XTL BIOPHARMACEUTICALS LTD
Form 6-K
January 05, 2017

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, 2017

Commission File Number: **001-36000**

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' PRECLINICAL STUDIES of hCDR1 DEMONSTRATE therapeutic potental IN THE TREATMENT OF Sjögren's SYNDROME

- ***New patent application filed for hCDR1 in the treatment of Sjögren's syndrome***
- ***Substantial unmet medical need in estimated 4 million U.S. patients***
- ***Second indication significantly expands market opportunity for XTL's lead drug candidate***

RAANANA, Israel - (January 5, 2017) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTLB.TA) ("XTL" or the "Company"), a clinical-stage biopharmaceutical company developing treatments for autoimmune diseases, today announced the Company intends to pursue Sjögren's syndrome as the second indication for its lead drug candidate hCDR1. Currently in development for the treatment of systemic lupus erythematosus (SLE), hCDR1 has been tested in over 400 patients, and is set to enter a global Phase 2 trial for SLE.

New *in-vitro* data from studies evaluating cells obtained from serum samples of patients with Sjögren's syndrome demonstrate that incubation with hCDR1 resulted in a significant reduction of gene expression of three cytokines considered to be pathogenic in Sjögren's syndrome. These data correspond to some of the *in vitro* data obtained in studies testing serum samples from patients with SLE.

Josh Levine, CEO of XTL, stated, "Sjögren's syndrome impacts more than twice the number of people as SLE does in the U.S. and represents a significant unmet therapeutic need. While there are currently only a handful of drugs in clinical trials to treat Sjögren's syndrome, there is no specific FDA approved therapy to treat the systemic manifestations of the disease. Given the similarities of the disease manifestations between Sjögren's syndrome and SLE, these new *in-vitro* data further support the clinical results achieved in the prior Phase 2 trial of hCDR1 in SLE. Based on hCDR1's well established mechanism of action and its favorable safety profile in over 400 patients, we plan to pursue an accelerated clinical development path with hCDR1 for this new indication."

A patent application has been filed with the U.S. Patent and Trademark Office for hCDR1 in the treatment of Sjögren's syndrome.

About Sjögren's syndrome

Sjögren's syndrome is a systemic autoimmune disease with some autoantibodies and clinical manifestations similar to those detected in SLE. Although many patients experience dry eyes, dry mouth, fatigue and joint pain, Sjögren's syndrome also causes dysfunction of organs such as the kidneys, gastrointestinal system, blood vessels, lungs, liver,

pancreas, and the central nervous system. Patients also have a substantially higher risk of developing lymphoma. Today, as many as four million Americans are living with this disease, according to the Sjögren's Syndrome Foundation.

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Current standard of care in the U.S. includes treating specific symptoms such as dry eyes, dry mouth, and arthritis. Systemic manifestations are often treated with drugs used to treat other autoimmune diseases, such as hydroxychloroquine, methotrexate, or azathioprine. However, these treatments are not sufficient in many patients and may have significant side effects. There is no approved specific drug for the treatment of systemic manifestations in Sjögren's syndrome.

About hCDR1

hCDR1 is a novel compound with a unique mechanism of action and 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 (full article).

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. The Company's lead drug candidate, hCDR1, is a world-class clinical asset for the treatment of autoimmune diseases including systemic lupus erythematosus (SLE) and Sjögren's Syndrome (SS). The few treatments currently on the market for these diseases 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.

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.

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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 Form 20-F filed with the U.S. Securities and Exchange Commission on March 31, 2016.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

XTL BIOPHARMACEUTICALS LTD.

Date: January 5, 2017 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer