XTL BIOPHARMACEUTICALS LTD
Form 6-K
October 13, 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 October, 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 Biopharmaceuticals announces agreement with yeda research and development company ltd. to amend license agreement for lupus asset

RAANANA, Israel - (October 13, 2015) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL) ("XTL" or the "Company"), a clinical-stage biopharmaceutical company focused on the development and commercialization of pharmaceutical products for the treatment of unmet clinical needs with a focus on treatments for autoimmune diseases, today announced that it has reached agreement with Yeda Research and Development Company Ltd. ("Yeda") to amend the development milestones in the License Agreement signed between the parties in January 2014 for the development of hCDR1 for the treatment of systemic lupus erythematosus (SLE).

The amended agreement extends the time for achievement of key development milestones by approximately five additional months including delivery to Yeda of a full protocol for an upcoming clinical trial on hCDR1, raising an aggregate of US$5 million (of which US$4 million was raised in April 2015), and commencing a clinical trial on hCDR1 by January 2017.

Josh Levine, Chief Executive Officer of XTL, commented, "We are pleased with Yeda's affirmation of their support and confidence in our ability to develop hCDR1 for the treatment of SLE. The amended agreement recognizes XTL's efforts to date to advance hCDR1to a clinical trial including: assembling a world-class Clinical Advisory Board with leading names in SLE, strengthening the Company's Board with Directors with drug development and financial market experience, transferring the IND relating to hCDR1from Teva Pharmaceutical Industries Limited to the Company, manufacturing the drug substance for the upcoming trial, engaging in ongoing discussions with the FDA to seek opportunities to strengthen hCDR1intellectual property and optimize the regulatory pathway, and raising US $4 million out of the aggregate amount of US $5 million as required by the License Agreement."

"We believe the amended agreement provides XTL with the time needed to properly develop our hCDR1 program and bring the product to an advanced clinical trial in the near future. We believe our operational plan and activities over the last several months should allow us to achieve the amended development milestones well within the revised timeline. The recent publication of the encouraging results of a previous Phase 2b trial (the PRELUDE trial) on hCDR1in a peer reviewed article in the Lupus Science and Medicine journal (http://lupus.bmj.com/content/2/1/e000104.full), showing favorable safety and efficacy data on over 300 patients, further strengthens our commitment to advance the development of hCDR1 as soon as possible."

Amir Naiberg, Chief Executive Officer of Yeda commented: "We are encouraged by the progress that XTL has made to date with hCDR1. We look forward to XTL's continued development of the drug for the treatment of SLE."

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About Systemic Lupus Erythematosus (SLE)

Lupus is a chronic autoimmune disease involving many systems in the human body, including joints, kidneys, central nervous system, heart, hematological system and others. The biologic basis of the disease is a defect in the immune (defense) system, leading to production of self (auto) antibodies, attacking the normal organs and causing irreversible damage. According to the Lupus Foundation of America, at least 1.5 million Americans have the disease (more than 5 million worldwide) with more than 16,000 new cases diagnosed each year. The majority of patients are women of childbearing years. There has been only one drug approved by the FDA in the last over 50 years and recently two of the few drugs in advanced development did not meet their primary endpoints in Phase 3 trials.

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 with a focus on treatments for autoimmune diseases.

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.

For further information, please contact:

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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.

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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: October 13, 2015 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer