XTL BIOPHARMACEUTICALS LTD Form 6-K

March 29, 2007

# 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 March 29, 2007

Commission File Number: 000-51310 XTL Biopharmaceuticals Ltd.

(Translation of registrant's name into English)

750 Lexington Avenue, 20<sup>th</sup> Floor New York, New York 10022

(Address of principal executive offices)

Indicate by check mark whether the regist	trant files or will file ar	nual reports under cover Form 20-F or Form 40-F.
	Form 20-F x	Form 40-F o
Indicate by check mark if the registrant is 101(b)(1):	submitting the Form 6	-K in paper as permitted by Regulation S-T Rule
Indicate by check mark if the registrant is 101(b)(7):	submitting the Form 6	-K in paper as permitted by Regulation S-T Rule
	•	ontained in this Form, the registrant is also thereby 2g3-2(b) under the Securities Exchange Act of 1934
	Yes o	No x

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

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# XTL Biopharmaceuticals Inc. Announces the Completion of Phase I Study with XTL-6865 in Patients with Chronic Hepatitis C

New York, New York, March 29, 2007 - XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB; LSE: XTL; TASE: XTL) announced today the completion of the Phase I study with XTL-6865. The primary goal of this Phase I study was to evaluate safety and pharmacokinetic properties of XTL-6865 in patients with chronic hepatitis C. XTL-6865, which targets the E2 envelope protein of the hepatitis C virus, is comprised of two fully-human monoclonal antibodies and is administered intravenously. The study enrolled 32 patients into 8 cohorts, each comprised of 3 treated patients and 1 placebo patient. Of the 8 cohorts in the study, the first 7 were single administration cohorts with doses ranging from 5mg to 2400mg. The 8th cohort received 1200mg for 5 consecutive days.

In this study, XTL-6865 was shown to be safe at high doses (up to 1200mg for 5 consecutive daily doses and a single dose of 2400mg). The study also enabled the Company to establish the pharmacokinetic properties of XTL-6865 in patients with chronic hepatitis C. For all single doses, the  $t_{max}$  was reached immediately at the end of the XTL-6865 infusion. For the highest single dose, 2400mg, the  $C_{max}$  was between 500 and 1000 mg/ml and the  $t_{1/2}$  was approximately 5 days. For the lower single doses, the  $t_{1/2}$  was 2-3 days. The study provided evidence of binding of the antibody to circulating virus and the formation of immune complexes (antibody-virus), believed to be important for virus neutralization in the serum. No statistically significant changes in HCV-RNA were observed. Given the short duration of administration of XTL-6865, and the fact the patients in this study had a high rate of viral replication at baseline, no significant change in viral load was to be expected.

The results of this Phase I trial potentially pave the way for trials that would evaluate XTL-6865 in patients with hepatitis C undergoing liver transplantation - a potential target patient population for this drug - or in chronic hepatitis C patients with low viral load. XTL intends to seek a collaborative partnership for the future development of this compound.

Ron Bentsur, CEO of XTL Biopharmaceuticals, commented, "This trial enabled us to determine the pharmacokinetic properties of XTL-6865, and to demonstrate that it could be safely administered to patients at high doses. This study also clearly demonstrated that the antibody binds to the circulating virus in the serum. We believe that XTL-6865 could potentially play a role in certain clinical settings, such as preventing re-infection of hepatitis C following liver transplantation or in chronic hepatitis C patients who have low viral loads following treatment with other anti-hepatitis C drugs. We believe this is now an appropriate time to seek to out-license the compound." Mr. Bentsur continued, "We intend to focus our resources on commencing our clinical program for Bicifadine, for the treatment of diabetic neuropathic pain, and on completing our Phase I study for XTL-2125, our small-molecule compound for the treatment of chronic hepatitis C."

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#### ABOUT XTL BIOPHARMACEUTICALS LTD.

XTL Biopharmaceuticals Ltd. ("XTL") is engaged in the acquisition, development and commercialization of therapeutics for the treatment of neuropathic pain and hepatitis C. XTL is developing Bicifadine, a serotonin and norepinephrine reuptake inhibitor, for the treatment of neuropathic pain. In addition, XTL is developing XTL-2125 - a small molecule, non-nucleoside inhibitor of the hepatitis C virus polymerase. XTL-2125 is currently in a Phase I clinical trial in patients with chronic hepatitis C. XTL is also developing XTL-6865 - a combination of two monoclonal antibodies against the hepatitis C virus. XTL's hepatitis C pipeline also includes several families of pre-clinical hepatitis C small molecule inhibitors. XTL also has an active in-licensing and acquisition program designed to identify and acquire additional drug candidates. XTL is publicly traded on the NASDAQ, London, and Tel-Aviv Stock Exchanges (NASDAQ: XTLB; LSE: XTL; TASE: XTL).

Contact:

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#### **Cautionary Statement**

Some of the statements included in this press release, particularly those anticipating future performance, clinical and business prospects for our clinical compound for neuropathic pain, Bicifadine, and for our clinical compounds for hepatitis C, XTL-2125 and XTL-6865, growth and operating strategies and similar matters, 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 Private Securities Litigation Reform Act of 1995. Among the factors that could cause our actual results to differ materially are the following: our ability to start a clinical trial with Bicifadine in 2007; our ability to meet the forecast reporting deadlines for the XTL-2125 clinical trial that we mentioned above; our ability to successfully complete cost-effective clinical trials for the drug candidates in our pipeline which would affect our ability to continue to fund our operations with our available cash reserves, our ability to meet anticipated development timelines for the drug candidates in our pipeline due to recruitment, clinical trial results, manufacturing capabilities or other factors; and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission and the London Stock Exchange, including our annual report on Form 20-F filed with the Securities and Exchange Commission on March 23, 2007. 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 http://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.

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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: March 29, 2007 By: /s/ Ron Bentsur

Ron Bentsur Chief Executive Officer

This report on Form 6-K shall be deemed to be incorporated by reference in the prospectus included in the Registration Statement on Form F-3 (File No. 333-141529) filed with the Securities and Exchange Commission and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.