XTL BIOPHARMACEUTICALS LTD
Form 6-K
September 07, 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 September, 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): ¨

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. 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 the european patent office has issued a PATENT for its LUPUS DRUG HCDR1

RAANANA, Israel - (September 7, 2016) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTLB.TA) ("XTL" or the "Company"), a clinical-stage biopharmaceutical company developing its lead product for the treatment of lupus, today announced the European Patent Office (EPO) has granted a patent for the Company's lupus drug candidate, hCDR1. Patent EP1594434 entitled, "Parenteral Formulations of Peptides for the Treatment of Systemic Lupus Erythematosus," claims formulations of hCDR1 and use of these pharmaceutical compositions in the treatment of systemic lupus erythematosus (SLE) that may be validated in the EPO's 27 member countries.

"This important patent in Europe augments the robust intellectual property position we are building globally. hCDR1 has been granted patents in markets including the U.S., Canada, Australia, Korea, Japan, India, and China. We continue to strengthen our intellectual property portfolio through new patent filings on the most recent inventions like the patent just filed in the U.S. for a different dosing regimen of hCDR1," stated Josh Levine, CEO of XTL. "Europe is one of the largest markets in the world for SLE, with few effective treatment options available. Through our upcoming Phase 2 trial, we look forward to developing hCDR1 as a potential treatment to serve this unmet need."

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 Systemic Lupus Erythematosus (SLE)

Lupus is a chronic inflammatory 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 dysregulation of 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 50 years and recently two of the few drugs in advanced development did not meet their primary endpoints in Phase 3 trials.

XTL Biopharmaceuticals Ltd.

5 Hacharoshet Street, Raanana, 43656, Israel

Tel: +972 9 955 7080; email: ir@xtlbio.com

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). Treatments currently on the market for SLE 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.

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

XTL Biopharmaceuticals Ltd.

5 Hacharoshet Street, Raanana, 43656, Israel

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: September 7, 2016 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer