

XTL BIOPHARMACEUTICALS LTD
Form 6-K
October 07, 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 October 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 October 7, 2008 is hereby incorporated by reference into the registration statements on Form F-3 (File No. 333-141529, File No. 333-147024 and File No. 333-153055) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007, October 30, 2007 and August 15, 2008, 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.

XTL Biopharmaceuticals Announces Completion of the Bicifadine Phase 2b Study for Diabetic Neuropathic Pain

Valley Cottage, New York, October 7, 2008 - XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL) announced today that the last patient randomized into the Bicifadine Phase 2b clinical trial for the treatment of diabetic neuropathic pain has completed the study. This milestone officially marks the completion of this randomized, double-blind, placebo-controlled Phase 2b clinical trial which enrolled 351 patients at approximately 40 sites in the United States, Germany, Israel and India. The Company expects to report top-line results from this study within 6-8 weeks.

Bicifadine is a first-in-class triple reuptake inhibitor for the treatment of diabetic neuropathic pain. Bicifadine's main effect is as a serotonin and norepinephrine reuptake inhibitor with a moderate effect on dopamine reuptake inhibition, believed to be potentially complementary in treating neuropathic pain. The Phase 2b trial is aimed at demonstrating the efficacy of Bicifadine for the treatment of diabetic neuropathic pain, using a study design that is similar to the successful registration trials of Cymbalta®, a dual-reuptake inhibitor of serotonin and norepinephrine that is approved for this indication, and other approved agents for neuropathic pain.

The Phase 2b trial is a randomized, double-blind, placebo-controlled study comparing 200mg 3x/day (tid) and 400mg 3x/day (tid) of Bicifadine versus placebo, with a 1:1:1 randomization between the three arms, in patients with diabetic neuropathic pain. Following randomization, all patients entered a 2-week titration period to allow them to gradually escalate up to their target treatment dose. This was followed by a 12-week steady-state treatment period at the target treatment dose. The primary endpoint of the study is to compare the efficacy of each of the two active doses of Bicifadine (200mg tid and 400mg tid) versus placebo in reduction of pain associated with diabetic neuropathy, at baseline (at the time of randomization) versus week 14 (week 12 of the steady-state phase). Pain is measured based on a 24-hour pain rating using the 11-point Pain Intensity Numeric Rating Scale (formerly referred to as the LIKERT scale).

"The completion of the Bicifadine Phase 2b clinical trial is an important and significant milestone for XTL," stated Ron Bentsur, CEO of the Company, who continued, "We are grateful for the dedication of all the investigators who participated in the study, and we look forward to reporting top-line data from the study later this quarter."

XTL in-licensed the worldwide rights to Bicifadine from Dov Pharmaceutical, Inc. (NASDAQ OTC: DOVP) in January 2007.

ABOUT XTL BIOPHARMACEUTICALS LTD.

XTL Biopharmaceuticals Ltd. ("XTL") is engaged in the development of therapeutics for the treatment of diabetic neuropathic pain and HCV. XTL is developing Bicifadine, a triple reuptake inhibitor of serotonin, norepinephrine and dopamine, which is currently in a Phase 2b study for the treatment of diabetic neuropathic pain. XTL has out-licensed its novel pre-clinical HCV small molecule inhibitor program. XTL is publicly traded on the NASDAQ and Tel-Aviv Stock Exchanges (NASDAQ: XTLB; TASE: XTL).

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Cautionary Statement

Some of the statements included in this press release, particularly those anticipating future clinical and business prospects for our clinical compound for neuropathic pain, Bicifadine, the likelihood of successful results from a clinical trial with Bicifadine, 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 obtain positive trial results from the Phase 2b clinical trial of Bicifadine, raise the funding necessary for our future operations, and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, including our annual report on Form 20-F filed with the Securities and Exchange Commission on March 27, 2008. 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.

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: October 7, 2008

By: /s/ Bill Kessler

Bill Kessler
Director of Finance