

XTL BIOPHARMACEUTICALS LTD

Form 6-K

March 30, 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 March, 2017

Commission File Number: **001-36000**

XTL Biopharmaceuticals Ltd.

(Translation of registrant's name into English)

5 Hacharoshet St.

PO Box 4423

Raanana 4365603, Israel

(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): _____

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 2016 FINANCIAL RESULTS & PROVIDES CLINICAL and Operational UPDATE

RAANANA, Israel - (March 30, 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 financial results for the year ended December 31, 2016 and provided an update on the development program for its lead drug candidate hCDR1.

“2016 was an important year for us, as we continued to lay the foundation for the advancement of hCDR1 towards a global Phase 2 trial designed to have a high likelihood of success based on prior clinical study findings in lupus (SLE)” said Josh Levine, CEO of XTL. In addition, we strengthened the intellectual property of our lead asset, hCDR1, by filing patents on the dosing of our drug for lupus and identifying a potential second indication for our lead asset by filing a use patent for the treatment of Sjögren’s syndrome (SS) based on pre-clinical in vitro data. This new data has the potential to significantly increase the market size for hCDR1 in a second indication and further supports the findings found in previous clinical studies performed on lupus.”.

Clinical and Operational Update

The Company raised a net total of approximately \$5 million in February and March 2017 in a public offering to institutional investors and a private placement with existing investors. The transactions included the issuance of ADSs and unregistered warrants to purchase ADSs.

XTL generated new in-vitro data from studies evaluating cells obtained from serum samples of patients with SS demonstrating that incubation with hCDR1 resulted in a significant reduction of gene expression of several cytokines considered to be pathogenic in SS. These data correspond to some of the in vitro data obtained in studies testing serum samples from patients with SLE. SS impacts more than twice the number of people as SLE does in the U.S. and represents a significant unmet therapeutic need. A patent application has been filed with the U.S. Patent and Trademark Office for hCDR1 in the treatment of SS.

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We added two leading experts in rheumatology, Robert Fox, MD and Simon Bowman, MD, to the Company's clinical advisory board to help guide a planned Phase II trial to evaluate hCDR1 for the treatment of SS.

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

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The Company 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.

We completed 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 showed a statistically significant effect of a 0.5 mg dose of hCDR1 on the BILAG index.

Financial Overview

XTL reported \$2.0 million in cash and cash equivalents as of December 31, 2016. These funds, together with the approximately \$5 million raised to date in 2017, will be used to advance the hCDR1 clinical program for the treatment of SLE and SS and to identify additional assets to add to the XTL portfolio.

Research and development expenses for the year ended December 31, 2016 were \$443,000 compared with \$578,000 for 2015. Expenses incurred in 2016 include, among other things, chemistry, manufacturing and control (CMC) costs for production of the drug product, pre-clinical experiments on the use of hCDR1 for the treatment of SS patients, as well as clinical and regulatory consulting fees. The decrease in expenses in 2016 compared to 2015 is mainly due to professional consulting expenses in 2015 related to the preparation and submission to the FDA of our pre-IND meeting package for our planned clinical study of the hCDR1 drug for the treatment of SLE patients.

XTL reported an operating loss for the year ended December 31, 2016 of \$2.6 million compared with \$3.6 million for 2015. The 2016 loss includes \$0.8 million for the full impairment in the Company's intangible asset related to its secondary clinical asset as it focuses its efforts and resources on the development of its lead asset, hCDR1 for the treatment of SLE. The Company reported a total net loss for the year ended December 31, 2016 of \$2.5 million or 0.009 per share, compared to \$4.3 million or 0.017 per share in 2015.

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XTL Biopharmaceuticals, Ltd. and Subsidiaries

(USD in thousands)

Consolidated Statements of Financial Position - Selected Data

	As of	
	December 31,	
	2016	2015
Cash, Cash Equivalents	2,019	3,817
Other current assets	735	448
Non-current assets	263	1,058
Total assets	3,017	5,323
Total liabilities	330	436
Total shareholders' equity	2,687	4,887

XTL Biopharmaceuticals, Ltd. and Subsidiaries

(USD in thousands, except per share amounts)

Consolidated Statements of Comprehensive Income - Selected Data

	Year ended	
	December 31,	
	2016	2015
	Audited	
Research and development expenses	(443)	(578)
General and administrative expenses	(1,270)	(1,419)
Impairment of intangible assets	(848)	(1,604)
Other gains (losses), net	-	(10)

Operating loss	(2,561)	(3,611)
Finance income (expenses), net	16	(11)
Loss from continuing operations	(2,545)	(3,622)
Loss from discontinued operations	-	(689)
Total loss for the period	(2,545)	(4,311)
Loss for the period attributable to:		
Equity holders of the Company	(2,545)	(4,313)
Non-controlling interests from discontinued operations		2
	(2,545)	(4,311)
Basic and diluted loss per share (in U.S. dollars):		
From continuing operations	(0.009)	(0.014)
From discontinued operations	-	(0.003)
Loss per share for the period	\$(0.009)	\$(0.017)

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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 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. 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 30, 2017.

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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: March 30, 2017 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer