XTL BIOPHARMACEUTICALS LTD
Form 6-K
April 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 April, 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 Unveils expanded hcdr1 preclinical data for the treatment of sjogren's syndrome

- ***Additional data shows a statistically significant effect in the gene expression of two additional genes that have a role in the pathogenesis of Sjögren's syndrome (SS)***
- ***Substantial unmet medical need in estimated four million U.S. patients***
- ***Filed patent covers the effect of hCRD1 on such gene expression with implications for the treatment of SS***

RAANANA, Israel - (April 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 has received additional preclinical data regarding the role of hCDR1 as a potential treatment for Sjögren's syndrome (SS) from Prof. Edna Mozes of The Weizmann Institute of Science and the developer of hCDR1.

The expansion of these *in-vitro* data includes peripheral blood mononuclear cells (PBMC) obtained from additional blood samples from patients with primary SS. The data to date show that incubation with hCDR1 results in a statistically significant reduction in the gene expression of four pathogenic cytokines known to be involved in SS and lupus (including B-lymphocyte stimulator or BLyS), as well as upregulation of an immunosuppressive gene and a marker for activity of regulatory T cells. Such effects were previously seen in similar studies involving lupus patients. Concurrently, hCDR1 is in development for the treatment of systemic lupus erythematosus (SLE), has been tested in over 400 patients, and is ready to enter a global Phase 2 trial for SLE.

"We are pleased by the results of this extension study, which reinforce the potential of hCDR1 to provide patients with Sjögren's syndrome with the first-ever approved therapy to treat the systemic manifestations of the disease," said Josh Levine, CEO of XTL. "Given Sjögren's syndrome and systemic lupus erythematosus may have similar but distinct disease manifestations, these data further support the positive results of our prior Phase 2 study of hCDR1 in treating systemic lupus erythematosus. Both SLE/lupus and SS have large unmet clinical needs, with few satisfactory treatment options and both indications have seen recent failures in clinical studies with the notable exception of the recent successful Phase 2 in Lupus Nephritis of Voclosporin being developed by Aurinia Pharmaceuticals."

Based on hCDR1's well known mechanism of action and favorable safety profile, XTL plans to pursue an accelerated clinical development path for the treatment of SS. Additionally, a second patent application has been filed with the U.S. Patent and Trademark Office for hCDR1 in the treatment of SS.

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 may also cause 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.

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 many 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/A filed with the U.S. Securities and Exchange Commission on April 3, 2017.

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