

XTL BIOPHARMACEUTICALS LTD

Form 6-K

August 11, 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 August, 2016

Commission File Number: **001-36000**

**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)

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

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

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 NEW PATENT filing in  
u.s. FOR LUPUS DRUG hCDR1**

**RAANANA, Israel - (August 11, 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 that it has filed a new patent application with the U.S. Patent and Trademark Office to protect doses of hCDR1 lower than 0.5 mg weekly, in the treatment of Systemic Lupus Erythematosus (SLE).

The new patent application is based on clinical evidence that lower doses of hCDR1 may be as efficient, or in some instances more efficient, than the higher doses previously tested in the treatment of SLE. Lower doses of hCDR1 may improve clinical outcomes in SLE patients when used as a standalone treatment, or when used as a combination therapy in addition to standard of care. Improved outcomes may include the potential to control disease activity in patients who do or do not require steroids. For patients who do require steroids, an hCDR1 combination therapy may decrease the dosage of steroids required to control disease activity.

“We are pleased to expand the intellectual property assets around hCDR1, based on clinical data showing hCDR1 may be effective at doses lower than the 0.5 mg weekly, which has shown statistically significant efficacy as compared to placebo in a prior Phase 2 study,” said Josh Levine, CEO of XTL. “While, as a new chemical entity, hCDR1 already will be entitled to data exclusivity, this patent application adds to a robust and growing portfolio of applications and issued patents in key markets around the world.”

XTL completed its Phase 2 clinical trial design for hCDR1 in the treatment of SLE earlier this year. The trial design includes a treatment arm dosing weekly at 0.5 mg hCDR1 and BILAG as the measure for the primary efficacy endpoint. Data from the prior Phase 2 study clearly showed a statistically significant effect of a 0.5 mg dose of hCDR1 on the BILAG index.

**About hCDR1**

hCDR1 is a novel compound with a unique mechanism of action and has 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 (<http://lupus.bmj.com/content/2/1/e000104.full>).

### **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.

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5 Hacharoshet Street, Raanana, 43656, Israel Page 1

Tel: +972 9 955 7080; email: [ir@xtlbio.com](mailto: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:**

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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, except as may be required under applicable securities laws. 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: August 11, 2016 By: /s/ Josh Levine  
Josh Levine  
Chief Executive Officer