Risk Factors

Before you invest in our ordinary shares or 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 a limited operating history and have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by development stage companies. In addition, we have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future. As of December 31, 2005, we had an accumulated deficit of approximately $100 million. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates or technologies. Consequently, if those revenues are insufficient to cover development and other expenditures we may incur, we may never become profitable.

We have not received approval for the sale of any of our products in any market and, therefore, have not generated any commercial revenues from the sales of our products. We have relied on equity financings to fund our operations.

We have not yet commercialized any of our drug candidates or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidates and technologies and successfully commercialize them. Moreover, we have relied on equity financings to fund our operations, and we expect to use, rather than generate, funds from operations for the foreseeable future. See “- Risks Related to our Financial Condition” below.

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 is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients. 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 and the existence of competitive clinical trials. 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 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, contract research organizations and other third-party service providers to conduct the clinical trials of our drug candidates and technologies and expect to continue to do so. 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, 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 result in enforcement action against us.

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.

All of our drug candidates and technologies are in preclinical or clinical stages. Specifically, one of our drug candidates, HepeX-B, was recently studied in a Phase IIb trial, XTL-2125 and XTL-6865 are currently in a Phase I clinical trial and one of our programs under development, DOS, has not yet been tested in humans. In order for our candidates to proceed to later stage clinical testing, they must show positive preclinical or clinical data. While HepeX-B, XTL-6865 and XTL-2125 have shown promising preclinical data and HepeX-B has shown promising clinical data, preliminary results of pre-clinical or clinical tests do not necessarily predict the final results, and promising results in pre-clinical 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. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. 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. 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. Negative or inconclusive results or medical events during a clinical trial could cause us to delay or terminate our development efforts.

Clinical trials also have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. 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. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the US and abroad and, accordingly, may encounter unforeseen problems and delays in the approval 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 we license some of our proprietary technologies from third-parties, some of these third-parties could prevent us from licensing our drug candidates.

We do not own all of our drug candidates and technologies. We have licensed the patent rights to some of our drug candidates and/or the technologies on which they are based from others. Specifically, we have licensed the two human monoclonal antibodies comprising XTL-6865 from Stanford University and DRK-Blutspendedienst Baden-Wurttemberg, we have licensed XTL-2125 from B&C Biopharm Co. Ltd., and we have licensed certain other Hepatitis C virus, or HCV, compounds from VivoQuest Inc., or VivoQuest. We have also licensed the Trimera technology upon which certain of our current programs are based from the Yeda Research and Development Company Ltd., which we refer to as Yeda. 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. 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. In addition, see “- Risks Related to Our Intellectual Property” below regarding potential issues related to the use of patents owned by third-parties.

In addition, under the terms of our license agreement with Yeda, we are required to obtain their approval under the license in order to grant sub-licenses to collaborative partners to develop or commercialize products or products derived from technologies under the license. The requirement of obtaining these approvals, and any conditions that Yeda may impose upon such approvals, could have the effect of delaying or impeding our ability to enter into agreements with collaborative partners or result in our having to accept terms and conditions that might not be favorable to us. For a discussion of further required approvals, see "- Risks Relating to Operations in Israel" below regarding potential restrictions from the Office of the Chief Scientist regarding the manufacture of our drug candidates outside the State of Israel.

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.

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.

For example, in June 2004, we announced the completion of a license agreement with Cubist Pharmaceuticals, Inc., or Cubist, for the worldwide development and commercialization of HepeX-B. Under this agreement, we were responsible for certain clinical and product development activities of HepeX-B through August 2005, at the expense of Cubist. Thereafter, we transferred full responsibility for completing the development of HepeX-B to Cubist. Cubist will be responsible for completing the development and for registration and commercialization of the product worldwide. Accordingly, to a significant degree, we are unable to control whether HepeX-B will be scientifically or commercially successful. In addition, Cubist recently met with the FDA to discuss proposed changes to the method of manufacture and formulation of HepeX-B. The objective of the manufacturing change is to provide a stable platform for commercialization. Cubist is expected to meet again with the FDA in the next few months to discuss the implications of these changes on the next stage of the clinical program. There can be no assurance that they will be successful in developing HepeX-B for commercialization, and, as a result, no assurance that we will receive any proceeds from the sales of HepeX-B.

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;

- 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.

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 ourselves the compounds that we need to conduct our clinical trials and rely upon a limited number of manufacturers to supply our drug candidates. We have no experience in manufacturing compounds for clinical or commercial purposes and do not have any manufacturing facilities. We rely upon, and intend to continue to rely upon, third parties to manufacture our drug candidates for use in clinical trials and for future sales. In order to commercialize our products, such products will need to be manufactured in commercial quantities while adhering to all regulatory and other 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 expect to continue to rely on contract manufacturers and other third parties to produce sufficient quantities of our drug candidates for use in our clinical trials. See “Item 4: Information on the Company - Business Overview - Supply and Manufacturing” below. We believe that our existing manufacturing arrangements with these parties will be adequate to satisfy our current clinical supply needs for XTL-2125 and XTL-6865. Future supply of the HepeX-B clinical material will be manufactured by a contract manufacturer to be selected by our partner Cubist Pharmaceuticals Inc. 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, 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 drug candidates in strict compliance with current good manufacturing practices, or cGMP, in order to meet acceptable 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 governmental agencies to ensure strict compliance with, among other things, current good manufacturing practices, 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 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 more effectively market their drugs.

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. 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 April 30, 2006, we had 42 full-time employees. To successfully develop our drug candidates and technologies, we must be able to attract and retain highly skilled personnel. The retention of their services cannot be guaranteed. In particular, if we lose the services of Michael S. Weiss, our Chairman, or Ron Bentsur, our Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. Our agreement with Mr. Weiss provides that he may terminate his agreement with us upon 30 days' prior written notice if he is not re-elected as Chairman of our Board, his fees for service as Chairman are reduced by more than 10%, we breach any material term of his agreement, or there is a change of control or reorganization of our company. Our agreement with Mr. Bentsur provides that he may terminate his agreement with us upon 30 days' prior written notice if he is no longer the highest ranking member of our company's management team, his annual base salary is reduced by more than 10% (except where we have made similar deductions in the base salary of senior management throughout our company), we breach any material term of his agreement, or there is a change of control or reorganization of our company. We do not maintain a key man life insurance policy covering either Mr. Weiss or Mr. Bentsur.

Any acquisitions 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 to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes our ordinary shares or other securities, your equity in us may be significantly diluted. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions also involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- our inability to retain the management, key personnel and other employees of the acquired business;
- our inability to maintain the acquired company's relationship with key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired 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 could prove to be unsuccessful as the drugs or processes involved could fail to be scientifically or commercially viable.

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

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

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

We believe that we have obtained sufficient product liability insurance coverage for our 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

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. We currently have an average projected burn rate of approximately $1.1 million per month in 2006. Based on our current business plan, with the proceeds of our recent private placement that closed in March 2006, we believe that we have sufficient resources to fund our operations for approximately the next 24 months; however, the actual amount of funds that we will need will be determined by many factors, some of which are beyond our control. These factors include:

- the progress of our development activities;
- the progress of our research activities;
- the number and scope of our 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 may seek additional capital through a combination of public and private equity offerings, debt financings and collaborative, strategic alliance and licensing arrangements. 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. 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 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.

We may be exposed to a significant tax assessment in Israel, which, if payable, could adversely affect our available resources.

In 2005, we received an assessment from the Israeli tax authorities of approximately $730,000 (including fines and interest expenses) related to withholding taxes for taxable employee benefits and taxable income in Israel paid to foreign companies during the periods of 2001-2004. We have recorded an accrual which we believe reflects the probable liability associated with this assessment. There can be no assurance that this accrual will be sufficient to cover the actual assessment, if any.

We may become subject to taxation in the US, which could significantly increase our tax liability in the US for which we could not apply the net losses accumulated in Israel.

The residency of the Chairman of our Board of Directors and our Chief Executive Officer in the US, as well as other less significant contacts we have with the US could lead to a determination by the US Internal Revenue Service that we have a "permanent establishment" in the US beginning in 2005. As a result, any income attributable to such permanent establishment in the US could be subject to US corporate tax. If this is the case, we may not be able to utilize any of the accumulated loss carryforwards shown on our balance sheet at December 31, 2005, to offset any such tax liability since they were all accumulated under Israeli tax laws. 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.

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. Moreover, in certain parts of the world, such as in China, western companies are adversely affected by poor enforcement of intellectual property rights. See “Item 4: Information on the Company - Business Overview - License Agreements and Collaborations” below regarding our license of Ab65, a component of XTL-6865.

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 intend to apply for patent protection for each new monoclonal antibody produced. Such patents may include claims relating to novel human monoclonal antibodies directed at targets for which other human monoclonal antibodies already exist, or at targets which are protected by patents or patent applications filed by third parties. No assurance can be given that any such patent application by a third-party will not have priority over patent applications filed by us.

Several groups are attempting to produce and patent a chimeric mouse with human tissue. To the extent any patents issued to other parties claiming, in general, mouse-human chimeras, the risk increases that the potential products and processes of our or our future strategic partners may give rise to claims of patent infringement.

We plan to use the recombinant production of antibodies in Chinese Hamster Ovary cells, or CHO cells, in the development and production of some of our products. Patents relating to this method of antibody production are owned by third-parties. We are also aware that third parties have patent protection covering hepatitis C antigens and antibodies, which will be needed in order to commercialize XTL-6865. If we or our collaborative partners are unable to license such patent rights on commercially acceptable terms, the ability to develop, manufacture and sell these products could be impaired. Further, royalties payable to third parties may reduce the payments we will receive from our licensees or development partners.

In addition to patent protection, we may utilize orphan drug regulations to provide market exclusivity for certain of our drug candidates. The orphan drug regulations of the FDA provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the US, or, diseases that affect more than 200,000 individuals in the US but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. We believe that certain of the indications for our drug candidates will be eligible for orphan drug designation. However, we cannot guarantee that any drug candidates will qualify, and, if any do qualify, that we will be the holder of the first FDA approval of such qualifying drug candidates.

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, 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 traditionally been very 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 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.

Sales of substantial amounts of our ADRs in the public market could harm the market price of our ADRs.

We cannot predict the effect, if any, that future sales of our ADRs in the public market, or the availability of our ADRs for sale in the market, will have on the market price of our ADRs. We, therefore, can give no assurance that sales of substantial amounts of our ADRs in the public market, or the potential for large amounts of sales in the market, whether by investors in the recent private placement, under any registration statement or otherwise, would not cause the price of our ADRs to decline considerably or impair our future ability to raise capital through sales of our ADRs.

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;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- 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, 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 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.

If we make one or more significant acquisitions in which the consideration includes ordinary shares or other securities, your equity in us may be significantly diluted. 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, and we may elect to issue up to an additional $34.6 million in ordinary shares in lieu of cash to VivoQuest upon achievement of certain milestones. In the future, we may enter into additional arrangements with other third-parties permitting us to issue ordinary shares in lieu of certain cash payments such as milestones.

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

Our ordinary shares are traded on the London Stock Exchange and the Tel Aviv Stock Exchange and ADRs representing our ordinary shares are quoted on the Nasdaq National Market. Trading in our securities on these markets are 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, Israel and the United Kingdom. Consequently, the effective trading prices of our shares on these three markets may differ. Any decrease in the trading price of our shares on one of these markets could cause a decrease in the trading price of our shares on the other market.

Holders of our ordinary shares who are US 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 is at least 50%. The risk that we will be classified as a PFIC arises because under applicable rules issued by the US Internal Revenue Service, or the IRS, 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 a PFIC for the taxable year ended December 31, 2003. We believe that we were likely not a PFIC for the taxable years ended December 31, 2004 and 2005. 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 there is a significant likelihood that we will be classified as a PFIC in the 2006 taxable year and possibly in subsequent years.

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

A US holder may generally avoid this regime by electing to treat its PFIC shares as a "qualified electing fund." If a US holder elects to treat PFIC shares as a qualified electing fund, the US holder must include annually in gross income (for each year in which PFIC status is met) his pro rata share of the PFIC's ordinary earnings and net capital gains, whether or not such amounts are actually distributed to the US holder. Since fiscal 2005, we have complied with the record-keeping and reporting requirements that are a prerequisite to making a "qualified electing fund" election. While we plan to continue to comply with such requirements, if, in the future, meeting those record-keeping and reporting requirements becomes onerous, we may decide, in our sole discretion, that such compliance is impractical and will so notify US holders.

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 if we are a PFIC, see "Item 10: Additional Information - Taxation - 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 therefore depress the price of our ordinary shares.

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. The 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 shareholder with over 25% of the voting rights in the company. This rule does not apply if there is already another shareholder of the company with 25% or more of the voting rights. 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 voting rights in the company, unless there is a shareholder with 50% or more of the voting rights in 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 American Depositary Receipts, or ADRs, on our behalf. Each ADR is a certificate evidencing a specific number of American Depositary Shares, also referred to as 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. However, our ADR holders may not know about the meeting enough in advance to withdraw the 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 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 ADSs 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 the 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 or Pounds Sterling, 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 us to make them available to them.

Risks Relating to Operations in Israel

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

Certain of our research and development facilities and some of our 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 you 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 generate all of our revenues and hold most of our cash, cash equivalents, bank deposits and marketable securities 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 (approximately 20% in 2005). 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.

The Office of the Chief Scientist may refuse to approve the manufacture of our products outside the State of Israel.

We have in the past participated in programs offered by the Office of the Chief Scientist under the Industry, Trade and Labor Ministry of Israel that supports research and development activities. Through December 31, 2005, we have received $7.3 million in grants from the Office of the Chief Scientist for several projects, most of which are currently under development. Israeli law requires that the manufacture of products developed with government grants be carried out in Israel, unless the Office of the Chief Scientist provides a special approval to the contrary. This approval, if provided, is generally conditioned on an increase in the total amount to be repaid to the Office of the Chief Scientist to between 120% and 300% of the amount of funds granted. While we believe that the Office of the Chief Scientist does not unreasonably withhold approval if the request is based upon commercially justified circumstances and any payment obligations to the Office of the Chief Scientist are sufficiently assured, the matter is solely within its discretion. We cannot be sure that such approval, if requested, would be granted upon terms satisfactory to us or granted at all. Without such approval, we would be unable to manufacture any products developed by this research outside of Israel, which may greatly restrict any potential revenues from such products.

We may not continue to be entitled to certain tax benefits from the Israeli government.

We are entitled to receive certain tax benefits as a result of the Approved Enterprise status of our existing facilities in Israel. The Law for the Encouragement of Capital Investment, 1959, as amended, provides that a proposed capital investment in eligible facilities may, upon application to the Investment Center of the Ministry of Industry and Trade of the State of Israel, permit a company to recognize taxable income attributable to the Approved Enterprise subject to company tax at the maximum rate of 25% rather than the usual rate in 2006 of 31%. This usual rate is currently scheduled to decrease as follows: in 2007 - 29%, 2008 - 27%, 2009 - 26%, 2010 and after - 25%. For further discussion of these tax benefits, see “Item 10 - Additional Information - Taxation - Israeli Tax Considerations” below. To date we have not received any such tax benefits because we have not generated any taxable income to date. To maintain our eligibility for these tax benefits, we must meet certain reporting requirements and certain conditions that we have either obligated ourselves to meet or that are included in the Certificate of Approval from the Investment Center of the Ministry of Industry and Trade of the State of Israel. If we cease to become entitled to tax benefits, we may be required to pay repay corporate tax at the normal rate on all or part of the taxable income that we may generate from the eligible facilities in the future.

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 the Company

We are a biopharmaceutical company engaged in the acquisition, development and commercialization of pharmaceutical products for the treatment of infectious diseases, particularly the treatment of hepatitis C. We are developing XTL-2125, a small molecule non-nucleoside, polymerase inhibitor for the treatment of patients with hepatitis C. In May 2006, we announced the initiation of a Phase I clinical trial with XTL-2125 in patients with chronic hepatitis C. A second drug candidate, XTL-6865, is also being developed for the treatment of patients with hepatitis C. XTL-6865 is a combination of two monoclonal antibodies against the hepatitis C virus. The antibodies comprising XTL-6865 are expected to "trap" the virus in the patient's serum and prevent the infection of healthy liver cells. In September 2005, we announced the initiation of a Phase Ia clinical trial with XTL-6865 in patients with chronic hepatitis C. Our third program in the hepatitis C area is the Diversity Oriented Synthesis, or DOS, program. This program is focused on the development of novel hepatitis C small molecule inhibitors. These compounds are presently being optimized. We expect to identify the first clinical candidate from the DOS program and start investigational new drug enabling, or IND-enabling, good laboratory practices safety, or GLP-safety, studies with this clinical candidate in the second half of 2006. Another product under development, HepeX-B, is designed to prevent re-infection with hepatitis B in liver transplant patients, and was recently studied in a Phase IIb trial in liver transplant patients. Worldwide rights for HepeX-B were licensed to Cubist Pharmaceuticals Inc., or Cubist, in exchange for certain milestone payments and future royalties on Cubist's net sales. In December 2005, data from the Phase IIb trial in liver transplant patients showed that patients treated with HepeX-B experienced no evidence of viral reinfection. Cubist recently met with the FDA to discuss proposed changes to the method of manufacture and formulation of HepeX-B. Cubist is expected to meet again with the FDA in the next few months to discuss the implications of these changes on the next stage of the clinical program.

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 - γ and the hepatitis C virus.

Our ordinary shares are traded on the London Stock Exchange under the symbol "XTL," and on the Tel Aviv Stock Exchange under the symbol "XTL." Our ADRs are quoted on the Nasdaq Stock Market under the symbol "XTLB." We operate under the laws of the State of Israel, under the Israeli Companies Act, the regulations of the United Kingdom Listing Authority, which governs our listing on the London Stock Exchange, and in the US, the Securities Act, the Exchange Act and the regulation of the Nasdaq Stock Market.

Our principal offices are located at 750 Lexington Avenue, 20th Floor, New York, New York 10022 and our telephone number is 212-531-5960. The principal offices of XTL Biopharmaceuticals, Inc., our wholly-owned US subsidiary and agent for service of process in the US, are located at 750 Lexington Avenue, 20th Floor, New York, NY 10022, and its telephone number is 212-531-5960. Our primary internet address is www.xtlbio.com. None of the information on our website is incorporated by reference into this annual report.

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. Since inception, we raised net proceeds of approximately $128.8 million to fund our activities, including the estimated net proceeds from our recent private placement.

For the years ended December 31, 2005, 2004, and 2003 our capital expenditures were $38,000, $180,000 and $81,000, respectively. Our capital expenditures were primarily associated with the purchase of lab equipment for our research and development activities. There were no material divestitures during the years ended December 31, 2005, 2004 and 2003.