

XTL BIOPHARMACEUTICALS LTD
Form 6-K
August 14, 2008

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

Form 6-K

Report of Foreign Private Issuer

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

For the month of August, 2008

Commission File Number: **000-51310**

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

711 Executive Blvd., Suite Q
Valley Cottage, New York 10989
(Address of principal executive offices)

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

Form 20-F Form 40-F

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

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

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

Yes No

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

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. dated August 14, 2008 is hereby incorporated by reference into the registration statements on Form F-3 (File No. 333-141529 and File No. 333-147024) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007 and October 30, 2007, respectively, and the registration statements on Form S-8 (File No. 333-148058 and File No. 333-148574) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on December 14, 2007 and January 18, 2008, respectively.

The following is intended to update our risk factors as disclosed in our Annual Report on Form 20-F dated March 27, 2008. Investing in our ordinary shares or American Depositary Receipts (“ADRs”) representing American Depositary Shares involves a high degree of risk. The risks described below should be considered in connection with the risks described in our Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 27, 2008.

RISK FACTORS

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 FDA or other regulatory authorities imposed protocol requirements;
- 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.

If the clinical trials fail to satisfy the criteria required, the FDA 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.

Our International Clinical Trials May Be Delayed Or Otherwise Adversely Impacted By Social, Political And Economic Factors Affecting The Particular Foreign Country.

We are presently conducting clinical trials in the U.S., India, Germany and Israel. 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.

Because we are conducting clinical trials in India, Israel and Germany, and potentially other foreign countries in the future, any disruption to our international clinical trial program could significantly delay our product development

efforts.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XTL BIOPHARMACEUTICALS LTD.

Date: August 14, 2008

By: /s/ Ron Bentsur

Ron Bentsur
Chief Executive Officer

