

XTL BIOPHARMACEUTICALS LTD

Form 6-K

January 25, 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**

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(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): \_\_\_\_\_

**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 announces encouraging feedback from U.S. FDA on its upcoming ind filing for IUPUS drug hcdr1**

*Successful outcome of FDA guidance includes BILAG as the primary efficacy endpoint, patient inclusion criteria, and patient population for safety requirements for marketing approval*

**RAANANA, Israel- (January 25, 2016) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTLB)** (“XTL” or the “Company”), a clinical-stage biopharmaceutical company developing its lead product for the treatment of lupus, today announced the Company has received written guidance from the U.S. Food and Drug Administration (FDA) in response to a pre-investigational new drug (IND) meeting package regarding its upcoming IND filing for its drug candidate, hCDR1. Based on the FDA’s response, XTL plans to file its IND, and in the coming quarters initiate a global clinical trial for hCDR1 in the treatment of systemic lupus erythematosus (SLE) in the U.S., Europe and Israel.

The FDA provided encouraging guidance on several key aspects of XTL’s proposed clinical trial including: the primary efficacy endpoint to be based on the BILAG index, a measure of lupus disease activity which was the secondary efficacy endpoint in a prior Phase 2 study of hCDR1; the appropriate patient population; and total number of patients required to prove safety for a new drug application (NDA) for marketing approval. The FDA recommended that the trial be a Phase 2 study. The FDA has also provided additional guidance on other aspects of the trial design, which XTL intends to review with its Clinical Advisory Board as it finalizes the study protocol including doses and study duration.

“We are very pleased with the FDA’s written response to our pre-IND filing meeting package and see it as a vote of confidence in our ability to bring a much needed treatment to people living with lupus,” stated Josh Levine, Chief Executive Officer of XTL.

“This study has an increased likelihood to succeed, in our view, because the FDA’s guidance encourages the study to be substantially similar to the prior Phase 2 trial which demonstrated efficacy in the 0.5 mg dose using the BILAG index, the secondary endpoint of that trial. We believe the FDA’s guidance validates the value and relevance of the safety and efficacy data from the prior Phase 2 trial including data on the patient population and statistically significant effect of a 0.5mg dose of hCDR1 on the BILAG endpoint. Using a primary efficacy endpoint based on the BILAG index, we are hopeful that our upcoming study will produce robust data towards supporting a future NDA filing,” Levine added.

**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 and possibly more clinically meaningful endpoints. For more information please see a peer reviewed article in Lupus Science and Medicine journal (<http://lupus.bmj.com/content/2/1/e000104.full>).

XTL Biopharmaceuticals Ltd.

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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., 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). There currently is no effective treatment on the market for SLE. 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 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). 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.

**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 25, 2016

By: /s/ Josh Levine

Josh Levine

Chief Executive Officer