

XTL BIOPHARMACEUTICALS LTD
Form 6-K
December 06, 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 December, 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)

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 THIRD quarter 2016
FINANCIAL results & provides CLINICAL and Operational UPDATE**

RAANANA, Israel - (December 6, 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 autoimmune diseases including lupus, today reported financial results for the three and nine months ended September 30, 2016, as well as a clinical and operational update on the development program for its lead drug candidate hCDR1 in the treatment of Systemic Lupus Erythematosus (SLE).

“During the first nine months of 2016 we achieved important milestones towards commencing our Phase 2 hCDR1 study, which we believe is designed to reveal strong efficacy results for our drug in the treatment of SLE. The trial design is based on very encouraging feedback from the U.S. FDA regarding BILAG as the efficacy endpoint and 0.5 mg as the weekly dosage of hCDR1. These are parameters that produced successful results in a prior trial,” stated Josh Levine, CEO of XTL. “We continue to build our hCDR1 IP portfolio with three patents granted for hCDR1 and the filing of two new patent applications in the US since the beginning of the year. We are also investigating hCDR1’s potential use in other autoimmune indications.”

Clinical and Operational Update:

Prepared to Commence Phase 2 Trial

XTL completed the clinical trial design of its Phase 2 study of hCDR1 in the treatment of SLE. The protocol was designed in consultation with its world renowned Clinical Advisory Board and based on encouraging feedback from a pre-investigational new drug (IND) meeting package submission to the U.S. Food and Drug Administration (FDA). The trial design includes a treatment arm dosing weekly at 0.5 mg hCDR1 and BILAG, a measure of lupus disease activity, 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. 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.

Production Batches of hCDR1 Ready for Phase 2 Trial

XTL completed production of representative batches of hCDR1 with BioConnection NV earlier in 2016. These manufactured batches advance XTL's chemistry, manufacturing and controls (CMC) program for the planned Phase 2 trial of hCDR1.

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Strengthened Intellectual Property Portfolio

During the third quarter, hCDR1 was granted an important patent in Europe titled, “Parenteral Formulations of Peptides for the Treatment of Systemic Lupus Erythematosus,” which addresses non-oral drug formulations of hCDR1 in the treatment of SLE. Patents were also issued for hCDR1 in Hungary and Israel earlier this year. In a move to further broaden hCDR1’s intellectual property rights, two new patent applications were filed with the U.S. Patent and Trademark Office to protect doses of hCDR1 at and below 0.5 mg weekly in the treatment of SLE.

Financial Overview

XTL reported \$2.3 million in cash and cash equivalents as of September 30, 2016. Funds will be used to advance the hCDR1 clinical program for the treatment of SLE, to investigate its use in other indications and to identify additional assets for the treatment of other autoimmune diseases.

Research and development expenses for the quarter ended September 30, 2016 were \$35,000 compared with \$134,000 for the same period in 2015. For the nine months ended September 30, 2016 research and development expenses were \$390,000 compared with \$245,000 for the same period in 2015. The year to date increase reflects the Company's increased investment in the hCDR1 clinical program and preparations for a Phase 2 clinical trial. Development activities include the completion of the trial design for the planned Phase 2 trial of hCDR1 for the treatment of SLE, production of the drug product for that trial and investigation of the use of hCDR1 in other autoimmune indications. Initiation of the Phase 2 clinical trial in SLE will require the Company to raise additional capital.

General and administrative expenses for the three months ended September 30, 2016 were \$265,000, in line with the expenditure for the same period in 2015. For the nine months ended September 30, 2016 general and administrative expenses were \$978,000 compared to \$1,008,000 in the first nine months of 2015.

XTL reported an operating loss for the quarter ended September 30, 2016 of \$300,000 compared with \$396,000 for the same period in 2015. For the nine-month period ended September 30, 2016 XTL reported an operating loss of \$1,368,000 as compared to \$1,253,000 in the first nine months of the prior year.

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The Company reported a total comprehensive loss for the quarter ended September 30, 2016 of \$279,000, or \$0.001 per share, compared to \$443,000 or \$0.002 per share, in the same period in 2015. For the nine months ended September 30, 2016 XTL reported a total net loss of \$1,222,000 or \$0.005 per share, compared to \$1,946,000 or \$0.008 per share, in the first nine months of 2015. Total net loss in the first nine months of 2015 included a loss from discontinued operations of \$460,000, or \$0.002 per share.

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XTL Biopharmaceuticals, Ltd. and Subsidiaries*(USD in thousands)***Consolidated Statements of Financial Position - Selected Data**

	September 30,		December 31,
	2016	2015	2015
Cash, Cash Equivalents and bank deposits	\$2,322	\$4,300	\$ 3,817
Other current assets	612	487	448
Non-current assets	1,122	2,698	1,058
Total assets	4,056	7,485	5,323
Total liabilities	\$231	\$262	\$ 436
Total shareholders' equity	3,825	7,223	4,887

XTL Biopharmaceuticals, Ltd. and Subsidiaries*(USD in thousands, except per share amounts)***Consolidated Statements of Comprehensive Loss**

	Nine months ended		Three months ended		Year ended
	September 30,		September 30,		December 31,
	2016	2015	2016	2015	2015
	Unaudited				Audited
Research and development expenses	(390)	(245)	(35)	(134)	(578)
General and administrative expenses	(978)	(1,008)	(265)	(262)	(1,419)
Impairment of intangible asset	-	-	-	-	(1,604)
Other loss	-	-	-	-	(10)

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Operating loss	\$ (1,368)	\$ (1,253)	\$ (300)	\$ (396)	\$ (3,611)
Finance income	34	29	15	10	4
Finance expenses	(6)	(262)	(1)	(57)	(15)
Finance income (expenses), net	\$28	\$ (233)	\$14	\$ (47)	\$ (11)
Loss from continuing operations	\$ (1,340)	\$ (1,486)	\$ (286)	\$ (443)	\$ (3,622)
Loss from discontinued operations	\$-	\$ (460)	\$-	\$-	\$ (689)
Total loss for the period	\$ (1,340)	\$ (1,946)	\$ (286)	\$ (443)	\$ (4,311)
Other comprehensive income (loss):					
Revaluation of AFS financial assets	118	-	7	-	-
Total comprehensive loss for the period	\$ (1,222)	\$ (1,946)	\$ (279)	\$ (443)	\$ (4,311)
Loss for the period attributable to:					
Equity holders of the Company	(1,340)	(1,948)	(286)	(443)	(4,313)
Non-controlling interests	-	2	-	-	2
	\$ (1,340)	\$ (1,946)	\$ (286)	\$ (443)	\$ (4,311)
Comprehensive loss for the period attributable to:					
Equity holders of the Company	(1,222)	(1,948)	(279)	(443)	(4,313)
Non-controlling interests	-	2	-	-	2
	\$ (1,222)	\$ (1,946)	\$ (279)	\$ (443)	\$ (4,311)
Basic and diluted loss per share from continuing and discontinued operations (in U.S. dollars):					
From continuing operations	(0.005)	(0.006)	(0.001)	(0.002)	(0.014)
From discontinued operations	-	(0.002)	-	-	(0.003)
Loss per share for the period	\$ (0.005)	\$ (0.008)	\$ (0.001)	\$ (0.002)	\$ (0.017)

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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 ([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 three 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. 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 F-1/A filed with the U.S. Securities and Exchange Commission on November 8, 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: December 6, 2016 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer