XTL BIOPHARMACEUTICALS LTD
Form 6-K
June 30, 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 June 30, 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 x Form 40-F o

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): o

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): o

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 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

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. dated June 30, 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.

XTL Biopharmaceuticals Announces Completion of Patient Randomization into the Bicifadine Phase 2b Clinical Trial for the Treatment of Diabetic Neuropathic Pain

Valley Cottage, New York, June 30, 2008 - XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB; TASE: XTL) today announced that it has completed patient randomization into its Phase 2b study of Bicifadine - a serotonin and norepinephrine reuptake inhibitor (SNRI) - for the treatment of diabetic neuropathic pain. 350 patients were randomized into the study. Based on the completion of randomization, the Company expects to have the last patient complete the study in the next 4 months.

The Phase 2b trial is aimed at demonstrating the efficacy of Bicifadine in diabetic neuropathic pain, using a study design that is similar to the successful registration trials of Cymbalta®, a member of the SNRI class that is approved for this indication, and other approved agents for neuropathic pain.

The Phase 2b study 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. Approximately 40 clinical centers in the United States, Germany, Israel and India are participating in the study. Following randomization, all patients enter a 2-week titration period to allow them to gradually escalate up to their target treatment dose. This is 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).

Bicifadine is being developed for the treatment of diabetic neuropathic pain which represents a significant unmet medical need in the rapidly growing multi-billion dollar neuropathic pain market. Bicifadine is a member of the SNRI drug class, a proven class in the treatment of diabetic neuropathic pain. Bicifadine’s efficacy in reducing pain has been demonstrated in over 15 clinical trials in acute pain, and its safety profile has been established in over 3,000 patients. Importantly, Bicifadine has a unique ratio of reuptake inhibition of serotonin versus norepinephrine, which differentiates it from other members of the SNRI drug class.

Ron Bentsur, XTL's Chief Executive Officer, commented, "We are very excited to have completed this milestone of patient randomization ahead of our projected timeline, and we remain grateful for the tremendous dedication of the investigators who are participating in the study." Mr. Bentsur added, "We eagerly await the outcome of this study in Q4 2008."

XTL in-licensed the world-wide 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 serotonin and norepinephrine reuptake inhibitor, for the treatment of diabetic neuropathic pain, which is currently in a Phase 2b study. XTL has out-licensed its novel pre-clinical HCV small molecule inhibitor program. 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 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 successfully complete the Phase 2b clinical trial with Bicifadine and obtain positive trial results from the Phase 2b clinical trial, all of which will directly impact our ability to continue to fund our 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: June 30, 2008

By: /s/ Ron Bentsur

Ron Bentsur
Chief Executive Officer