reimbursed out-of-pocket expenses	$ —	$ —	$ —	$ 2,743	$ 3,269
License	5,940	907	454	454	185
	5,940	907	454	3,197	3,454
Cost of Revenues					
Reimbursed out-of-pocket expenses	—	—	—	2,743	3,269
License (with respect to royalties)	—	110	54	54	32
	—	110	54	2,797	3,301
Gross Margin	5,940	797	400	400	153

Research and development					
Research and development costs	11,490	18,998	10,229	7,313	11,985
Less participations	—	56	—	—	—
	11,490	18,942	10,229	7,313	11,985
In-process research and development	—	—	—	1,783	—
General and administrative	5,143	5,582	5,576	5,457	4,134
Business development costs	(1,102)	2,008	641	227	810
Operating loss	(9,591)	(25,735)	(16,046)	(14,380)	(16,776)
Other income (expense):					
Financial and other income, net	314	590	1,141	443	352
Income taxes	31	206	(227)	(78)	(49)
Loss for the period	$ (9,246)	$ (24,939)	$ (15,132)	$ (14,015)	$ (16,473)
Loss per ordinary share					
Basic and diluted	$ (0.03)	$ (0.11)	$ (0.08)	$ (0.08)	$ (0.12)
Weighted average shares outstanding	292,769,320	228,492,818	201,737,295	170,123,003	134,731,766

	As of December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents, bank deposits and trading and marketable securities	$ 2,924	$ 12,977	$ 25,347	$ 13,360	$ 22,924
Working capital	1,385	8,532	22,694	11,385	20,240
Total assets	3,430	14,127	26,900	15,151	25,624
Long-term obligations	—	194	738	1,493	2,489
Total shareholders' equity	1,426	8,564	22,760	11,252	19,602

Acquisition of the use patent on Erythropoietin

On March 18, 2009, we entered into an asset purchase agreement with Bio-Gal Ltd, a private company, for the rights to a use patent on Erythropoietin, or rHuEPO, for the treatment of multiple myeloma, or MM. We intend to develop rHuEPO for the prolongation of MM patients' survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. The course of the disease is progressive, and various complications occur, until death. In the United States alone, there are approximately 56,000 people living with MM, with about 20,000 new cases diagnosed annually, making MM the second most prevalent blood cancer.

In accordance with the terms of the asset purchase agreement, we will issue to Bio-Gal Ltd. ordinary shares representing just under 50% of the current issued and outstanding share capital of XTL. In addition, we will make a milestone payment of approximately $10 million in cash upon the successful completion of a Phase 2 clinical trial. Our Board of Directors may at its sole discretion issue additional ordinary shares to Bio-Gal Ltd in lieu of such milestone payment. We are also obligated to pay 1% royalties on net sales of the product. The closing of the transaction is subject to various conditions including: XTL's and Bio-Gal's shareholders' approval, as well as completion of a financing. Closing is expected to take place in the second or third quarter of 2009.

Risk Factors

Before you invest in our ordinary shares or American Depositary Receipts representing American Depositary Shares, which we refer to in this report as ADRs, you should understand the high degree of risk involved. You should carefully consider the risks described below and other information in this report, including our financial statements and related notes included elsewhere in this report, before you decide to purchase our ordinary shares or ADRs. If any of the following risks actually occur, our business, financial condition and operating results could be adversely affected. As a result, the trading price of our ordinary shares or ADRs could decline and you could lose part or all of your investment.

Risks Related to Our Business

We have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

You should consider our prospects in light of the risks and difficulties frequently encountered by development stage companies. We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future. As of December 31, 2008, we had an accumulated deficit of approximately $149.1 million. We have not yet commercialized any of our drug candidates or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, consummate out-licensing agreements, obtain regulatory approval for our drug candidates and technologies and successfully commercialize them.

If we are unable to successfully complete our clinical trial programs for our drug candidates, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete clinical trials depends in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate at which we are able to collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases as we are studying. In addition, the multi-national nature of our studies adds another level of complexity and risk as the successful completion of those studies is subject to events affecting countries outside the United States. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis.

If third parties on which we rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our products.

We depend on independent clinical investigators, and other third-party service providers to conduct the clinical trials of our drug candidates and technologies, and we expect to continue to do so. We also may, from time to time, engage a clinical research organization for the execution of our clinical trials. We rely heavily on these parties for successful execution of our clinical trials, but we do not control many aspects of their activities. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the general investigational plan and protocol. Our reliance on these third parties that we do not control does not relieve us of our responsibility to comply with the regulations and standards of the US Food and Drug Administration, or the FDA, and/or other foreign

regulatory agencies/authorities relating to good clinical practices. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trial's plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products, or could result in enforcement action against us.

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

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

- difficulty in establishing or managing relationships with clinical research organizations and physicians;
- different standards for the conduct of clinical trials and/or health care reimbursement;

- our inability to locate qualified local consultants, physicians, and partners;
- the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and
- general geopolitical risks, such as political and economic instability, and changes in diplomatic and trade relations.

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

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

Our drug candidates and technologies are either in preclinical or clinical stages. Specifically, our lead product candidate, Recombinant Erythropoietin (rHuEPO), is planned for a Phase 1-2 clinical program and the Diversity Oriented Synthesis, or DOS program has not yet been tested in humans. In order for our candidates to proceed to later stage clinical testing, they must show positive clinical or preclinical data. While Recombinant Erythropoietin (rHuEPO) has shown promising preclinical data and has also shown promising clinical observation data for the extension and improvement of the quality of life of Multiple Myeloma terminal patients prior to it being acquired by us, preliminary results of pre-clinical, clinical observations or clinical tests do not necessarily predict the final results, and promising results in pre-clinical, clinical observations or early clinical testing might not be obtained in later clinical trials. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. Any negative results from future tests may prevent us from proceeding to later stage clinical testing which would materially impact our corporate strategy and our financial results may be adversely impacted.

We have limited experience in conducting and managing clinical trials necessary to obtain regulatory approvals. If our drug candidates and technologies do not receive the necessary regulatory approvals, we will be unable to commercialize our products.

We have not received, and may never receive, regulatory approval for commercial sale for any of our products. We currently do not have any drug candidates or technologies pending approval with the FDA or with regulatory authorities of other countries. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. In order to obtain FDA approval to market a new drug product, we or our potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we or our potential partners will have to conduct extensive pre-clinical testing and “adequate and well-controlled” clinical trials.

Pre-clinical testing and clinical development are long, expensive and uncertain processes. Clinical trials are very difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. The commencement and rate of completion of clinical trials may be delayed by many factors, including:

- obtaining regulatory approvals to commence a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- slower than expected rates of patient recruitment due to narrow screening requirements;
- the inability of patients to meet protocol requirements imposed by the FDA or other regulatory authorities;
- the need or desire to modify our manufacturing process;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or “clinical holds” requiring suspension or termination of the trials.

Following the completion of a clinical trial, regulators may not interpret data obtained from pre-clinical and clinical tests of our drug candidates and technologies the same way that we do, which could delay, limit or prevent our receipt of regulatory approval. In addition, the designs of our ongoing clinical trials were not, and the designs of future clinical trials may not be, reviewed or approved by the FDA prior to their commencement, and consequently the FDA could determine that the parameters of any existing or future studies are insufficient to demonstrate proof of safety and efficacy in humans. Failure to approve a completed study could also result from several other factors, including unforeseen safety issues, the determination of dosing, low rates of patient recruitment, the inability to monitor patients adequately during or after treatment, the inability or unwillingness of medical investigators to follow our clinical protocols, and the lack of effectiveness of the trials.

Specifically, in 2008, Amgen Inc. announced that US regulators added black box, or black label, warnings to its erythropoietin drugs, Epogen and Aranesp. Similar warnings were also added to Johnson and Johnson's Procrit which is also licensed from Amgen. In the United States, a black box warning is a type of warning that appears on the package insert for prescription drugs that may cause serious adverse effects. A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects. The new warnings warn that the erythropoietin drugs increased death and accelerated tumor growth in patients with several types of cancer, including breast and cervical. Prior labeling warned of similar risks in other types of cancers.

If the clinical trials fail to satisfy the criteria required, the FDA and/or other regulatory agencies/authorities may request additional information, including additional clinical data, before approval of marketing a product. Negative or inconclusive results or medical events during a clinical trial could also cause us to delay or terminate our development efforts. If we experience delays in the testing or approval process, or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates and technologies may be materially impaired.

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after achieving promising results in earlier trials. It may take us many years to complete the testing of our drug candidates and technologies, and failure can occur at any stage of this process.

Even if regulatory approval is obtained, our products and their manufacture will be subject to continual review, and there can be no assurance that such approval will not be subsequently withdrawn or restricted. Changes in applicable legislation or regulatory policies, or discovery of problems with the products or their manufacture, may result in the imposition of regulatory restrictions, including withdrawal of the product from the market, or result in increased costs to us.

Because some of our proprietary drug candidates and technologies are licensed to us by third parties, termination of these license agreements could prevent us from developing our drug candidates.

We do not own all of our drug candidates and technologies. We have acquired and/or licensed the rights, patent or otherwise, to our drug candidates from third parties. Specifically, we have acquired the use patent on Recombinant Erythropoietin (rHuEPO) for the prolongation of multiple myeloma patients' survival and improvement of their quality of life from Bio-Gal Ltd., , who in turn licensed it from Mor Research Applications Ltd. and Yeda Research and Development Company Ltd., both Israeli private corporations, and we have licensed DOS from VivoQuest, Inc. These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed drugs and technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. While we have the right to defend patent rights related to our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent

rights, we will be obligated to cover all of the expenses associated with that effort. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates and technologies. From time to time, in the ordinary course of business, we may have disagreements with our licensors or collaborators regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development, collaboration and commercialization of our drug candidates or could require or result in litigation or arbitration, which could be time-consuming and expensive. For a further discussion on our license agreements, the patent rights related to those licenses, and the expiration dates of those patent rights, see “Item 4. Information on the Company - Business Overview - Intellectual Property and Patents” and “Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations,” below.

If we do not establish or maintain drug development and marketing arrangements with third parties, we may be unable to commercialize our drug candidates and technologies into products.

We are an emerging company and do not possess all of the capabilities to fully commercialize our drug candidates and technologies on our own. From time to time, we may need to contract with third parties to:

- assist us in developing, testing and obtaining regulatory approval for some of our compounds and technologies;
- manufacture our drug candidates; and
- market and distribute our products.

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

We can provide no assurance that we will be able to successfully enter into agreements with such third-parties on terms that are acceptable to us. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our drug candidates and technologies independently, which could result in delays. Further, such failure could result in the termination of license rights to one or more of our drug candidates and technologies. Moreover, if these development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we are unable to control whether such products will be scientifically or commercially successful.

Even if we or our collaborative/strategic partners or potential collaborative/strategic partners receive approval to market our drug candidates, if our products fail to achieve market acceptance, we will never record meaningful revenues.

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our product candidates will depend on a number of factors, including:

- perceptions by members of the health care community, including physicians, of the safety and efficacy of our products;
- the rates of adoption of our products by medical practitioners and the target populations for our products;
- the potential advantages that our products offer over existing treatment methods or other products that may be developed;
- the cost-effectiveness of our products relative to competing products including potential generic competition;
- the availability of government or third-party payor reimbursement for our products;
- the side effects or unfavorable publicity concerning our products or similar products; and
- the effectiveness of our sales, marketing and distribution efforts.

Specifically, Recombinant Erythropoietin (rHuEPO), if successfully developed and commercially launched for the treatment of multiple myeloma, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our product candidates. Physicians and other prescribers may not be inclined to prescribe our products unless our products bring clear and demonstrable advantages

over other products currently marketed for the same indications. Because we expect sales of our products to generate substantially all of our revenues in the long-term, the failure of our products to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

If the third parties upon whom we rely to manufacture our products do not successfully manufacture our products, our business will be harmed.

We do not currently have the ability to manufacture the compounds that we need to conduct our clinical trials and, therefore, rely upon, and intend to continue to rely upon, certain manufacturers to produce and supply our drug candidates for use in clinical trials and for future sales. See “Item 4. Information on the Company – Business Overview - Supply and Manufacturing,” below. In order to commercialize our products, such products will need to be manufactured in commercial quantities while adhering to all regulatory and other local requirements, all at an acceptable cost. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms, if at all.

We believe that we will either be able to purchase Recombinant Erythropoietin (rHuEPO) from existing pharmaceutical companies or to enter into collaborative agreements with contract manufacturers or other third-parties to obtain sufficient inventory to satisfy the clinical supply needs for our planned Phase 1-2 development program for the treatment of multiple myeloma. If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or sources, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our drug candidates.

Our contract manufacturers are required to produce our clinical drug candidates under strict compliance with current good manufacturing practices, or cGMP, in order to meet acceptable regulatory standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our drug candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our drug candidates. Any difficulties or delays in our contractors' manufacturing and supply of drug candidates could increase our costs, cause us to lose revenue or make us postpone or cancel clinical trials.

In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign or local governmental agencies to ensure strict compliance with, among other things, cGMP, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. No assurance can be given that our third-party manufacturers will comply with these regulations or other regulatory requirements now or in the future.

In the event that we are unable to obtain or retain third-party manufacturers, we will not be able to commercialize our products as planned. If third-party manufacturers fail to deliver the required quantities of our products on a timely basis and at commercially reasonable prices, our ability to develop and deliver products on a timely and competitive basis may be adversely impacted and our business, financial condition or results of operations will be materially harmed.

If our competitors develop and market products that are less expensive, more effective or safer than our products, our commercial opportunities may be reduced or eliminated.

The pharmaceutical industry is highly competitive. Our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our products. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. For a discussion of these competitors and their drug candidates, see "Item 4. Information on the Company - Business Overview – Competition," below. Some of these potential competing drugs are already commercialized or are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing safe, effective drugs, our products may not compete successfully with products produced by our competitors, who may be able to market their drugs more effectively.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields present substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop products that could render our technologies or our drug candidates

obsolete or noncompetitive.

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

As of March 31, 2009, we had 5 full-time employees. To successfully develop our drug candidates and technologies, we must be able to attract and retain highly skilled personnel, including consultants and employees. The retention of their services cannot be guaranteed. In addition, David Grossman, our co-Chief Executive Officer's pending employment agreement will require approval by our shareholders. We do not maintain a key man life insurance policy covering Mr. Grossman.

Any acquisitions or in-licensing transactions we make may dilute your equity or require a significant amount of our available cash and may not be scientifically or commercially successful.

As part of our business strategy, we may effect acquisitions or in-licensing transactions to obtain additional businesses, products, technologies, capabilities and personnel. If we complete one or more such transactions in which the consideration includes our ordinary shares or other securities, your equity in us may be significantly diluted. If we complete one or more such transactions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Specifically, as per the terms of our agreement with Bio-Gal Ltd., we will be issuing 58.0 million ordinary shares par value NIS 0.10 (equivalent to 290.0 million ordinary shares par value NIS 0.02) and we may at our option issue 100.4 million ordinary shares par value NIS 0.10 (equivalent to 500.2 million ordinary shares par value NIS 0.02) to Bio-Gal Ltd. on a successful completion of a Phase 2 clinical trial (see "Item 4. Information on the Company - Business Overview - Intellectual Property and Patents" and "Item 4. Information on the Company - Business Overview - Licensing Agreements and Collaborations," below).

Acquisitions and in-licensing transactions also involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology or personnel of the business;
- our inability to attract and retain management, key personnel and other employees necessary to conduct the business;
- our inability to maintain relationships with key third parties, such as alliance partners, associated with the business;
- exposure to legal claims for activities of the business prior to the acquisition;
- the diversion of our management's attention from our core business; and
- the potential impairment of substantial goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

In addition, the basis for completing the acquisition or in-licensing could prove to be unsuccessful as the drugs or processes involved could fail to be scientifically or commercially viable. In addition, we may be required to pay third parties substantial transaction fees, in the form of cash or ordinary shares, in connection with such transactions.

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

We may not be able to successfully complete our acquisition of the use patent on Erythropoietin, and as a result may be deemed a shell company with minimal operations, which would significantly impact our ability to raise additional capital and continue operations.

On March 18, 2009, we entered into an asset purchase agreement with Bio-Gal Ltd, a private company, for the rights to a use patent on rHuEPO, for the treatment of MM. We intend to develop rHuEPO for the prolongation of MM patients' survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. The course of the disease is progressive, and various complications occur, until death. In accordance with the terms of the asset purchase agreement, we will issue Bio-Gal Ltd. ordinary shares representing just under 50% of the current issued and outstanding share capital of XTL. In addition, we will make a milestone payment of approximately $10 million in cash upon the successful completion of a Phase 2 clinical trial. Our Board of Directors may at its sole discretion issue additional ordinary shares to Bio-Gal Ltd in lieu of such milestone payment. We are also obligated to pay 1% royalties on net sales of the product. The closing of the transaction is subject to various conditions including: XTL's and Bio-Gal's shareholders' approval, as well as completion of a financing. There can be no assurance that the conditions to the closing will be achieved, and that we will be able to consummate the acquisition of the use patent on rHuEPO. If we do not consummate this acquisition, we will be deemed a shell company, subject to de-listing from the NASDAQ Stock Market, if we are not then already de-listed, and our ability to raise additional capital and continue operations will be significantly impaired.

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

The use of our drug candidates and technologies in clinical trials, and the sale of any approved products, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates and technologies or limit commercialization of any approved products.

We believe that we will be able to obtain sufficient product liability insurance coverage for our planned clinical trials. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for a product;

- injury to our reputation;
- inability to continue to develop a drug candidate or technology;
- withdrawal of clinical trial volunteers; and
- loss of revenues.

Consequently, a product liability claim or product recall may result in material losses.

Risks Related to Our Financial Condition

Our current cash, cash equivalents and bank deposits may not be adequate to support our operations for the length of time that we have estimated. If we are unable to obtain additional funds on terms favorable to us, or at all, we may not be able to continue our operations.

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current business plan and forecast, we believe that our current cash, cash equivalents and bank deposits provide us with sufficient resources to fund our operations through July 2009; however, the actual amount of funds that we will need will depend on many factors, some of which are beyond our control. These factors include:

- the progress in successfully meeting the closing conditions for the agreement with Bio-Gal Ltd., including a financing;
- the progress of our planned research activities;
- the accuracy of our financial forecasts;
- the number and scope of our planned development programs;
- our ability to establish and maintain current and new licensing or acquisition arrangements;
- our ability to achieve our milestones under our licensing arrangements;
- the costs involved in enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

We do believe, however, that we will likely seek additional capital during the next couple of months through a planned rights offering and / or public or private equity offerings or debt financings. We have made no determination at this time as to the amount or method of any such financing. The global capital markets have been experiencing extreme volatility and disruption for more than twelve months. In recent months, the volatility and disruption have reached unprecedented levels. Given recent particularly adverse market conditions for small biotechnology companies, additional financing may not be available to us when we need it. We may also be forced to delay raising capital or bear an unattractive cost of capital. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our technology. If we raise additional funds by selling ordinary shares, ADRs, or other securities, the ownership interests of our shareholders will be diluted. If we need to raise additional funds through the sale or license of our drug candidates or technology, we may be unable to do so on terms favorable to us or at all. If we are not able to raise

capital in a timely manner, there is a material risk regarding our ability to continue as a going concern.

It is possible that we may be subject to taxation in the US, which could significantly increase our tax liability in the US for which we may not be able to apply the net losses accumulated in Israel.

We have had a “permanent establishment” in the United States, or US, which began in 2005, due to the residency of the former Chairman of our Board of Directors and our Chief Executive Officer in the US, as well as other less significant contacts that we have with the US. This may continue in 2009 as well. As a result, any income attributable to such US permanent establishment would be subject to US corporate income tax in the same manner as if we were a US corporation. If this is the case, we may not be able to utilize any of the accumulated Israeli loss carryforwards reflected on our balance sheet as of December 31, 2008 since these losses were not attributable to the US permanent establishment. However, we would be able to utilize losses attributable to the US permanent establishment to offset such US taxable income. As of December 31, 2008, we estimate that these US net operating loss carryforwards are approximately $22.6 million. These losses can be carried forward to offset future US taxable income, subject to limitation in the case of shifts in ownership of XTL, e.g. a planned offering or capital raise, resulting in more than 50 percentage point change over a three year lookback period, and expiring through 2028. US corporate tax rates are higher than those to which we are subject in the State of Israel, and if we are subject to US corporate tax, it would have a material adverse effect on our results of operations.

Our subsidiary's Lease Agreement with Suga Development with respect to its former offices in Valley Cottage, New York could obligate that subsidiary to pay the remaining lease payments even though they have delivered notice of termination and mitigation to the landlord.

On April 6, 2009, our wholly-owned subsidiary, XTL Biopharmaceuticals, Inc., delivered a termination notice to Suga Development, L.L.C., with respect to the leasing of approximately 33,200 sq. ft. located at 711 Executive Boulevard, Suite Q, Valley Cottage, New York 10989. We believe that the notice provided a clear indication of the termination of XTL Biopharmaceuticals, Inc.'s obligations under the lease, effective as of the date of the notice. In addition, XTL Biopharmaceuticals, Inc. informed Suga Development that upon receipt of the notice, they should use their best effort to re-rent the premises and to mitigate any damages. There can be no assurance that the landlord will not dispute the termination of the lease, and attempt to hold XTL Biopharmaceuticals, Inc. responsible for the full amount of all future unpaid lease payments, approximately $335,000.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents and technologies against third-party challenges. As part of our business strategy, our policy is to actively file patent applications in the US and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and composition and improvements in each of these. See "Item 4. Information on the Company - Business Overview - Intellectual Property and Patents," below regarding our patent position with regard to our product candidates. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

Generally, patent applications in the US are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. We cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the US that claim compounds or technology also claimed by us, we may choose to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. While we have the right to defend patent rights related to the licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort.

We also rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into

confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to some of our drug candidates and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our proprietary information will be at risk.

Specifically, we plan to pursue patent protection in the US and in certain foreign countries relating to our development and commercialization of Recombinant Erythropoietin ("rHuEPO") for the prolongation of multiple myeloma patients' survival and improvement of their quality of life. A main use patent (United States Patent 6,579,525 "Pharmaceutical Compositions Comprising Erythropoietin for Treatment of Cancer") was submitted by Mor Research Applications Ltd., an Israeli corporation and Yeda Research and Development Company Ltd., an Israeli corporation, in April 1998 and PCT was filed in April 1999. The patent was granted in the United States, Europe, Israel and Hong Kong. Patent applications are pending in Canada and Japan. Currently, under the license agreement which we are acquiring from Bio-Gal Ltd., we will have exclusive worldwide rights to the above patent for the use of Recombinant Erythropoietin ("rHuEPO") in multiple myeloma. See "Item 4. Information on the Company – Business Overview - Intellectual Property and Patents." However, we cannot guarantee the scope of protection of any issued patents, or that such patents will survive a validity or enforceability challenge, or that any pending patent applications will issue as patents.

Litigation or third-party claims of intellectual property infringement could require us to spend substantial time and money defending such claims and adversely affect our ability to develop and commercialize our products.

Third parties may assert that we are using their proprietary technology without authorization. In addition, third parties may have or obtain patents in the future and claim that our products infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected products could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all. In addition, any legal action against us that seeks damages or an injunction relating to the affected activities could subject us to monetary liability and/or require us to discontinue the affected technologies or obtain a license to continue use thereof.

In addition, there can be no assurance that our patents or patent applications or those licensed to us will not become involved in opposition or revocation proceedings instituted by third parties. If such proceedings were initiated against one or more of our patents, or those licensed to us, the defense of such rights could involve substantial costs and the outcome could not be predicted.

Competitors or potential competitors may have filed applications for, may have been granted patents for, or may obtain additional patents and proprietary rights that may relate to compounds or technologies competitive with ours. If patents are granted to other parties that contain claims having a scope that is interpreted to cover any of our products (including the manufacture thereof), there can be no assurance that we will be able to obtain licenses to such patents at reasonable cost, if at all, or be able to develop or obtain alternative technology.

Risks Related to Our Ordinary Shares and ADRs

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

The trading volume of our ADRs has historically been low. Even if the trading volume of our ADRs increases, we can give no assurance that it will be maintained or will result in a desirable stock price. As a result of this low trading volume, it may be difficult to identify buyers to whom you can sell your ADRs in desirable volume and you may be unable to sell your ADRs at an established market price, at a price that is favorable to you, or at all. A low volume market also limits your ability to sell large blocks of our ADRs at a desirable or stable price at any one time. You should be prepared to own our ordinary shares and ADRs indefinitely.

Our stock price can be volatile, which increases the risk of litigation and may result in a significant decline in the value of your investment.

The trading price of the ADRs representing our ordinary shares is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- developments concerning our drug candidates;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;

- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in interim operating results and near-term working capital;
- expiration or termination of licenses, research contracts or other collaboration agreements;

- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- delisting from the Nasdaq Stock Market
- changes in the market valuations of similar companies; and
- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our ordinary shares or ADRs, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources even if we prevail in the litigation, all of which could seriously harm our business.

Future issuances or sales of our ordinary shares could depress the market for our ordinary shares and ADRs.

Future issuances of a substantial number of our ordinary shares, or the perception by the market that those issuances could occur, could cause the market price of our ordinary shares or ADRs to decline or could make it more difficult for us to raise funds through the sale of equity in the future. We believe that our cash, cash equivalents and bank deposits as of December 31, 2008 provide us with sufficient resources to fund our operations through July 2009; however, prior to the end of that period it will be necessary for us to return to the capital markets through the sale of ADRs or ordinary shares.

Also, if we successfully close the Bio-Gal Ltd. transaction or make one or more significant acquisitions in which the consideration includes ordinary shares or other securities, your portion of shareholders' equity in us may be significantly diluted. In addition, pursuant to a license agreement with VivoQuest, Inc., or VivoQuest, a privately held biotechnology company based in the US, we licensed (in all fields of use) certain intellectual property and technology related to VivoQuest's HCV program. Pursuant to the license agreement, we may elect to issue up to an additional $34.6 million in ordinary shares to VivoQuest in lieu of cash upon achievement of certain milestones. Additionally, pursuant to the Bio Gal Ltd. agreement, we may issue 100.4 million ordinary shares par value NIS 0.10 (equivalent to 500.2 million ordinary shares par value NIS 0.02) upon a successful Phase 2 program. In the future, we may also enter into additional arrangements with other third-parties permitting us to issue ordinary shares in lieu of certain cash payments.

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

Following the planned closing of the Bio-Gal Ltd. transaction, Bio-Gal Ltd.'s stockholders and their affiliates will hold approximately 49% of our then outstanding ordinary shares. As a result, these persons, acting together, may have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of our ADRs or ordinary shares.

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

ADRs representing our ordinary shares are quoted on the NASDAQ Capital Market and our ordinary shares are traded on the Tel Aviv Stock Exchange, or TASE. Trading in our securities on these markets is made in different currencies and at different times, including as a result of different time zones, different trading days and different public holidays in the US and Israel. Consequently, the effective trading prices of our shares on these two markets may differ. Any decrease in the trading price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

Were we to be delisted from the Nasdaq Stock Market, we may then be required to follow the full rules and regulations of the Tel Aviv Stock Exchange. This would include the need to file regulatory documents in both Hebrew and English, the need to use International Financial Reporting Standards, and the need to comply with the rules and regulations of the United States Securities and Exchange Commission and the Tel Aviv Stock Exchange.

We are currently not in compliance with NASDAQ rules for continued listing on the NASDAQ Capital Market and are at risk of being delisted, which may subject us to the SEC's penny stock rules and decrease the liquidity of our ADRs and ordinary shares.

On January 27, 2009, we received a Staff Determination Letter from The Nasdaq Stock Market, or Nasdaq, notifying us that the staff of Nasdaq's Listing Qualifications Department determined, using its discretionary authority under Nasdaq Marketplace Rule 4300, that our ADRs would be delisted from Nasdaq. The letter further stated that Nasdaq would suspend trading on our ADRs at the opening of trading on February 5, 2009, unless we appealed Nasdaq's delisting determination. Nasdaq's determination to delist our ADRs was based on Nasdaq's belief that the Company is a public shell, and that we do not meet the stockholder's equity requirement or any of its alternatives. On February 3, 2009, we appealed the determination by the Nasdaq Listing Qualification Staff to delist our ADRs from the Nasdaq Capital Market. On March 19, 2009, we participated in an oral hearing before the Nasdaq Hearings Panel (the "Panel"). Nasdaq's delisting action has been stayed, pending a final written determination by the Panel following the hearing. At the hearing, the Company presented its plan to remedy its "public shell" determination and for future compliance with all other applicable Nasdaq listing requirements.

We intend to continue to work with Nasdaq to try to find an acceptable manner in which our ADRs can remain listed on the NASDAQ Capital Market. However, we cannot provide assurance that we will be successful in that effort, or that in the future we will continue to meet the listing requirements of the NASDAQ Capital Market, including, without limitation, bid price, stockholders' equity and/or market value of listed securities minimum requirements. Additionally, our efforts to continue to meet the listing requirements may be limited by current market conditions, including volatility in the market.

If we are delisted from The NASDAQ Stock Market, our ADRs may be traded over-the-counter on the OTC Bulletin Board or the "pink sheets." These alternative markets, however, are generally considered to be less efficient than, and not as broad as, the NASDAQ Capital Market. Many OTC stocks trade less frequently and in smaller volumes than securities traded on the NASDAQ markets, which could have a material adverse effect on the liquidity of our ADRs.

If our ADRs are delisted from the NASDAQ Stock Market, there may be a limited market for our ADRs, trading in our ADRs may become more difficult and our ADR price could decrease even further. In addition, if our ADRs are delisted, our ability to raise additional capital may be impaired.

In addition, our ADRs may become subject to penny stock rules. The SEC generally defines "penny stock" as an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. We presently qualify for an exemption from the penny stock rules, as our ADRs are quoted on the NASDAQ Stock Market. However, if we were delisted, our ADRs would become subject to the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our securities. If our ADRs were considered penny stock, the ability of broker-dealers to sell our ADRs and the ability of our shareholders to sell their ADRs in the secondary market would be limited and, as a result, the market liquidity for our ADRs would be adversely affected. We cannot assure you that trading in our securities will not be subject to these or other regulations in the future.

Holders of our ordinary shares or ADRs who are US citizens or residents may be required to pay additional income taxes.

There is a risk that we will be classified as a passive foreign investment company, or PFIC, for certain tax years. If we are classified as a PFIC, a US holder of our ordinary shares or ADRs representing our ordinary shares will be subject to special federal income tax rules that determine the amount of federal income tax imposed on income derived with respect to the PFIC shares. We will be a PFIC if either 75% or more of our gross income in a tax year is passive income or the average percentage of our assets (by value) that produce or are held for the production of passive

income in a tax year is at least 50%. The risk that we will be classified as a PFIC arises because cash balances, even if held as working capital, are considered to be assets that produce passive income. Therefore, any determination of PFIC status will depend upon the sources of our income and the relative values of passive and non-passive assets, including goodwill. A determination as to a corporation's status as a PFIC must be made annually. We believe that we were likely not a PFIC for the taxable year ended December 31, 2008. However, we believe that we were a PFIC for the taxable years ended December 31, 2006 and 2007. Although such a determination is fundamentally factual in nature and generally cannot be made until the close of the applicable taxable year, based on our current operations, we believe that we may be classified as a PFIC in the 2009 taxable year and possibly in subsequent years. Although we may not be a PFIC in any one year, the PFIC taint remains with respect to those years in which we were or are a PFIC and the special PFIC taxation regime will continue to apply.

In view of the complexity of the issues regarding our treatment as a PFIC, US shareholders are urged to consult their own tax advisors for guidance as to our status as a PFIC. For further discussion of tax consequences of being a PFIC, see "US Federal Income Tax Considerations - Tax Consequences If We Are A Passive Foreign Investment Company," below.

Provisions of Israeli corporate law may delay, prevent or affect a potential acquisition of all or a significant portion of our shares or assets and thereby depressing the price of our ordinary shares.

We are incorporated in the State of Israel. Israeli corporate law regulates acquisitions of shares through tender offers. It requires special approvals for transactions involving significant shareholders and regulates other matters that may be relevant to these types of transactions. These provisions of Israeli law may delay or prevent an acquisition, or make it less desirable to a potential acquirer and therefore depress the price of our shares. Further, Israeli tax considerations may make potential transactions undesirable to us or to some of our shareholders.

Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of such acquisition, the purchaser would become a 25% or greater shareholder of the company. This rule does not apply if there is already another 25% or greater shareholder of the company. Similarly, Israeli corporate law provides that an acquisition of shares in a public company must be made by means of a tender offer if, as a result of the acquisition, the purchaser's shareholdings would entitle the purchaser to over 45% of the shares in the company, unless there is a shareholder with 45% or more of the shares in the company. These requirements do not apply if, in general, the acquisition (1) was made in a private placement that received the approval of the company's shareholders; (2) was from a 25% or greater shareholder of the company which resulted in the purchaser becoming a 25% or greater shareholder of the company, or (3) was from a 45% or greater shareholder of the company which resulted in the acquirer becoming a 45% or greater shareholder of the company. These rules do not apply if the acquisition is made by way of a merger. Regulations promulgated under Israeli corporate law provide that these tender offer requirements do not apply to companies whose shares are listed for trading outside of Israel if, according to the law in the country in which the shares are traded, including the rules and regulations of the stock exchange or which the shares are traded, either:

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

Finally, in general, Israeli tax law treats specified acquisitions less favorably than does US tax law. See "Item 10. Additional Information - Taxation - Israeli Tax Considerations," below.

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

The Bank of New York, as depositary, executes and delivers our ADRs on our behalf. Each ADR is a certificate evidencing a specific number of ADSs. Our ADR holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying our ADRs. Holders of our ADRs will have ADR holder rights. A deposit agreement among us, the depositary and our ADR holders, and the beneficial owners of ADRs, sets out ADR holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADRs. Our shareholders have shareholder rights. Israeli law and our Articles of Association, or Articles, govern shareholder rights. Our ADR holders do not have the same voting rights as our shareholders. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares. Our ADR holders may instruct the depositary to vote the ordinary shares underlying their ADRs, but only if we ask the depositary to ask for their instructions. If we do not ask the depositary to ask for the instructions, our ADR holders are not entitled to receive our notices of general meeting or instruct the depositary how to vote. Our ADR holders will not be entitled to attend and vote at a general meeting unless they withdraw the ordinary shares from the depository. However, our ADR holders may not know

about the meeting enough in advance to withdraw the ordinary shares. If we ask for our ADR holders' instructions, the depositary will notify our ADR holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depositary will try, as far as is practical, subject to the provisions of the deposit agreement, to vote the shares as our ADR holders instruct. The depositary will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADR holders. We cannot assure our ADR holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their shares. In addition, there may be other circumstances in which our ADR holders may not be able to exercise voting rights.

Our ADR holders do not have the same rights to receive dividends or other distributions as our shareholders. Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary stock and we do not anticipate paying any cash dividends in the foreseeable future). Dividends may be paid on shares of one class but not another and at different rates for different classes. Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares will be paid to the depositary, which has agreed to pay to our ADR holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. Our ADR holders will receive these distributions in proportion to the number of shares their ADRs represent. In addition, there may be certain circumstances in which the depositary may not pay to our ADR holders amounts distributed by us as a dividend or distribution. See the risk factor "– There are circumstances where it may be unlawful or impractical to make distributions to the holders of our ADRs," below.

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

The deposit agreement with the depositary allows the depositary to distribute foreign currency only to those ADR holders to whom it is possible to do so. If a distribution is payable by us in New Israeli Shekels, the depositary will hold the foreign currency it cannot convert for the account of the ADR holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, our ADR holders may lose some of the value of the distribution.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADR holders. This means that our ADR holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for the depository to make such distributions available to them.

Risks Relating to Operations in Israel

Conditions in the Middle East and in Israel may harm our operations.

Our headquarters and some of our planned clinical sites and suppliers are located in Israel. Political, economic and military conditions in Israel directly affect our operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors, as well as incidents of civil unrest, military conflicts and terrorist actions. There has been a significant increase in violence since September 2000, which has continued with varying levels of severity through to the present. This state of hostility has caused security and economic problems for Israel. To date, we do not believe that the political and security situation has had a material adverse impact on our business, but we cannot give any assurance that this will continue to be the case. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its present trading partners could adversely affect our operations and could make it more difficult for us to raise capital.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Our results of operations may be adversely affected by inflation and foreign currency fluctuations.

We have generated all of our revenues and hold most of our cash, cash equivalents, bank deposits and marketable securities in US dollars. In the past, a substantial amount of our operating expenses were in US dollars (approximately 96% in 2008), and we incurred a portion of our expenses in New Israeli Shekels and in certain other local currencies. In addition, we also pay for some of our services and supplies in the local currencies of our suppliers. As a result, we are exposed to the risk that the US dollar will be devalued against the New Israeli Shekel or other currencies, and as result our financial results could be harmed if we are unable to guard against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may in the future enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New

Israeli Shekel in relation to the dollar or that the timing of any devaluation may lag behind inflation in Israel.

It may be difficult to enforce a US judgment against us, our officers or our directors or to assert US securities law claims in Israel.

Service of process upon us, since we are incorporated in Israel, and upon our directors and officers and our Israeli auditors, some of whom reside outside the US, may be difficult to obtain within the US. In addition, because substantially all of our assets and some of our directors and officers are located outside the US, any judgment obtained in the US against us or any of our directors and officers may not be collectible within the US. There is a doubt as to the enforceability of civil liabilities under the Securities Act or the Exchange Act pursuant to original actions instituted in Israel. Subject to particular time limitations and provided certain conditions are met, executory judgments of a US court for monetary damages in civil matters may be enforced by an Israeli court. For more information regarding the enforceability of civil liabilities against us, our directors and our executive officers, see “Item 10. Additional Information - Memorandum and Articles of Association - Enforceability of Civil Liabilities,” below.

ITEM 4. INFORMATION ON THE COMPANY

History and Development of XTL

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

Our lead compound is Recombinant Erythropoietin, or rHuEPO, a known compound that we are developing for the prolongation of MM patients' survival and improvement of their quality of life. MM is a severe and incurable malignant hematological cancer of plasma cells. The course of the disease is progressive, and various complications occur, until death. This devastating disease affects the bone marrow, bones, kidneys, heart and other vital organs. It is characterized by pain, recurrent infections, anemia and pathological fractures. In the course of the disease, many patients become gradually disabled and bed-ridden. The median duration of survival with chemotherapy and other novel treatments is about five years. Most of these treatments have severe side effects

We signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal Ltd., a private biotechnology company based in Gibraltar, in March 2009. In accordance with the terms of the asset purchase agreement, we will issue to Bio-Gal Ltd. ordinary shares representing just under 50% of the current issued and outstanding share capital of our company. In addition, we will make milestone a payment of approximately $10 million in cash upon the successful completion a Phase 2 clinical trial. Our company’s Board of Directors may, in its sole discretion, issue additional ordinary shares to Bio-Gal Ltd in lieu of such milestone payment. We are also obligated to pay 1% royalties on net sales of the product. The closing of the transaction is subject to various conditions including XTL’s and Bio-Gal’s shareholders’ approvals, as well as completion of a financing. Closing is expected to take place in the second or third quarter of 2009.

Our second program is the Diversity Oriented Synthesis program, or DOS, which is focused on the development of novel pre-clinical hepatitis C small molecule inhibitors, which we had out-licensed to Presidio Pharmaceuticals, Inc., or Presidio, a private specialty pharmaceutical company based in San Francisco, California, in 2008.

Our legal and commercial name is XTL Biopharmaceuticals Ltd. We were established as a private company limited by shares under the laws of the State of Israel on March 9, 1993, under the name Xenograft Technologies Ltd. We re-registered as a public company on June 7, 1993, in Israel, and changed our name to XTL Biopharmaceuticals Ltd. on July 3, 1995. We commenced operations to use and commercialize technology developed at the Weizmann Institute, in Rehovot, Israel. Until 1999, our therapeutic focus was on the development of human monoclonal antibodies to treat viral, autoimmune and oncological diseases. Our first therapeutic programs focused on antibodies against the hepatitis B virus, interferon – and the hepatitis C virus.

During 2007, our legacy hepatitis C clinical programs, XTL-6865 and XTL-2125, were terminated, and in July 2007, Cubist Pharmaceuticals terminated their license agreement with us for HepeX-B for the treatment of hepatitis B. On December 31, 2007, the Yeda Research and Development Company Ltd. (“Yeda”), the commercial arm of the Weizmann Institute, and XTL mutually terminated our research and license agreement dated April 7, 1993, as amended, and subject to certain closing conditions which were completed in March 2008, all rights in and to the licensed technology and patents reverted to Yeda.

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

as a result we ceased development of Bicifadine for diabetic neuropathic pain.

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

Our ADRs are quoted on the NASDAQ Capital Market under the symbol "XTLB." Our ordinary shares are traded on the Tel Aviv Stock Exchange under the symbol "XTL." We operate under the laws of the State of Israel, under the Israeli Companies Act, and in the US, the Securities Act, the Exchange Act and the regulations of the NASDAQ Capital Market.

Our principal offices are located at Kiryat Weizmann Science Park, 3 Hasapir Street, Building 3, PO Box 370 Rehovot 76100, Israel, and our telephone number is +972-8-930-4444. XTL Biopharmaceuticals, Inc., our wholly-owned US subsidiary and agent for service of process in the US, can be reached at XTL Biopharmaceuticals, Inc., c/o Corporation Trust Company, Corporation Trust Center, 1209 N. Orange Street, Wilmington, Deleware 19801, or by telephone at (800) 677-3394. Our primary internet address is www.xtlbio.com. None of the information on our website is incorporated by reference into this annual report.

On November 20, 2007, we completed a private placement of 72,485,020 ordinary shares (equivalent to 7,248,502 ADRs) at $0.135 per ordinary share (equivalent to $1.35 per ADR). Total proceeds to us from this private placement were approximately $8.8 million, net of offering expenses of approximately $1.0 million. In addition, on March 22, 2006, we completed a private placement of 46,666,670 ordinary shares (equivalent to 4,666,667 ADRs) at $0.60 per share ($6.00 per ADR), together with warrants for the purchase of an aggregate of 23,333,335 ordinary shares (equivalent to 2,333,333.5 ADRs) at an exercise price of $0.875 ($8.75 per ADR). Total proceeds to us from this private placement were approximately $24.4 million, net of offering expenses of approximately $3.6 million. The private placement closed on May 25, 2006. Since inception, we have raised net proceeds of approximately $137.5 million to fund our activities, including the net proceeds from our 2007 and 2006 private placements.

For the years ended December 31, 2008, 2007, and 2006 our capital expenditures were $2,000, $65,000 and $21,000, respectively. During 2008, we completed the disposition of certain assets (primarily lab equipment) associated with the DOS program, with $327,000 in proceeds from disposals of those assets in 2008.During 2007, we completed the disposition of certain unused assets (primarily lab equipment) which were held for sale during 2007, with $308,000 in proceeds from disposals of property and equipment in 2007. There were no material divestitures during the year ended December 31, 2006.

Business Overview

Introduction

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of unmet medical needs, particularly the treatment of MM and also hepatitis C.

Our lead compound is rHuEPO, which we are developing for the survival extension of MM patients.

Erythropoietin (EPO) is a glycoprotein hormone produced mainly by the kidney. It is the major growth regulator of the erythroid lineage. EPO stimulates erythropoiesis, the production of red blood cells, by binding to its receptor (EPO-R) on the surface of erythroid progenitor cells, promoting their proliferation and differentiation and maintaining their viability. Over the last decade, several reports have indicated that the action of EPO is not restricted to the erythroid compartment, but may have additional biological, and consequently potential therapeutic properties, broadly beyond erythropoiesis. Erythropoietin is available as a therapeutic agent produced by recombinant DNA technology in mammalian cell culture. rHuEPO is used in clinical practice for the treatment of various anemias including anemia of kidney disease and cancer-related anemia. For over a decade, two types of rHuEPO have been used: recombinant erythropoietin α and β; more recently, novel long acting erythropoiesis stimulating proteins have been developed (Amgen's AraNESP, Roche’s CERA).

Currently incurable, MM is a severe plasma cell malignancy characterized by the accumulation and proliferation of clonal plasma cells in the marrow, leading to the gradual replacement of normal hematopoiesis. The course of the disease is progressive, and various complications occur, until death. This devastating disease affects the bone marrow, bones, kidneys, heart and other vital organs. It is characterized by pain, recurrent infections, anemia and pathological fractures. In the course of the disease, many patients become gradually disabled and bed-ridden.

In the first months, after the diagnosis, 15 % of the patients die. When no treatment is given MM has a progressive course with a median survival of 6-10 months. The median overall survival duration today with chemotherapy and other novel treatments is about five years, with perhaps 20% of the patients living for more than ten years. These treatments have severe side effects, including the suppression of the immune system, susceptibility to infections, nausea, vomiting and bleeding disorders.

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

To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any commercial revenues from the sales of our drug candidates. Moreover, preliminary results of our pre-clinical or clinical tests do not necessarily predict the final results, and acceptable results in early preclinical or clinical testing might not be obtained in later clinical trials. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing.

Our Strategy

Under our current strategy, we plan to:

- initiate a prospective, multi-center, double blind, placebo controlled Phase 1-2 clinical study intended to assess the safety and efficacy of rHuEPO when given to patients with advanced MM;
- advance the development of rHuEPO towards approval as treatment of MM either alone or with a corporate partner; and
- seek to in-license or acquire additional candidates.

Products Under Development

rHuEPO for the treatment of MM

Market Opportunity

We intend to develop the use of rHuEPO for the prolongation of MM patients' survival. According to the MM Research Foundation, in the United States alone, there are approximately 56,000 people living with MM, with about 20,000 new cases diagnosed annually. MM is the second most prevalent blood cancer representing approximately 1% of all cancers in white US residents and 2% of all cancers in African Americans. The average age at diagnosis is 62 years for men and 61 years for women, and is also more common in men than women, and in African Americans than Caucasians.

Scientific Background

Erythropoietin, a glycoprotein hormone produced mainly by the kidney, is the major growth regulator of the erythroid lineage. EPO stimulates erythropoiesis by binding to its receptor (EPO-R) on the surface of erythroid progenitor cells, promoting their proliferation and differentiation and maintaining their viability. The cloning of the EPO gene led to the introduction of recombinant human EPO (rHuEPO) into clinical practice for the treatment of various anemias including anemia of kidney disease and cancer-related anemia.

Over the last decade, several reports (Mittelman PNAS 2001, Mittelman European Journal of Hematology 2004; Katz Acta Haematol 2005; Prutchi-Sagiv BJH 2006; Prutchi-Sagiv Exp Hematol 2008; Brines PNAS 2001; Baz Acta Haematol 2007) have indicated that the action of EPO is not restricted to the erythroid compartment, but may have additional biological, and consequently potential therapeutic properties, broadly beyond erythropoiesis.

A clinical observation made by Professor Moshe Mittelman and colleagues (Mittelman M, Zeidman A, Kanter P, Katz O, Oster H, Rund D, Neumann D. Erythropoietin has an anti-myeloma effect - a hypothesis based on a clinical observation supported by animal studies. Eur J Haematol. 2004 Mar;72(3):155-65) confirmed the high success rate of rHuEPO in treating the anemia in patients with MM. Six patients continued treatment with rHuEPO beyond the initial designed 12 week period with very poor prognostic features of MM, whose expected survival was less than 6 months, , and surprisingly, they lived for 45–133 months cumulatively with the MM diagnosis and 38–94 months with rHuEPO (with a good quality of life).

This clinical observation was further supported by pre-clinical animal studies. These animal studies not only confirmed the anti-myeloma effect of rHuEPO but also detected a new unrecognized hitherto immune-mediated effect to rHuEPO, probably mediated via T cells (Mittelman M., Neumann D., Peled A., Kanter P. and Haran- Ghera N.

(2001) Erythropoietin induces tumor regression and antitumor immune responses in murine myeloma models. PNAS, vol. 98: 9. 5181 - 5186; Katz O, Barzilay E, Skaat A, Herman A, Mittelman M, Neumann D.Erythropoietin induced tumour mass reduction in murine lymphoproliferative models. Acta Haematol. 2005; 114 (3):177-9.). Recently, it was also shown that treatment of stage II-III MM patients with rHuEPO is associated with a significant improvement of various immunological parameters and functions (Prutchi-Sagiv British Journal of Hematology 2006; Prutchi-Sagiv Experimental Hematology 2008; Lifshitz Molecular Immunology 2009).

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

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

- Ludwig H et al.: Forty two patients with various types of cancers were treated with rHuEPO for their anemia. The malignant diseases were: 18 multiple myeloma (MM), 10 myelodysplastic syndromes (MDS), 9 breast cancers and 5 colon cancers. The median time period of treatment with rHuEPO was 16 weeks. The study was designed to treat anemia (not the cancer). Response was defined as an increase of the initial hemoglobin (Hb) level by at least 2 g/dl. The response rates varied: 44.4% for breast cancer, 40% for colon cancer, 77.8% for MM, 10% for MDS. The median survival time of responders was 28.0 months as compared to only 9.2 months for non-responders. (Ludwig H et al; Erythropoietin treatment for chronic anemia of selected hematological malignancies and solid tumorsAnn Oncol 1993; 4:161-7).

- Wallvik J et al.: This Swedish group reports its experience with a long-term follow-up of 68 MDS patients treated with rHuEPO. The median Hb response duration was 15 months. The median overall survival time from start of rHuEPO treatment was 26 months, significantly longer for responders than for non-responders (49 vs. 18 months, p=0.018) (Wallvik J et al.; Serum erythropoietin (EPO) levels correlate with survival and independently predict response to EPO treatment in patients with myelodysplastic syndromes. Eur J Haematol 2002; 68: 180-5).

Development Status

We plan on performing a prospective, multi-center, double blind, placebo controlled phase 1-2 study intended to assess safety of rHuEPO when given to patients with advanced MM and demonstrate its effects on survival, biological markers related to the disease, immune improvements and quality of life. We intend to initiate the clinical trial in the second half of 2009. We have begun preliminary discussions with potential clinical sites and third party vendors for the planned study.

DOS

Market Opportunity

We had been developing the DOS program for the treatment of hepatitis C, prior to us out-licensing it to Presidio in March 2008. Chronic hepatitis C is a serious life-threatening disease which affects around 170 to 200 million people worldwide, according to a Datamonitor report from April 2005. We estimate that between eight to 10 million of these people reside in the US, Europe and Japan. According to the BioSeeker Group, 20% to 30% of chronic hepatitis patients will eventually develop progressive liver disease that may lead to decomposition of the liver or hepatocellular carcinoma (liver cancer). According to the National Digestive Diseases Information Clearing House, each year 10,000 to 12,000 people die from HCV in the US alone. The Centers for Disease Control, or the CDC, predicts that by the end of this decade, the number of deaths due to HCV in the US will surpass the number of deaths due to AIDS.

According to the PharmaDD, the worldwide market for the treatment of chronic HCV in 2005 was estimated at $3 billion and consists entirely of Interferon-based treatments. Interferon alpha was first approved for use against chronic hepatitis C in 1991. At present, the optimal regimen appears to be a 24 or 48 week course of the combination of Pegylated-Interferon and Ribavirin. In studies done at the St. Louis University School of Medicine, a 24 week course of this combination therapy yields a sustained response rate of approximately 40% to 45% in patients with genotype 1 (the most prevalent genotype in the western world according to the CDC) and a better sustained response with a 48 week course.

Given the limited efficacy of the present standard of care and significant side effects associated with it, there is a clear need for novel treatments for Hepatitis C.

Development Status

In March 2008, and as revised in August 2008, we signed an agreement to out-license the DOS program to Presidio, a specialty pharmaceutical company focused on the discovery, in-licensing, development and commercialization of novel therapeutics for viral infections, including HIV and HCV. Under the terms of the license agreement, as revised, Presidio becomes responsible for all further development and commercialization activities and costs relating to our DOS program. In accordance with the terms of the license agreement, we received a $5.94 million, non-refundable, upfront payment in cash from Presidio and will receive up to an additional $59 million upon reaching certain development and commercialization milestones. In addition, we will receive a royalty on direct product sales by Presidio, and a percentage of Presidio's income if the DOS program is sublicensed by Presidio to a third party. DOS is a pre-clinical program focused on the development of novel hepatitis C small molecule inhibitors. DOS applies proprietary, fully synthetic chemistry methodologies to rapidly synthesize and diversify complex chemical compounds such as natural products. Compounds in each family inhibited HCV replication in a pre-clinical cell-based assay with potencies against the most prevalent HCV genotypes comparable or superior to clinical stage drugs. They also retained their potency against isolates that are resistant to clinical stage drugs. Presidio is currently in the process of identifying drug leads to be tested in formal toxicological studies in anticipation of the commencement of clinical trials in humans thereafter. See "Item 10. Additional Information -Material Contracts."

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

Intellectual Property and Patents

General

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

Generally, patent applications in the US are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. Granted patents can be challenged and ruled invalid at any time, therefore the grant of a patent is not of itself sufficient to demonstrate our entitlement to a proprietary right. The disallowance of a claim or invalidation of a patent in any one territory can have adverse commercial consequences in other territories.

If our competitors prepare and file patent applications in the US that claim technology also claimed by us, we may choose to participate in interference proceedings declared by the US Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. While we have the right to defend patent rights related to our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort.

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

rHuEPO for the treatment of MM

A main use patent, United States Patent 6,579,525 “Pharmaceutical Compositions Comprising Erythropoietin for Treatment of Cancer,” was submitted by Mor Research Applications Ltd. and Yeda Research and Development Company Ltd., Israeli corporations, in April 1998 and a PCT was filed in April 1999. The patent was granted in the United States, Europe, Israel and Hong Kong. Patent applications are pending in Canada and Japan. The issued patent will expire in 2019. Pursuant to our agreement with Bio-Gal Ltd., we will have exclusive worldwide rights to the above patent for the use of rHuEPO in MM.

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

The original EPO patent is currently owned by Amgen and Johnson & Johnson.

DOS

The lead molecules that are included in the VivoQuest license are covered by two issued patents and four patent applications. The patent applications describe both the structure of the compounds and their use for treating HCV infection. The two issued VivoQuest patents will expire in 2023. Additional patent applications, if issued, will expire in 2023, 2024 and 2025. We have also filed additional patent applications that cover the lead compounds discovered since the licensing of the DOS from VivoQuest. These additional patent applications, if issued, will expire in 2026 and 2027. Based on the provisions of the Patent Term Extension Act, we currently believe that we would qualify for certain patent term extensions.

We believe that Presidio will have sufficient time to commercially utilize the inventions from our small molecule development program directed to the treatment and prevention of hepatitis C infection.

Other Intellectual Property Rights

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

Licensing Agreements and Collaborations

We have formed strategic alliances with a number of companies for the production and commercialization of our drug candidates. Our current key strategic alliances are discussed below. See “Item 5. Operating and Financial Review and Prospects - Obligations and Commitments” which describes contingent milestone payments we have undertaken to make to certain licensors over the life of the licenses described below.

Bio-Gal Ltd.

In March 2009, we signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of MM from Bio-Gal Ltd., a private biotechnology company based in Gibraltar. In accordance with the terms of the asset purchase agreement, we will issue to Bio-Gal Ltd. ordinary shares representing just under 50% of the current issued and outstanding share capital of our company. In addition, we will make a milestone payment of approximately $10 million in cash upon the successful completion of a Phase 2 clinical trial. Our company’s Board of Directors may, in its sole discretion, issue additional ordinary shares to Bio-Gal Ltd in lieu of such milestone payment. We are also obligated to pay 1% royalties on net sales of the product. The closing of the transaction is subject to various conditions including XTL’s and Bio-Gal’s shareholders’ approvals, as well as completion of a financing. Closing is expected to take place in the second or third quarter of 2009.

VivoQuest License

In August 2005, we entered into a license agreement with VivoQuest covering a proprietary compound library, including certain HCV compounds. Under the terms of the license agreement, we have exclusive worldwide rights to VivoQuest's intellectual property and technology in all fields of use. To date we have made approximately $0.9 million in license payments to VivoQuest under the license agreement. The license agreement also provides for additional milestone payments triggered by certain regulatory and sales targets. These additional milestone payments total $34.6 million, $25.0 million of which will be due upon or following regulatory approval or actual product sales, and are payable in cash or ordinary shares at our election. In addition, the license agreement requires that we make royalty payments to VivoQuest on product sales.

Presidio License

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

Bicifadine License

In January 2007, XTL Development had signed an agreement with DOV to in-license the worldwide rights for Bicifadine, a serotonin and norepinephrine reuptake inhibitor (SNRI). XTL Development was developing Bicifadine for the treatment of diabetic neuropathic pain - a chronic condition resulting from damage to peripheral nerves. In accordance with the terms of the license agreement, XTL Development paid an initial up-front license fee of $7.5 million in cash in 2007. In addition, XTL Development will make milestone payments of up to $126.5 million over the life of the license, of which up to $115 million will be due upon or after regulatory approval of the product. These milestone payments may be made in either cash and/or our ordinary shares, at our election, with the exception of $5 million in cash, due upon or after regulatory approval of the product. XTL Development is also obligated to pay royalties to DOV on net sales of Bicifadine. In November 2008, we announced that the Phase 2b clinical trial failed to meet its primary and secondary endpoints, and as a result we ceased development of Bicifadine for diabetic neuropathic pain in 2008.

Competition

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

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

Competing Products for Treatment of MM

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

High dose chemotherapy, particularly melphalan, with autologous haematopoietic stem cell transplantation improves response rates and their duration and survival compared with conventional chemotherapy. It is now commonly used as consolidation treatment. Unfortunately, even after haematopoietic stem cell transplantation, relapse is only a matter of time, although a minority of patients seems to survive over a decade in remission ("operational cure"). Maintenance treatment after transplantation with corticosteroids or ainterferon is often prescribed in an attempt to delay relapse. Although this probably does prolong the duration of remission, it is unclear if it confers a survival benefit.

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

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

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

Competing Products for Treatment of Chronic Hepatitis C

We believe that a certain number of the drugs that are currently under development will become available in the future for the treatment of hepatitis C. At present, the only approved therapies for treatment of chronic HCV are Interferon-based. There are multiple drugs presently under development for the treatment of HCV, most of which are in the pre-clinical or early stage of clinical development. These compounds are being developed by both established pharmaceutical companies and biotech companies. Examples of such companies are: Anadys Pharmaceuticals, Inc., F. Hoffman-LaRoche & Co., Intercell AG, Schering-Plough Corporation, Gilead Sciences, Inc., Idenix Pharmaceuticals, Inc., InterMune, Inc., Pharmasset, Ltd., Vertex Pharmaceuticals Incorporated and Viropharma Incorporated. Many of these companies and organizations, either alone or with their collaborative partners, have substantially greater financial, technical and human resources than we do.

Supply and Manufacturing

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

rHuEPO for the treatment of MM

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

DOS

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

General

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

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

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

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

Government and Industry Regulation

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

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

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

- is intended to treat a serious or life-threatening condition;
- is intended to treat a serious aspect of the condition; and
- has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

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

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

- Phase 1: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.
- Phase 2: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.
- Phase 3: Studies establish safety and efficacy in an expanded patient population.
- Phase 4: The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations, such as children.

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

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

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

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

- insufficient supply of the drug candidates;

- adverse medical events or side effects in treated patients; and
- ineffectiveness of the drug candidates.

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

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

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

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

Should we wish to market our products outside the US, we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the EU, registration procedures are available to companies wishing to market a product in more than one EU member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or

identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country. Our current development strategy calls for us to seek marketing authorization for our drug candidates outside the United States.

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

Organizational structure

Our wholly-owned subsidiaries, XTL Biopharmaceuticals, Inc. and XTL Development, Inc., are each incorporated in Delaware.

Property, Plant and Equipment

We lease an aggregate of approximately 414 square meters in Rehovot, Israel, expiring in April 2009. To our knowledge, there are no environmental issues that affect our use of the properties that we lease.

There are no encumbrances on our rights in these leased properties or on any of the equipment that we own. However, to secure the lease agreements in Israel, we provided a bank guarantee in the amount of approximately $68,000, linked to the Israeli Consumer Price Index. As of December 31, 2008, the guarantee is secured by pledge on a restricted deposit amounting to $71,000, which is included in the balance sheet as a restricted deposit.

On April 6, 2009, our wholly-owned subsidiary, XTL Biopharmaceuticals, Inc., delivered a termination notice to Suga Development, L.L.C., with respect to the leasing of approximately 33,200 sq. ft. located at 711 Executive Boulevard, Suite Q, Valley Cottage, New York 10989. We believe that the notice provided a clear indication of the termination of XTL Biopharmaceuticals, Inc.'s obligations under the lease, effective as of the date of the notice. In addition, XTL Biopharmaceuticals, Inc. informed Suga Development that upon receipt of the notice, they should use their best effort to re-rent the premises and to mitigate any damages. There can be no assurance that the landlord will not dispute the termination of the lease, and attempt to hold XTL Biopharmaceuticals, Inc. responsible for the full amount of all future unpaid lease payments, approximately $335,000.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

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

You should read the following discussion and analysis in conjunction with our audited consolidated financial statements, including the related notes, prepared in accordance with US GAAP for the years ended December 31, 2008, 2007 and 2006, and as of December 31, 2008 and 2007, contained in "Item 18. Financial Statements" and with any other selected financial data included elsewhere in this annual report.

Selected Financial Data

The table below presents selected statement of operations and balance sheet data for the fiscal years ended and as of December 31, 2008, 2007, 2006, 2005 and 2004. We have derived the selected financial data for the fiscal years ended December 31, 2008, 2007, and 2006, and as of December 31, 2008 and 2007, from our audited consolidated financial statements, included elsewhere in this annual report and prepared in accordance with US GAAP. We have derived the selected financial data for fiscal years ended December 31, 2005 and 2004 and as of December 31, 2006, 2005 and 2004, from audited financial statements not appearing in this annual report, which have been prepared in accordance with US GAAP. You should read the selected financial data in conjunction with "Item 5. Operating and Financial Review and Prospects," "Item 8. Financial Information" and "Item 18. Financial Statements," including the related notes.

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	Year Ended December 31,				
	2008	2007	2006	2005	2004
	(In thousands, except share and per share amounts)				
Statements of Operations Data:					
Revenues					
Reimbursed out-of-pocket expenses	$ —	$ —	$	$ 2,743	$ 3,269
License	5,940	907	454	454	185
	5,940	907	454	3,197	3,454
Cost of Revenues					
Reimbursed out-of-pocket expenses	—	—	—	2,743	3,269
License (with respect to royalties)	—	110	54	54	32
	—	110	54	2,797	3,301
Gross Margin	5,940	797	400	400	153
Research and development					
Research and development costs	11,490	18,998	10,229	7,313	11,985
Less participations	—	56	—	—	—
	11,490	18,942	10,229	7,313	11,985
In-process research and development	—	—	—	1,783	—
General and administrative	5,143	5,582	5,576	5,457	4,134
Business development costs	(1,102)	2,008	641	227	810
Operating loss	(9,591)	(25,735)	(16,046)	(14,380)	(16,776)
Other income (expense):					
Financial and other income, net	314	590	1,141	443	352
Income taxes	31	206	(227)	(78)	(49)
Loss for the period	$ (9,246)	$ (24,939)	$ (15,132)	$ (14,015)	$ (16,473)
Loss per ordinary share					
Basic and diluted	$ (0.03)	$ (0.11)	$ (0.08)	$ (0.08)	$ (0.12)

Weighted average shares outstanding	292,769,320	228,492,818	201,737,295	170,123,003	134,731,766

	As of December 31,				
	2008	2007	2006	2005	2004
	(In thousands)				
Balance Sheet Data:					
Cash, cash equivalents, bank deposits and trading and marketable securities	$ 2,924	$ 12,977	$ 25,347	$ 13,360	$ 22,924
Working capital	1,385	8,532	22,694	11,385	20,240
Total assets	3,430	14,127	26,900	15,151	25,624
Long-term obligations	—	194	738	1,493	2,489
Total shareholders' equity	1,426	8,564	22,760	11,252	19,602

Overview

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical products for the treatment of unmet medical needs, particularly the treatment multiple myeloma, or MM, and hepatitis C. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any commercial revenues from the sales of our drug candidates.

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

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

Our revenues have consisted of license fees and reimbursed out of pocket expenses from Cubist and license fees from Presidio. We recognized the license fee revenues from our agreement with Cubist for HepeX-B ratably over the expected life of the arrangement; un-amortized amounts were recorded as deferred revenues. We also recognized revenue related to reimbursed out of pocket expenses at the time that we provided development services to Cubist. In July 2007, Cubist terminated the license agreement with us. We recognized the upfront non-refundable payment from Presidio as license fee revenue over our period of significant involvement. See "Item 4. Information on the Company – History and Development of XTL."

Our cost of revenues consisted of costs associated with the Cubist program for HepeX-B which consisted primarily of salaries and related personnel costs, fees paid to consultants and other third-parties for clinical and laboratory development, facilities-related and other expenses relating to the design, development, testing, and enhancement of our former product candidate out-licensed to Cubist. In addition, we recognized license fee expenses associated with our agreement with Yeda proportional to our license fee agreement with Cubist, with unamortized amounts recorded as deferred expenses. On December 31, 2007, we mutually terminated the research and license agreement with Yeda. See "Item 4. Information on the Company – History and Development of XTL."

Our research and development costs consist primarily of salaries and related personnel costs, fees paid to consultants and other third-parties for clinical and laboratory development, license and milestone fees, facilities-related and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our research and development costs as they are incurred.

Our historical participations consist primarily of grants received from the Israeli government in support of our legacy research and development activities, which are no longer being developed by us. These grants are recognized as a reduction of expense as the related costs are incurred. See "- Research and Development, Patents and Licenses – Israeli Government Research and Development Grants," below.

Our general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, professional fees, director fees and other corporate expenses, including investor relations, and facilities related expenses. We expense our general and administrative expenses as they are incurred.

Our business development costs consist primarily of salaries and related expenses for business development personnel, travel, professional fees and transaction advisory fees to third party intermediaries. Our business development activities are related to partnering activities for our drug programs, seeking new development collaborations and in-licensing opportunities. We expense our business development expenses as they are incurred. The transaction advisory fee associated with the Bicifadine transaction in the form of a SAR will be revalued, based on the then current fair value, at each subsequent reporting date, until payment of the stock appreciation rights have been satisfied.

Our results of operations include non-cash compensation expense as a result of the grants of stock options. Compensation expense for awards of options granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual stock options. The expense is included in the respective categories of expense in the statement of operations. We experienced a significant increase in non-cash compensation in the fiscal year ended December 31, 2005, and continue to expect to incur significant non-cash compensation as a result of adopting Statement of Financial Accounting Standards, or SFAS, No. 123, "Share Based Payment," or SFAS 123R, on January 1, 2005.

For awards of options and warrants to consultants and other third-parties, compensation expense is determined at the "measurement date." The expense is recognized over the vesting period for the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the

fair value of the award at the reporting date. Unvested options are revalued at every reporting period and amortized over the vesting period in order to determine the compensation expense.

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

Results of Operations

Years Ended December 31, 2008 and 2007

Revenues. Revenues for the year ended December 31, 2008, increased by $5,033,000 to $5,940,000, as compared to revenues of $907,000 for the year ended December 31, 2007. Revenues for the year ended December 31, 2008, were due to the recognition of license revenue associated with the Presidio out-licensing agreement. Revenue for the year ended December 31, 2007 was due to the recognition of unamortized deferred revenue upon termination of the HepeX-B license by Cubist in July 2007. We do not anticipate to recognize material revenue in 2009.

Cost of Revenues. There was no cost of revenues for the year ended December 31, 2008. The $110,000 of cost of revenues for the year ended December 31, 2007 was due to the recognition of unamortized license fees that were recorded as deferred expenses upon termination of the HepeX-B license by Cubist in July 2007.

Research and Development Costs. Research and development costs net of participations decreased by $7,452,000 to $11,490,000 for the year ended December 31, 2008, as compared to $18,942,000 for the year ended December 31, 2007. The decrease in research and development costs was due primarily to the absence of the $7.5 million initial upfront license fee paid to DOV in 2007 in connection with the in-licensing of Bicifadine, the absence of $1,477,000 in development expenses associated with our legacy hepatitis C projects that were terminated in 2007, and also due to a decline of $3,361,000 in expenses associated with the pre-clinical DOS program that we out-licensed to Presidio in 2008, offset by an increase of $4,830,000 in clinical development expenses associated with the now terminated Bicifadine clinical program. See 2008 Restructuring below and also see “Item 10. Additional Information -Material Contracts” and “Item 4. Information on the Company.”

Excluding the impact of the Bio-Gal Ltd transaction and non-cash compensation expenses associated with stock option grants, we expect our overall research and development expenses to decrease in 2009 primarily due the smaller expected size and geographic scope associated with our planned clinical program for Recombinant Erythropoietin for the treatment of MM versus the larger size and geographic scope associated with the Phase 2b and open label studies for the Bicifadine clinical program terminated in November 2008.

General and Administrative Expenses. General and administrative expenses decreased by $439,000 to $5,143,000 for the year ended December 31, 2008, as compared to expenses of $5,582,000 for the year ended December 31, 2007. The decrease in general and administrative expenses was due primarily to a decrease in legal and patent related expenses as well as second–year Sarbanes-Oxley compliance costs, offset by an increase of severance related expenses associated with the 2008 Restructuring. Excluding non-cash compensation costs, we expect a significant decline in our level of our general and administrative costs during 2008.

Business Development Costs. Business development costs decreased by $3,110,000 to a negative expense, or income of $1,102,000 for the year ended December 31, 2008, as compared to expenses of $2,008,000 for the year ended December 31, 2007. The decrease in business developments costs was due primarily to the reversal of $1,553,000 in transaction advisory fees in the form of stock appreciation rights associated with the in-licensing of Bicifadine in 2008 that was recorded in 2007. The transaction advisory fee in the form of a SAR is revalued, based on the then current fair value, at each subsequent reporting date, until payment of the stock appreciation rights have been satisfied (see “Item 10. Additional Information -Material Contracts” and “Item 4. Information on the Company”).

Financial and Other Income. Financial and other income for the year ended December 31, 2008, decreased by $276,000 to $314,000, as compared to financial and other income of $590,000 for the year ended December 31, 2007. The decrease in financial and other income was due primarily to a lower level of invested funds when compared to the comparable period last year.

Income Taxes. Income tax expense increased by $175,000 to a negative expense, or income of $31,000 for the year ended December 31, 2008, as compared to a negative expense, or income, of $206,000 for the year ended December 31, 2007. The negative expense for the year ended December 31, 2008, was due to a carryback claim to the year ended December 31, 2004 of the US consolidated tax group consisting of XTL Biopharmaceuticals, Inc. and XTL Development which incurred net operating losses in 2008 offset by New York State Franchise tax associated with the US permanent establishment. The US consolidated tax group will file a carryback claim for those losses to the year ended December 31, 2004 in order to receive a refund for US federal income taxes paid for that year. For the year ended December 31, 2007, the US consolidated tax group incurred net operating losses. The group filed a carryback claim for those losses to the years ended December 31, 2006 and December 31, 2005 to receive a refund for US federal income taxes paid for those years. Our income tax expense (income) is attributable to taxable income (losses) from the continuing operations of our US subsidiaries and the US permanent establishment. This income is eliminated upon consolidation of our financial statements.

Years Ended December 31, 2007 and 2006

Revenues. Revenues for the year ended December 31, 2007, increased by $453,000 to $907,000, as compared to revenues of $454,000 for the year ended December 31, 2006. The increase in revenues for the year ended December 31, 2007, was due to the recognition of unamortized deferred revenue upon termination of the HepeX-B license by Cubist in July 2007.

Cost of Revenues. Cost of revenues for the year ended December 31, 2007, increased by $56,000 to $110,000, as compared to cost of revenues of $54,000, for the year ended December 31, 2006. The increase in cost of revenues was due to the recognition of unamortized license fees that were recorded as deferred expenses upon termination of the HepeX-B license by Cubist in July 2007.

Research and Development Costs. Research and development costs net of participations increased by $8,713,000 to $18,942,000 for the year ended December 31, 2007, as compared to $10,229,000 for the year ended December 31, 2006. The increase in research and development costs was due primarily to an increase of $13,476,000 in expenses related to our Bicifadine clinical program (including the $7.5 million initial upfront license fee to DOV) (see “Item 10. Additional Information -Material Contracts” and “Item 4. Information on the Company”), offset by a decrease of $4,166,000 in expenses related to our legacy programs XTL-6865 and XTL-2125, that were terminated in 2007, and also due to a $597,000 decrease in expenses associated with our preclinical DOS program.

General and Administrative Expenses. General and administrative expenses increased by $6,000 to $5,582,000 for the year ended December 31, 2007, as compared to expenses of $5,576,000 for the year ended December 31, 2006. The increase in general and administrative expenses was due primarily to an increase in legal and patent related expenses as well as Sarbanes-Oxley compliance costs, offset by a decrease of $208,000 in non-cash compensation costs related to option grants.

Business Development Costs. Business development costs increased by $1,367,000 to $2,008,000 for the year ended December 31, 2007, as compared to expenses of $641,000 for the year ended December 31, 2006. The increase in business development costs was due primarily to $1,560,000 in transaction advisory fees in the form of stock appreciation rights associated with the in-licensing of Bicifadine offset by reduced legal and due diligence expenses in 2007 as compared to 2006. The transaction advisory fee in the form of a SAR will be revalued, based on the then current fair value, at each subsequent reporting date, until payment of the stock appreciation rights have been satisfied (see “Item 10. Additional Information -Material Contracts” and “Item 4. Information on the Company”).

Financial and Other Income. Financial and other income for the year ended December 31, 2007, decreased by $551,000 to $590,000, as compared to financial and other income of $1,141,000 for the year ended December 31, 2006. The decrease in financial and other income was due primarily to a lower level of invested funds when compared to the comparable period last year.

Income Taxes. Income tax expense decreased by $433,000 to a negative expense, or income, of $206,000 for the year ended December 31, 2007, as compared to expenses of $227,000 for year ended December 31, 2006. For the year ended December 31, 2007, the US consolidated tax group consisting of XTL Biopharmaceuticals, Inc. and XTL Development incurred net operating losses. The group will file a carryback claim for those losses to the years ended December 31, 2006 and December 31, 2005 in order to receive a refund for US federal income taxes paid for those years. Our income tax expense (income) is attributable to taxable income (losses) from the continuing operations of our subsidiaries in the US. This income is eliminated upon consolidation of our financial statements.

2008 Restructuring

During the first half of 2008, we terminated the employment of 11 research and development employees in the DOS program, which was out-licensed to Presidio in 2008. As a result, we incurred a charge of $191,000 in research and development during 2008 related to employee dismissal costs, all of which were paid in 2008.

In December 2008, we implemented a restructuring plan following the failure of the Bicifadine Phase 2b clinical trial. We notified nine of our remaining employees (six in research and development, two in general and administrative and one in business development) that they will be terminated, representing approximately 75% of our then remaining workforce. In addition, in December 2008, we announced that our then Chief Executive Officer would be departing in 2009. The remaining employees were tasked with seeking potential assets or a company to merge into XTL, or for assisting in the liquidation and/or disposition of XTL's remaining assets. As a result, we took a charge of $420,000 in 2008 relating to employee dismissal costs, $110,000 of which was included in research and development costs, $305,000 of which was included in general and administrative expenses and $5,000 was included in business development expenses.

As of December 31, 2008, 5 employees left XTL under the 2008 Restructuring and $0 of dismissal costs were paid. As of December 31, 2008 approximately $420,000 in employee dismissal obligations were included in "liability in respect to employee severance obligations," and was all subsequently paid in the first quarter of 2009.

Critical Accounting Policies

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

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

Stock Compensation. We have granted options to employees, directors and consultants, as well as warrants to other third parties. SFAS No. 123R “Share - Based Payment,” or SFAS 123R, addresses the accounting for share-based payment transactions in which a company obtains employee services in exchange for (a) equity instruments of a company or (b) liabilities that are based on the fair value of a company’s equity instruments or that may be settled by the issuance of such equity instruments.

The fair value of stock options granted with service conditions was determined using the Black-Scholes valuation model. Such value is recognized as an expense over the service period, net of estimated forfeitures, using the straight-line method under SFAS 123R. The fair value of stock options granted with market conditions was determined using a Monte Carlo Simulation method. Such value is recognized as an expense using the accelerated method under SFAS 123R.

We account for equity instruments issued to third party service providers (non-employees) in accordance with the fair value method prescribed by SFAS 123R, and the provisions of Emerging Issues Task Force Issue No 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services,” or EITF 96-18. Until the vesting date is reached, the total amount of compensation expense remains uncertain. We record option compensation based on the fair value of the options at the reporting date. Unvested options are then revalued, or the compensation is recalculated based on the then current fair value, at each subsequent reporting date and are amortized over the vesting period in order to determine the compensation expense. This may result in a change to the amount previously recorded in respect of the option grant, and additional expense or a negative expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, until the measurement date is reached and the compensation expense is finalized.

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

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred to date in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. With respect to clinical

site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful accrual of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Revenue Recognition. We recognize license revenue consistent with the provisions of Staff Accounting Bulletin ("SAB") No. 104 and EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." We analyze each element of our licensing agreement to determine the appropriate revenue recognition. We recognize revenue on upfront payments and milestone payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We may recognize milestone payments in revenue upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria would be recognized as deferred revenue.

Purchase Price Allocation. The purchase price allocation for acquisitions requires extensive use of accounting estimates and judgments to allocate the purchase price to the identifiable tangible and intangible assets acquired, including in-process research and development, and liabilities assumed based on their respective fair values. Additionally, we must determine whether an acquired entity is considered to be a business or a set of net assets, because a portion of the purchase price can only be allocated to goodwill in a business combination.

Accounting Related to the Valuation of In-Process Research and Development. In accordance with SFAS No. 142, "Goodwill and Other Intangible Assets," or SFAS 142, in-process research and development costs represent the relative fair value of purchased in-process research and development costs that, as of the transaction date, have not reached technological feasibility and have no proven alternative future use. As VivoQuest was a development stage enterprise that had not yet commenced its planned principal operations, we accounted for the transaction as an acquisition of assets pursuant to the provisions of SFAS 142. Accordingly, the purchase price was allocated to the individual assets acquired, based on their relative fair values, and no goodwill was recorded.

The fair value of the in-process research and development acquired was estimated by management with the assistance of an independent third-party appraiser, using the "income approach." In the income approach, fair value is dependent on the present value of future economic benefits to be derived from ownership of an asset. Central to this approach is an analysis of the earnings potential represented by an asset and of the underlying risks associated with obtaining those earnings. Fair value is calculated by discounting future net cash flows available for distribution to their present value at a rate of return, which reflects the time value of money and business risk. In order to apply this approach, the expected cash flow approach was used. Expected cash flow is measured as the sum of the average, or mean, probability-weighted amounts in a range of estimated cash flows. The expected cash flow approach focuses on the amount and timing of estimated cash flows and their relative probability of occurrence under different scenarios. The probability weighted expected cash flow estimates are discounted to their present value using the risk free rate of return, since the business risk is incorporated in adjusting the projected cash flows to the probabilities for each scenario. The valuation was based on information that was available to us as of the transaction date and the expectations and assumptions deemed reasonable by our management. No assurance can be given, however, that the underlying assumptions or events associated with such assets will occur as projected.

Recently Issued Accounting Standards

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS 141R"). SFAS 141R changes the accounting for business combinations. Among the more significant changes, it expands the definition of a business and a business combination, changes the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance and income tax uncertainties. SFAS 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is prohibited. We were required to adopt SFAS 141R on January 1, 2009. We are currently assessing the impact that SFAS 141R may have on its consolidated financial statements in the event of a future acquisition.

In December 2007, the FASB issued SFAS No. 160, "Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51" ("SFAS 160"). SFAS 160 amends ARB 51 to establish accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. An ownership interest in subsidiaries held by parties other than the parent should be presented in the consolidated statement of financial position within equity, but separate from the parent's equity. SFAS 160 requires that changes in a parent's ownership interest while the parent retains its controlling financial interest in its subsidiary should be accounted for

similarly as equity transactions. When a subsidiary is deconsolidated, any retained noncontrolling equity investment in the former subsidiary should be initially measured at fair value, with any gain or loss recognized in earnings. SFAS 160 requires consolidated net income to be reported at amounts that include the amounts attributable to both the parent and the noncontrolling interest. It also requires disclosure, on the face of the consolidated income statement, of the amounts of consolidated net income attributable to the parent and to the noncontrolling interests. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. Earlier adoption is prohibited. The statement shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirement which shall be applied retrospectively for all periods presented. We were required to adopt SFAS 160 on January 1, 2009. We do not expect the adoption of this Statement to have a material effect on our consolidated financial statements, since as of December 31, 2008, we did not have any non-controlling interests.

In December 2007, the FASB ratified EITF Issue No. 07-1, "Accounting for Collaborative Arrangements" ("EITF 07-1"). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. EITF 07-1 shall be applied using a modified version of retrospective transition for those arrangements in place at the effective date. Companies are required to report the effects of applying EITF-07-1 as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects of the change retrospectively. We were required to adopt EITF 07-1 on January 1, 2009. We do not expect the adoption of EITF 07-1 to have a material effect on our consolidated financial statements.

In February 2008, the FASB issued FSP FAS 157-2, "Effective Date of FASB Statement No. 157" ("FSP FAS 157-2"). FSP FAS 157-2 delays the effective date of SFAS 157 from 2008 to 2009 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually).

In April 2008, the FASB issued FSP 142-3, "Determination of the Useful Life of Intangible Assets" ("FSP 142-3"). FSP 142-3 amends the factors that should be considered in developing renewal or extension assumptions on legal and contractual provisions used to determine the useful life of a recognized intangible asset under SFAS No. 142, "Goodwill and Other Intangible Assets." FSP 142-3 is effective for fiscal years beginning after December 15, 2008. We will be required to adopt FSP 142-3 on January 1, 2009. We do not expect the adoption of this FSP to have a material effect on our Consolidated Financial Statements.

In November 2008, the FASB ratified EITF Issue No. 08-7, "Accounting for Defensive Intangible Assets," ("EITF 08-7"). EITF 08-7 applies to defensive intangible assets, which are acquired intangible assets that the acquirer does not intend to actively use but intends to hold to prevent its competitors from obtaining access to them. As these assets are separately identifiable, EITF 08-7 requires an acquiring entity to account for defensive intangible assets as a separate unit of accounting. A defensive intangible asset shall be assigned a useful life in accordance with paragraph 11 of Statement 142. EITF 08-7 is effective for intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Earlier application is not permitted. We were required to adopt EITF 08-7 on January 1, 2009. We do not expect the adoption of EITF 08-7 to have a material effect on our Consolidated Financial Statements.

Impact of Inflation and Currency Fluctuations

We generate all of our revenues and hold most of our cash, cash equivalents and bank deposits in US dollars. While a substantial amount of our operating expenses are in US dollars, we incur a portion of our expenses in New Israeli Shekels. In addition, we also pay for some of our services and supplies in the local currencies of our suppliers. As a result, we are exposed to the risk that the US dollar will be devalued against the New Israeli Shekel or other currencies, and as result our financial results could be harmed if we are unable to guard against currency fluctuations in Israel or other countries in which services and supplies are obtained in the future. Accordingly, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of currencies. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the dollar or that the timing of any devaluation may lag behind inflation in Israel. To date, our business has not been materially adversely affected by changes in the US dollar exchange rate or by effects of inflation in Israel.

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

Israeli companies are generally subject to income tax at the corporate tax rate of 27% in 2008 (29% in 2007), which will be reduced as follows: 2009 - 26%, 2010 and after - 25%.

As of December 31, 2008, XTL Biopharmaceuticals Ltd. did not have any taxable income. As of December 31, 2008, our net operating loss carryforwards for Israeli tax purposes amounted to approximately $153.5 million. Under Israeli law, these net-operating losses may be carried forward indefinitely and offset against future taxable income, including capital gains from the sale of assets used in the business, with no expiration date.

As of December 31, 2008, we had a “permanent establishment” in the US, which began in 2005 due to the residency of our former Chairman of the Board of Directors and the departing Chief Executive Officer in the US. This may continue in 2009 as well. Any income attributable to such US permanent establishment would be subject to US corporate income tax in the same manner as if we were a US corporation. The maximum US corporate income tax rate (not including applicable state and local tax rates) is currently at 35%. In addition, if we had income attributable to the permanent establishment in the US, we may be subject to an additional branch profits tax of 30% on our US effectively connected earnings and profits, subject to adjustment, for that taxable year if certain conditions occur, unless we qualified for the reduced 12.5% US branch profits tax rate pursuant to the United States-Israel tax treaty. We would be potentially able to credit any foreign taxes that may become due in the future against its US tax liability in connection with income attributable to its US permanent establishment and subject to both US and foreign income tax. As of the signing date of our financial statements, there was a change in our Board and senior management composition, such that the residences of our newly appointed Chairman and co-Chief Executive Officer were outside of the United States, as of the end of the first quarter of 2009.

As of December 31, 2008, we did not earn any taxable income for US federal tax purposes. If we eventually earn taxable income attributable to its US permanent establishment, we would be able to utilize accumulated loss carryforwards to offset such income only to the extent these carryforwards were attributable to its US permanent establishment. As of December 31, 2008, we estimate that these US net operating loss carryforwards are approximately $22.6 million. These losses, subject to limitation in the case of shifts in ownership of the Company, e.g. a planned offering or capital raise, resulting in more than 50 percentage point change over a three year lookback period, can be carried forward to offset future US taxable income and expire through 2028. For the year ended December 31, 2008, the Company was subject to a State franchise tax of $10,000 in regards to the permanent establishment.

Liquidity and Capital Resources

We have financed our operations from inception primarily through various private placement transactions, our initial public offering, a placing and open offer transaction, and option and warrant exercises. As of December 31, 2008, we had received net proceeds of approximately $76.4 million from various private placement transactions, including the November 2007 private placement, net proceeds of $45.7 million from our initial public offering, net proceeds of $15.4 million from the 2004 placing and open offer transaction, and proceeds of $2.1 million from the exercise of options and warrants.

As of December 31, 2008, we had $2.9 million in cash, cash equivalents, and short-term bank deposits, a decrease of $10.1 million from December 31, 2007. Cash used in operating activities for the year ended December 31, 2008, was $10.6 million, as compared to $21.4 million for the year ended December 31, 2007. This decrease in cash used in operating activities was due primarily to the absence of the $7.5 million initial upfront license fee for Bicifadine and from our revenue from the out-licensing of the DOS program to Presidio in 2008. For the year ended December 31, 2008, the net cash provided by investing activities of $10.9 million, as compared to net cash provided by investing activities of $10.6 million for the year ended December 31, 2007, was primarily the result of the maturity of short-term bank deposits. For the year ended December 31, 2008, net cash provided by financing activities of $0.2 million, as compared to $8.8 million for the year ended December 31, 2007, was the result of our $8.8 million private placement that closed in November 2007.

We currently anticipate that our cash and cash equivalents and restricted short-term bank deposits are sufficient to finance our operations through July 2009. Continuation of our current operations after utilizing our current cash reserves is dependent upon the generation of additional financial resources either through agreements for the monetization of our residual in the DOS program or through external financing. These matters raise substantial doubt about our ability to continue as a going concern. We do believe, however, that we will likely seek additional capital during the next couple of months through a planned rights offering and / or public or private equity offerings or debt financings. We have made no determination at this time as to the amount, method or timing of any such financing. Such additional financing may not be available when we need it.

Our forecast of the period of time through which our cash, cash equivalents and short-term investments will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the costs involved in closing the Bio-Gal transaction, including the required financing;
- the accuracy of our financial forecasts;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;

- the timing of expenses associated with product development and manufacturing of the proprietary drug candidate that we have acquired from Bio-Gal Ltd. and those that may be in-licensed, partnered or acquired;
- our ability to achieve our milestones under licensing arrangements; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

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

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The factors discussed above, taken together with our limited cash and cash equivalents raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern. In addition, the report of our independent registered public accounting firm covering our 2008 Consolidated Financial Statements, included in this Annual Report, contains an explanatory paragraph that makes reference to uncertainty about our ability to continue as a going concern.

Off-Balance Sheet Arrangements

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

Obligations and Commitments

As of December 31, 2008, we had known contractual obligations, commitments and contingencies of $464,000. Of this amount, $0 relates to research and development agreements. The $464,000 relates to our operating lease obligations, of which $457,000 is due within the next year, with the remaining balance due as per the schedule below.

		Payment due by period			
Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Research & development agreements	$ —	$ —	$ —	$ —	$ —
Operating leases	464,000				