

XTL BIOPHARMACEUTICALS LTD
Form 6-K
December 27, 2005

**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 December 25, 2005

Commission File Number: **000-51310**

XTL Biopharmaceuticals Ltd.

(Translation of registrant's name into English)

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

(Address of principal executive offices)

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

Form 20-F 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

CUBIST PHARMACEUTICALS REPORTS RESULTS FROM PHASE 2 STUDY HEPEX-B™ , WHICH WAS LICENSED FROM XTLBIO

Rehovot, Israel; Thursday, 22 December 2005 - XTL Biopharmaceuticals Ltd. ("XTLbio") (LSE: XTL; NASDAQ: XTLB; TASE: XTL) announces that Cubist Pharmaceuticals, Inc. (Nasdaq: CBST) today provided data from a recently concluded Phase 2 study of HepeX-B™ which was licensed to Cubist by XTLbio in 2004. In the Phase 2 study, HepeX-B was studied as maintenance therapy to prevent reinfection with hepatitis B in patients with liver transplants. Data from liver transplant patients who were treated with monthly infusions of 20 or 40 mg HepeX-B versus 5000 IU of HBIg showed that patients with either dose of HepeX-B experienced no evidence of viral reinfection. The data also showed fewer and less serious adverse experiences reported in both HepeX-B groups as compared to the HBIg group, although the differences were not statistically significant given the number of patients in the trial. Patients who were treated with HepeX-B as well as HBIg also received concurrent HBV polymerase inhibitor. Cubist will be reviewing Phase 2 results with the U.S. Food and Drug Administration (FDA) early in 2006.

The data released today is derived from patients who have completed at least 6 months of therapy, which was the treatment duration at which the primary endpoint was measured. Eleven patients received monthly 20 mg infusions of HepeX-B; ten received monthly infusions of 40 mg HepeX-B; and nine received monthly infusions of 5000 IU HBIg (current standard of care).

Cubist recently met with the FDA to discuss proposed changes to the method of manufacture and formulation of HepeX-B. Specifically, Cubist plans to shift from the use of hybridoma cells to Chinese Hamster Ovary (CHO) cells and to switch to subcutaneous delivery prior to Phase 3. The objective of the manufacturing change is to provide a stable platform for commercialization. The switch to subcutaneous administration is meant to increase patient convenience and compliance with chronic therapy. Cubist will meet again with the FDA in early 2006 to discuss the implications of these changes on the next stage of the clinical program.

Michael S. Weiss, Chairman of XTLbio, commented: "We are very pleased with the results of this Phase 2 trial and the fact that reinfection was not observed in any of the patients treated with HepeX-B. We are proud of being responsible for HepeX-B's discovery and early clinical development, and we are pleased with the progress of this product towards commercialization in the hands of our partner Cubist."

Contact XTLbio:

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About Hepatitis B (HBV)

The hepatitis B virus, according to Datamonitor, has infected more than 2 billion people around the world. Although a vaccine against HBV was introduced in 1982, globally, 350 million people are infected chronically with the disease and approximately 1 million people die each year as a result of complications from HBV infection. Current treatment regimens for chronic HBV often include use of interferon alpha or an antiviral drug. Despite these treatment options, chronic HBV can lead to severe liver damage and patients may require liver transplantation. To prevent re-infection of the new liver with HBV, patients are currently treated with hepatitis B immune globulin (HBIg) combined with an antiviral compound, such as Lamivudine. The global market for HBIg is estimated to be about \$100 million annually.

About HepeX-B™

HepeX-B is a combination of two fully human monoclonal antibodies that target HBV surface antigens. It is currently in evaluation for the prevention of infection by HBV in liver transplant patients who have been maintained on HBIg. HepeX-B already has been granted Orphan Drug Status in both the U.S. and the European Union.

About XTLbio

XTL Biopharmaceuticals Ltd (XTLbio) is engaged in the research, development and commercialization of therapeutics for the treatment of infectious diseases, with a particular focus on hepatitis C. XTLbio's most advanced therapeutic in Hepatitis C is XTL-6865 - a combination of two monoclonal antibodies against the hepatitis C virus - presently in Phase 1 clinical trials in patients with chronic hepatitis C. XTLbio's second Hepatitis C therapeutic is XTL-2125 - a small molecule inhibitor of the hepatitis C Virus polymerase - expected to enter Phase 1 clinical trials in 1H2006. XTLbio hepatitis C pipeline also includes several families of pre-clinical hepatitis C small molecule inhibitors. In 2004, XTLbio licensed HepeX-B - an antibody therapeutic against hepatitis B - to Cubist Pharmaceuticals. XTLbio is publicly traded on the London, NASDAQ, and Tel-Aviv Stock Exchanges (LSE: XTL; NASDAQ: XTLB; TASE: XTL).

Cautionary Statement

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the U.S. Private Securities Litigation Reform Act of 1995. Among the factors that could cause our actual results to differ materially, and therefore affect interest by investors in our ADR's, are the following: the performance of HepeX-B in further clinical trials and its ability to continue to prevent reinfection following liver transplantation; the effect of the proposed changes in the manufacture of HepeX-B on its performance in clinical trials; Cubist's ability to shift the manufacturing process for HepeX-B without causing a delay in further clinical trials or ultimate commercialization; and other risk factors identified from time to time in our reports filed with the regulatory authorities in Israel, the United Kingdom and the United States. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.xtlbio.com. The information in our website is not incorporated by reference into this press release and is included as an inactive textual reference only.

SIGNATURES

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

XTL BIOPHARMACEUTICALS LTD.

Date: December 25, 2005

By: /s/ Jonathan Burgin

Jonathan Burgin
Chief Financial Officer