XTL BIOPHARMACEUTICALS LTD
Form 6-K
June 01, 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 June, 2016

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 reports first quarter 2016 FINANCIAL results & provides CLINIcAL and Operational UPDATE

RAANANA, Israel - (June 1, 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 financial results for the three months ended March 31, 2016 and provided an update on the development program for its lead drug candidate hCDR1 in the treatment of Systemic Lupus Erythematosus (SLE).

"We achieved numerous milestones in the first quarter including key clinical events that move hCDR1 towards an upcoming Phase 2 trial designed to have a high likelihood of success based on prior clinical study findings. We strengthened our intellectual property portfolio, advanced chemistry, manufacturing and controls for hCDR1, and added a world renowned thought leader as our Medical Director," said Josh Levine, CEO of XTL.

Clinical and Operational Update

- Received Encouraging Feedback from U.S. FDA

In January, XTL announced it received very encouraging feedback from the U.S. Food and Drug Administration (FDA) in response to its pre-investigational new drug (IND) meeting package for hCDR1. This successful outcome included BILAG, a measure of lupus disease activity, as the primary efficacy endpoint. Based on prior positive efficacy data using BILAG as the measure, XTL believes the FDA's guidance will improve the likelihood of a successful trial. The FDA's guidance also included parameters on patient inclusion criteria and patient population for safety requirements for marketing approval.

- Received European Medicines Agency's SME Status

In February, XTL announced it received the European Medicines Agency's Small or Medium Sized Business Enterprise (SME) status in Europe, offering numerous benefits including fee reductions for pre and post marketing phases, scientific and procedural advice, and eligibility for funding and grants.

- Completed Production of Representative Batches of hCDR1

In February, XTL completed production of representative batches of drug product with BioConnection NV to advance its chemistry, manufacturing and controls (CMC) program for the planned Phase 2 trial of hCDR1.

. Granted Patent in Israel

In February, XTL announced hCDR1 was granted a patent in Israel titled, “Pharmaceutical Compositions Comprising a Peptide and a Substituted ß Cyclodextrin for use in Treating Systemic Lupus Erythematosus and Processes for their Manufacture,” which addresses the pharmaceutical composition and manufacturing processes of hCDR1.

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- Completed Phase 2 Trial Design

In March, XTL announced completion of the Phase 2 clinical trial design for hCDR1 in the treatment of SLE, in consultation with its world renowned Clinical Advisory Board. 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.

- Granted Patent in Hungary

In March, XTL announced the Hungarian Intellectual Property Office granted a patent for hCDR1 in the treatment of lupus titled "Synthetic Human Peptides and Pharmaceutical Compositions Comprising Them for the Treatment of Systemic Lupus Erythematosus."

- Appointed Medical Director

In March, XTL appointed Dr. Daphna Paran, a world renowned expert in the treatment of lupus and an internal medicine and rheumatology specialist, as Medical Director.

Financial Overview

XTL reported $3.1 million in cash, cash equivalents and bank deposits as of March 31, 2016. Funds will be used to advance the hCDR1 clinical program for the treatment of SLE.

Research and development expenses for the quarter ended March 31, 2016 were $233,000 compared with $42,000 for the same period in 2015, reflecting the Company's increased investment in the hCDR1 clinical program and preparations for a Phase 2 clinical trial. First quarter development activities included the completion of the trial design for the planned Phase 2 trial of hCDR1 for the treatment of SLE and production of the drug product for that trial.

General and administrative expenses for the three months ended March 31, 2016 were $369,000 compared with $334,000 for the same period in 2015.

XTL reported an operating loss for the quarter ended March 31, 2016 of $602,000 compared with $376,000 for the same period in 2015 reflecting increased spending on research and development. The Company reported a total net loss for the period ended March 31, 2016 of approximately $600,000 or $0.002 per share, compared to $1.1 million or $0.005 per share in the same period in 2015. Total net loss in the first quarter of 2015 included a loss from discontinued operations of approximately $689,000.

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XTL Biopharmaceuticals, Ltd. and Subsidiaries

(USD in thousands)

Consolidated Statements of Financial Position - Selected Data

	As of March 31,	
	2016	2015
Cash, Cash Equivalents and bank deposits	$3,109	$1,753
Other current assets	527	636
Non-current assets	1,122	2,624
Total assets	4,758	5,013
Total liabilities	$372	$376
Total shareholders' equity	4,386	4,637

XTL Biopharmaceuticals, Ltd. and Subsidiaries

(USD in thousands, except per share amounts)

Consolidated Statements of Comprehensive Income - Selected Data

	For the three months ended March 31,	
	2016	2015
Research and Development expenses	(233)	(42)
General and administrative expenses	(369)	(334)
Operating Loss	$(602)	$(376)
Finance income	$27	$5
Finance expenses	(2)	(16)
Finance income (expenses), net	$25	$(11)
Total loss from continuing operations	$(577)	$(387)
Total loss from discontinued operations	$-	$(689)
Total loss for the period	$(577)	$(1,076)
Other comprehensive income (loss):		
Revaluation of AFS financial assets	$27	$-

Total comprehensive loss for the period	$(550)	$(1,076)
Total loss for the period attributable to:		
Equity holders of the Company	$(577)	$(1,078)
Non-controlling interests	-	2
	$(577)	$(1,076)
Total comprehensive loss for the period attributable to:		
Equity holders of the Company	$(550)	$(1,078)
Non-controlling interests	-	2
	$(550)	$(1,076)
Basic and diluted loss per share from continuing and discontinued operations (in U.S. dollars):		
From continuing operations	(0.002)	(0.003)
From discontinued operations	-	(0.002)
Total basic and diluted loss per share (in U.S. dollars)	$(0.002)	$(0.005)
Weighted average number of issued ordinary shares	273,646,688	233,561,229

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 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. 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.

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. Robust clinical data on hCDR1 has been produced 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 prices 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 law. 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.

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: June 1, 2016 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer