

XTL BIOPHARMACEUTICALS LTD
Form 6-K
September 10, 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 September 10, 2007

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 September 10, 2007 is hereby incorporated by reference into the registration statement on Form F-3 (File No. 333-141529) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on March 23, 2007.

**XTL Biopharmaceuticals Initiates Phase IIb Clinical Trial of Bicifadine
for the Treatment of Diabetic Neuropathic Pain**

**Company to Hold a Conference Call Tomorrow (Tuesday) at 8:30 am EDT to
Discuss the Clinical Trial**

Valley Cottage, New York, September 10, 2007 - XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB; LSE: XTL; TASE: XTL) today announced the initiation of a Phase IIb clinical trial of Bicifadine - a serotonin and norepinephrine reuptake inhibitor (SNRI) - for the treatment of diabetic neuropathic pain.

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 clearly demonstrated in over 15 clinical trials in acute pain, and its favorable 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.

The Phase IIb trial that was launched today 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 IIb 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. The Phase IIb study is designed to enroll approximately 330 patients. Approximately 45 clinical centers in the United States, Europe and India will participate in the study. Following randomization, all patients will enter a 2-week titration period to allow them to gradually escalate up to their target treatment dose. This will be 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 will be 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 lead investigators in the study are Dr. Andrew Boulton, M.D. and Dr. Sherwyn Schwartz, M.D. Dr. Boulton is Professor of Medicine, Division of Endocrinology, Diabetes and Metabolism, at the University of Miami and the University of Manchester, UK. Professor Boulton has been active in clinical research in diabetic neuropathy over the last 25 years and has published over 250 peer reviewed articles on the subject. He was co-chair of the committee that formulated the American Diabetes Association statement on diabetic neuropathy published in Diabetes Care in 2005. Dr. Schwartz is Chief Executive Officer and Chief Medical Officer of DGD Research, Inc. which is the largest diabetes and endocrinology practice in the United States. Dr. Schwartz has over 20 years of clinical research experience in diabetes and diabetic complications, and has participated in hundreds of clinical trials in the field.

Dr. Christine Sang, Director of Translational Pain Research at the Brigham and Women's Hospital, Harvard Medical School, and Chair of XTL's Scientific Advisory Board, commented, "Based on the evidence for the role of SNRI's in the treatment of neuropathic pain, I believe that Bicifadine has strong potential to be successfully developed as a treatment for diabetic neuropathic pain. I am also encouraged by the drug's activity observed in previous acute pain studies and its safety exposure in over 3,000 patients to date."

Dr. Andrew Boulton, Co-Lead Investigator in the study, commented, "This study design is similar to the design of the successful registration trials of duloxetine (Cymbalta®) in diabetic neuropathic pain and those of other approved agents. This study is well powered to demonstrate a clinical benefit that is comparable to the approved agents for this disease. I am happy to be involved in this important program."

Dr. Sherwyn Schwartz, Co-Lead Investigator in the study, commented, "As the head of the largest diabetes center in the country, I believe that diabetic neuropathic pain continues to be an area of tremendous unmet medical need, as many patients do not adequately respond to the limited number of therapies that are available. I am intrigued by the possibility of having another SNRI with a unique ratio of reuptake inhibition of serotonin versus norepinephrine to offer to my patients."

Ron Bentsur, XTL's Chief Executive Officer, commented, "We are very excited to be initiating this late-stage clinical trial for Bicifadine and are enthusiastic about the strong support for this trial from many of the top clinical investigative sites from around the world."

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

CONFERENCE CALL INFORMATION

XTL will hold a conference call tomorrow, Tuesday, September 11, 2007, at 8:30 am EDT to discuss Bicifadine and the Phase IIb clinical trial. In order to participate in the conference call, please call +1-877-502-9272 (in the United States), +1-913-981-5581 (outside the United States), call in passcode: 2040477. An audio recording of the conference call will be available for replay by calling +1-888-203-1112 (in the United States), +1-719-457-0820 (outside the United States), replay passcode 2040477, for a period of 45 days after the call.

ABOUT DIABETIC NEUROPATHIC PAIN

Diabetic neuropathic pain is a chronic pain condition resulting from damage to nerves in patients with diabetes. Diabetic neuropathic pain, which manifests itself primarily in the feet, can often be debilitating thus preventing patients from carrying out their normal day-to-day activities. In the United States, it is estimated that 4.5 million patients with diabetes suffer from diabetic neuropathic pain. Diabetic neuropathic pain is the largest segment in the rapidly growing market for neuropathic pain drugs. This market was estimated at \$1.8 billion in 2005, and is expected to grow to \$5.5 billion by 2015. Only two oral drugs have been approved to date by the FDA for the treatment of diabetic neuropathic pain (Eli Lilly's Cymbalta®, an SNRI, and Pfizer's Lyrica®); however, the response rates to these drugs are limited. Consequently, millions of patients remain without adequate treatment options and seek new drugs that could provide better relief for their chronic pain.

ABOUT THE SNRI DRUG CLASS

Serotonin and Norepinephrine Reuptake Inhibitors (SNRI's) are drugs that increase the levels of serotonin and norepinephrine in the brain, thus blocking pain signals. SNRI is a proven drug class in diabetic neuropathic pain as well as Major Depressive Disorder. One SNRI (Eli Lilly's Cymbalta®) is already approved for the treatment of diabetic neuropathic pain, while a second SNRI (Wyeth's Effexor®) has demonstrated efficacy in treatment of diabetic neuropathic pain in large, randomized and placebo-controlled studies. Both Cymbalta® and Effexor® are also approved for depression. A third SNRI (Cypress' Milnacipran®) recently demonstrated efficacy in a Phase III trial in a related neuropathic pain indication (fibromyalgia), providing further evidence of the efficacy of the SNRI class in neuropathic pain.

ABOUT BICIFADINE

Bicifadine is an SNRI which is presently being developed for the treatment of diabetic neuropathic pain. As a member of the proven SNRI class, Bicifadine is expected to demonstrate efficacy in the treatment of diabetic neuropathic pain. Bicifadine has already demonstrated its efficacy as an analgesic in 15 clinical trials in patients suffering from acute pain, including in two large, randomized, placebo-controlled Phase III trials. In addition, Bicifadine has already demonstrated a favourable safety profile, having been evaluated in more than 3,000 patients.

Bicifadine is different from other approved members of the SNRI class in its unique ratio of inhibition reuptake of serotonin versus norepinephrine (which is weighted towards norepinephrine reuptake inhibition). This unique ratio is expected to translate into a unique response profile of patients to Bicifadine.

As the treatment paradigm in neuropathic pain involves switching patients among drugs (both within the same drug class, as well as among drug classes), in order to find the specific drug to which the patient responds best, Bicifadine is expected to offer a unique alternative to patients who do not adequately respond to the currently approved drugs. Furthermore, if clinical trials demonstrate that Bicifadine has an advantage over the currently approved drugs in either overall efficacy rates, safety profile, or onset of action, it has the potential to become a first-line treatment for diabetic neuropathic pain.

ABOUT XTL BIOPHARMACEUTICALS LTD.

XTL Biopharmaceuticals Ltd. (“XTL”) is engaged in the development 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 diabetic neuropathic pain. XTL is also developing several novel 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).

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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 launch a Phase IIb clinical trial with Bicifadine, recruit adequate participants for such a Phase IIb clinical trial, obtain positive trial results from a Phase IIb clinical trial, and our ability to successfully complete cost-effective pre-clinical trials for our DOS program, all of which will directly impact our ability to continue to fund our operations; our ability to meet anticipated development timelines for all of our drug candidates 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.

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: September 10, 2007

By: /s/ Bill Kessler

Bill Kessler
Director of Finance
