XTL BIOPHARMACEUTICALS LTD
Form 6-K
January 07, 2014

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, 2014

Commission File Number: **000-51310**

XTL Biopharmaceuticals Ltd.

(Translation of registrant's name into English)

85 Medinat Hayehudim St., Herzliya
Pituach, PO Box 4033,

Herzliya 4614001, 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): ____

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ¨ No x

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82- N/A

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. dated January 7, 2013 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) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on December 14, 2007, January 18, 2008, and October 28, 2008, respectively.

Re: XTL Biopharmaceuticals In-licenses hCDR1, a Phase II Clinical Stage Asset for the Treatment of Lupus

HERZLIYA, Israel, January 7, 2014 - XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL) ("**XTL**" or the "**Company**"), a clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of pharmaceutical products for the treatment of unmet clinical needs, today announced that it has signed a licensing agreement with Yeda Research and Development Company Ltd. ("**Yeda**") to develop hCDR1, a Phase II-ready asset for the treatment of Systemic Lupus Erythematosus ("**SLE**").

The terms of the licensing agreement include, among other things, expense reimbursement for patent expenses, certain milestone payments to Yeda, low single-digit royalties based on net sales, and additional customary royalties to the Office of the Chief Scientist.

"Lupus is a debilitating disease affecting approximately five million people worldwide and represents a tremendous unmet medical need. In fact, only one new treatment, Benlysta, has been approved in the last 50 years," stated Josh Levine, Chief Executive Officer of XTL.

hCDR1, a peptide developed by Prof. Edna Mozes of the Department of Immunology, The Weizmann Institute of Science, acts as a disease-specific treatment to modify the SLE-related autoimmune process by specific upstream immunomodulation through the generation of regulatory T cells, reducing inflammation and resuming immune balance. More than 40 peer-reviewed papers have been published on hCDR1.

Two placebo controlled Phase I trials and a placebo controlled Phase II trial (PRELUDE) were conducted by Teva Pharmaceutical Industries ("**Teva**"), which had previously in-licensed hCDR1 from Yeda. The Phase I and Phase II studies consisted of over 400 patients, demonstrating that hCDR1 is well tolerated by patients and has a favorable safety profile. The PRELUDE trial did not achieve its primary efficacy endpoint based on the SLEDAI scale, resulting in Teva returning the asset to Yeda. However, the PRELUDE trial showed encouraging results in its secondary clinical endpoint, the BILAG index, and, in fact, the 0.5mg weekly dose showed a substantial effect. Multiple post-hoc analyses showed impressive results for this dose using the BILAG index. Such dose will be the focus of our clinical development plan moving forward.

The FDA has since directed that the primary endpoint in future trials for Lupus therapies, including those for hCDR1, should be based on either the BILAG index or the SLE Responder Index (SRI). Given the FDA's recommendation and the positive findings from the PRELUDE trial, XTL intends to initiate a new Phase II clinical trial, which will include the 0.5mg (and a 0.25mg) weekly dose of hCDR1.

Mr. Levine concluded, "We believe we have a greater likelihood to successfully develop hCDR1 given the knowledge we have gained from the PRELUDE trial as well as outcomes related to previous clinical trials for other Lupus therapies, including Benlysta. As we take these lessons into consideration, we expect to further develop and advance hCDR1 towards potential commercialization."

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.

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. XTL is focused on late stage clinical development of drugs for the treatment of multiple myeloma, schizophrenia and lupus.

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 Bluetech-50.

Cautionary Statement

Some of the statements included in this Form 6-K may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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 7, 2014 By: /s/ Josh Levine
Josh Levine

Chief Executive Officer