XTL BIOPHARMACEUTICALS LTD
Form 6-K
August 26, 2015

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 August, 2015

Commission File Number: **000-36000**

XTL Biopharmaceuticals Ltd.

(Translation of registrant's name into English)

5 HaCharoshet St.,

Raanana 4365603
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 x 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): ____

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. is hereby incorporated by reference into the registration statements on Form S-8 (File No. 333-148085, File No. 333-148754 and File No. 333-154795) and Form F-3 (File No. 194338).

XTL ANNNOUNCES PUBLICATION OF RESULTS OF PHASE 2 STUDY ON hCDR1 (Edratide) IN PATIENTS WITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) IN LUPUS SCIENCE & MEDICINE

RAANANA, Israel - (August 26, 2015) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL) ("XTL" or the "Company"), announced today that previously reported results of a Phase 2b study on the safety and efficacy of its lead drug candidate, hCDR1 (Edratide) for the treatment of SLE (lupus) were published in the Lupus Science & Medicine Journal. See link for full article (http://lupus.bmj.com/content/2/1/e000104.full).

The article, authored by leading rheumatologists, Dr. Murray Urowitz, Dr. David Isenberg and Dr. Dan Wallace, reported the results of a study conducted by Teva Pharmaceuticals in which Edratide demonstrated efficacy in one and possibly more clinically meaningful endpoints. According to the article, dose ranging studies demonstrated that the 0.5mg dose administered weekly as a subcutaneous injection was the most effective dose and that the drug showed no safety signals in the 26 week study.

Further the article stated that the study (PRELUDE) showed that Edratide was safe and well tolerated and while the primary endpoints based solely on SLEDAI-2K and AMS were not met, the secondary predefined endpoint, BILAG, was met for the 0.5 mg Edratide arm in the intention to treat (ITT) cohort (N=316) (OR=2.09, p=0.03) with trends in the 1.0 and 2.5 mg doses. The article also stated that there was a positive trend in the Composite SLE Responder Index of the ITT cohort and post hoc analysis showed that the BILAG secondary endpoint was also met for the 0.5 mg Edratide for a number of subgroup dose levels, including low or no steroids, seropositivity and patients with 2 grade BILAG improvement.

The article concluded that the favorable safety profile and encouraging clinically significant effects noted in some of the endpoints support the need for additional longer term Edratide studies that incorporate recent advances in the understanding and treatment of SLE, including steroid treatment algorithms, and using a composite primary endpoint which is likely to include BILAG.

Josh Levine, Chief Executive Officer of XTL, commented, "The encouraging data published in a peer-reviewed article in Lupus Science & Medicine regarding Edratide, our lead drug candidate for the treatment of SLE, further strengthens XTL's resolve to bring this drug candidate to market as soon as possible. With the recent announcements of drugs being developed for the treatment of lupus by UCB and Eli Lilly failing to reach their primary endpoints in Phase 3 trials, there remains a significant unmet medical need in SLE."

“We believe that there is a substantial opportunity for our lead drug candidate, hCDR1 (Edratide). We look forward to continuing the development of Edratide in advanced clinical trials and providing a measure of hope to patients suffering from this disease and the clinicians who treat them. We will continue to share our progress with you in the coming months.”

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About XTL Biopharmaceuticals Ltd. (“XTL")

XTL Biopharmaceuticals Ltd., a biopharmaceutical company, focuses on the acquisition, development, and commercialization of pharmaceutical products for the treatment of unmet clinical needs.

XTL is a public company, traded on the Nasdaq Capital Market (NASDAQ: XTLB) and the Tel Aviv Stock Exchange (TASE: XTL). XTL shares are included in the following indices: Tel-Aviv Biomed, Tel-Aviv MidCap, and Tel-Aviv Tech Index.

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Cautionary Statement

This press release may contain forward-looking statements, about XTL's expectations, beliefs or intentions regarding, among other things, its product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, XTL or its representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should" or "anticipate" or their negatives or other variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical or current matters. These forward-looking statements may be included in, but are not limited to, various filings made by XTL with the U.S. Securities and Exchange Commission, press releases or oral statements made by or with the approval of one of XTL's authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause XTL's actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause XTL's actual activities or results to differ materially from the activities and results anticipated in such forward-looking statements, including, but not limited to, the factors summarized in XTL's filings with the SEC and in its periodic filings with the TASE. In addition, XTL operates in an industry sector where securities values are highly volatile and may be influenced by economic and other factors beyond its control. XTL does not undertake any obligation to publicly update these forward-looking statements, whether as a result of new information, future events or otherwise. Please see the risk factors associated with an investment in our ADSs or ordinary shares, which are included in our Annual Report on Form 20-F as filed with the U.S. Securities and Exchange Commission on April 28 2015.

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: August 26, 2015 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer