XTL BIOPHARMACEUTICALS LTD
Form 6-K
January 11, 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 January, 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 SUBMITS PROTOCOL TO YEDA FOR ADVANCED CLINICAL TRIAL OF hCDR1 IN THE TREATMENT OF LUPUS

hCDR1 addresses significant unmet medical need for lupus, a chronic and complex disease for which there is currently no cure

RAANANA, Israel - (January 11, 2016) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL) ("XTL" or the "Company"), a clinical-stage biopharmaceutical company developing its lead product for the treatment of lupus, today announced that it has submitted the full protocol for its advanced stage clinical trial of hCDR1 for the treatment of systemic lupus erythematosus (SLE) to Yeda Research and Development Company Ltd. (Yeda).

XTL previously announced that it has submitted a Pre-IND meeting package to the US Food and Drug Administration and expects to receive written responses regarding its proposed clinical study in the coming weeks. A Phase 2b clinical trial of hCDR1 was previously completed and the compound has shown a favorable safety profile in over 400 patients and efficacy in at least one clinically relevant endpoint.

Submission of this clinical trial protocol marks a milestone for XTL in its development of hCDR1, which the Company is developing under license from Yeda, the technology transfer arm of the world-renowned Weizmann Institute of Science.

Josh Levine, Chief Executive Officer of XTL, commented, "We are pleased to have met this important milestone and to continue our partnership with Yeda in the development of this novel drug for the benefit of lupus patients. We are making good progress in all of our regulatory, clinical and chemistry, manufacturing and control (CMC) activities and expect to meet the remaining development milestones."

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

About hCDR1

hCDR1 is a novel compound with a unique mechanism of action and with clinical data on over 400 patients in 3 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).

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5 Hacharoshet Street, Raanana, 43656, Israel Page 1
Tel: +972 9 955 7080; email: ir@xtlbio.com

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 Yeda Research and Development Company

Yeda Research and Development Company Ltd. is the commercial arm of the Weizmann Institute of Science, one of the world's leading multidisciplinary research institutions.

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:

Investor Relations, XTL Biopharmaceuticals Ltd.

Tel: +972 9 955 7080

Email: ir@xtlbio.com

www.xtlbio.com

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.

XTL Biopharmaceuticals Ltd.
5 Hacharoshet Street, Raanana, 43656, Israel Page 3
Tel: +972 9 955 7080; email: ir@xtlbio.com

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: January 11, 2016 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer