XTL BIOPHARMACEUTICALS LTD
Form 6-K
March 21, 2016

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 March, 2016

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. 333-194338).

xtl biopharmaceuticals completes phase 2 trial design for lead compound hcdr1 in the treatment of lupus

Company to file IND with FDA and plans to commence trial in 2016

RAANANA, Israel - (March 21, 2016) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTLB.TA) ("XTL" or the "Company"), a clinical-stage biopharmaceutical company developing its lead product for the treatment of lupus, today announced it has completed the clinical trial design for its upcoming Phase 2 study of hCDR1 in the treatment of systemic lupus erythematosus (SLE). The global study is planned to commence in 2016, following the Company's investigational new drug (IND) filing with the U.S. Food and Drug Administration (FDA).

The study, developed in consultation with XTL's Clinical Advisory Board, is based on encouraging feedback received from the FDA in response to the Company's pre-IND meeting package.

The planned global Phase 2 trial is a double-blind, placebo controlled 26 week study to evaluate the safety and efficacy of hCDR1 in the treatment of SLE. The study will include three arms. Two arms will treat subjects with a different hCDR1 weekly dose, one of which will be the 0.5 mg dose which was the most effective dose tested in the previous Phase 2 study, and the third arm will be placebo. The primary efficacy endpoint of the study will be the proportion of subjects achieving a favorable response at 26 weeks in at least one organ system. BILAG is a standard diagnostic measure of the severity of lupus in organ systems and the recommended measure for efficacy for our trial by the FDA. Data from a prior Phase 2 study clearly showed a statistically significant effect of a 0.5 mg dose of hCDR1 on the BILAG index.

Secondary endpoints include proportions of patients achieving a substantial response by BILAG 2004, proportion of patients achieving a response by SLEDAI-2K Responder Index 50, and additional endpoints presented and accepted by the FDA. Steroid dosing of subjects will be restricted to improve patient outcomes. Prior studies showed that reduced steroid usage corresponded with improved efficacy in patients treated with hCDR1.

"We worked closely with the world-renowned lupus experts on our Clinical Advisory Board to develop this study design based on the BILAG index as a measure of hCDR1's efficacy. The FDA's recent guidance indicating that BILAG is an appropriate efficacy endpoint for our trial was a very significant and positive milestone. It enabled us to optimize our study design, and in our opinion, improves the likelihood of the study's success based on the efficacy

results of the prior Phase 2 trial when a 0.5 mg dose of hCDR1 was used with the BILAG index," said Josh Levine, CEO of XTL. "We look forward to filing our IND in the U.S. and commencing the trial this year."

XTL Biopharmaceuticals Ltd.

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About hCDR1

hCDR1 is a novel compound with a unique mechanism of action and has clinical data on over 400 patients in three clinical studies. The drug has a favorable safety profile, is well tolerated by patients and has demonstrated efficacy in at least one clinically meaningful endpoint. For more information please see a peer reviewed article in Lupus Science and Medicine journal (http://lupus.bmj.com/content/2/1/e000104.full).

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 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., is a clinical-stage biotech company focused on the development of pharmaceutical products for the treatment of autoimmune diseases including lupus. The Company’s lead drug candidate, hCDR1, is a world-class clinical asset for the treatment of systemic lupus erythematosus (SLE). Treatments currently on the market for SLE are not effective enough for most patients and some have significant side effects. hCDR1 has robust clinical data in three clinical trials with 400 patients and over 200 preclinical studies with data published in more than 40 peer reviewed scientific journals. Based on encouraging safety and efficacy data shown in a completed Phase 2 study, the Company expects to initiate a Phase 2 trial in 2016.

XTL is traded on the Nasdaq Capital Market (NASDAQ: XTLB) and the Tel Aviv Stock Exchange (TASE: XTLB.TA). 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 Registration Statement on Form F-1 as filed with the U.S. Securities and Exchange Commission on December 31, 2015.

XTL Biopharmaceuticals Ltd.

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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: March 21, 2016 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer