XTL BIOPHARMACEUTICALS LTD

Form 6-K

December 01, 2015
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20540
Washington, D.C. 20549
Form 6-K
Report of Foreign Private Issuer
Pursuant to Rule 13a-16 or 15d-16
ruisuant to Ruie 13a-10 of 15u-10
of the Securities Exchange Act of 1934
For the month of December, 2015
Commission File Number: 000-36000
Commission File Number. 000-30000
XTL Biopharmaceuticals Ltd.
(Translation of registrant's name into English)
5 HaCharoshet St.,
o muchanosite da,
Raanana 4365603
<u>Israel</u>
(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).

Edgar Filing: XTI	BIOPHARMACEUTICALS	LTD - Form 6-ł	K
-------------------	--------------------	----------------	---

XTL Biopharmaceuticals REPORTS THIRD Quarter 2015 RESULTS and confirms intention to start lupus trial in 2016

RAANANA, Israel - (December 1, 2015) – XTL Biopharmaceuticals Ltd. (NASDAQ: XTLB, TASE: XTL) ("XTL" or the "Company"), a clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of pharmaceutical products for the treatment of unmet clinical needs, particularly for autoimmune diseases, today provided its financial and operational results for the third quarter and the nine months ended September 30, 2015.

Josh Levine, Chief Executive Officer of XTL, commented, "During the third quarter we continued to make significant strides in developing our clinical asset, hCDR1 for the treatment of lupus (SLE) and preparing it for advanced clinical trials."

"Following the publication in August by the Lupus Science and Medicine journal of a peer reviewed article (http://lupus.bmj.com/content/2/1/e000104.ful) analyzing the results of a Phase 2b trial on our lupus drug (PRELUDE trial) showing favorable safety and efficacy data on over 300 patients, the Company convened a meeting of its Clinical Advisory Board in September at which the Company finalized a draft protocol for its planned clinical trial. In November, the Company submitted a request to the FDA for a pre-IND meeting and expects a written response to its pre-meeting package in early 2016. Also in November, the Company contracted with BioConnection (www.bioconnection.eu) for the production of drug product for the upcoming clinical trial expected to commence in the middle of 2016. With few Phase 3 studies ongoing in this space and with hCDR1's unique mechanism of action, we believe there remains a substantial opportunity for the Company's lead drug candidate."

Financial Overview

The Company reported US\$4.3 million in cash and cash equivalents as of September 30, 2015.

Research and development expenses for the three months ended September 30, 2015 were US\$134,000 compared to US\$40,000 for the same period in 2014. Research and development expenses for the three months ended September

30, 2015 were comprised mainly of expenses related to preparations for initiating an advanced clinical trial of the Company's clinical asset, hCDR1. The increase in research and development expenses reflects the Company's increased investment in bringing hCDR1 to an advanced clinical trial in the middle of 2016.

General and administrative expenses for the three months ended September 30, 2015 were US\$262,000 compared to US\$327,000 for the same period in 2014.

Financial expenses, net for the three months ended September 30, 2015 were US\$47,000 compared to US\$72,000 in the three months ended September 30, 2014. The decrease in financial expenses, net, was mainly due to changes in fair value of marketable securities held in InterCure, a former subsidiary.

XTL Biopharmaceuticals Ltd. 5 Hacharoshet Street, Raanana, 43656, Israel Page 1 Tel: +972 9 955 7080; email: ir@xtlbio.com

Loss from continuing operations for the three months ended September 30, 2015 was US\$443,000, compared to US\$439,000 in the same period last year.

Total loss for the quarter ended September 30, 2015 was \$443,000 compared to \$568,000 during the same period in 2014. The decrease in loss was primarily attributable to an increase in research and development expenses offset by losses in 2014 from discontinued operations related to InterCure, a former subsidiary.

Research and development expenses for the nine months ended September 30, 2015 were US\$245,000 compared to US\$121,000 for the same period in 2014. Research and development expenses for the nine months ended September 30, 2015 were comprised mainly of expenses related to preparations for initiating an advanced clinical trial of the Company's clinical asset, hCDR1. The increase in research and development expenses reflects the Company's increased investment in bringing hCDR1 to an advanced clinical trial in the middle of 2016.

General and administrative expenses for the nine months ended September 30, 2015 were US\$1,008,000 compared to US\$1,243,000 for the same period in 2014. The decrease in general and administrative expenses was due to lower rent and maintenance costs, reflecting the Company's continued efforts to reduce overhead costs, as well as a reduction in salary and share based compensation costs in the nine months ended September 30, 2015.

Financial expenses, net for the nine months ended September 30, 2015 were US\$233,000 compared to US\$55,000 in the nine months ended September 30, 2014. The increase in financial expenses, net, was mainly due to changes in fair value of marketable securities held in InterCure, a former subsidiary.

Loss from continuing operations for the nine months ended September 30, 2015 was US\$1,486,000, compared to US\$1,419,000 for the same period last year.

Total loss for the nine months ended September 30, 2015 was US\$1,946,000 compared to US\$2,039,000 for the same period last year. The loss from discontinued operations for the nine months ended September 30, 2015 and 2014 relates to losses from XTL's investment in InterCure, a former subsidiary.

XTL's consolidated financial results for the nine months ended September 30, 2015 are presented in accordance with International Financial Reporting Standards.

XTL Biopharmaceuticals Ltd.

5 Hacharoshet Street, Raanana, 43656, Israel Page 2

Tel: +972 9 955 7080; email: <u>ir@xtlbio.com</u>

XTL Biopharmaceuticals, Ltd. and Subsidiaries

(USD in thousands)

Consolidated Statements of Financial Position - Selected Data

	As of		
	September 30,		December 31.
	2015	2014	2014
Cash, Cash Equivalents and bank deposits	\$4,300	\$2,905	\$ 2,159
Other current assets	518	994	963
Non-current assets	2,667	2,789	2,522
Total assets	7,485	6,688	5,644
Total liabilities	\$262	\$1,211	\$ 965
Total shareholders' equity	7,223	5,393	4,660
Non-controlling interests	-	84	19

XTL Biopharmaceuticals, Ltd. and Subsidiaries

(USD in thousands, except per share amounts)

Consolidated Statements of Comprehensive Income

	Nine months ended	Three months ended	Year ended
	September 30,	September 30,	December 31,
	2015 2014	2015 2014	2014
	Unaudited		Audited
Research and development expenses	(245) (121)	(134) (40) (278)
General and administrative expenses	(1,008) (1,243)	(262) (327)) (1,744)
Operating loss	\$(1,253) \$(1,364)	\$(396) \$(367)) \$ (2,022)

Finance income	29 15 10 (7) 41
Finance expenses	(262) (70) (57) (65) (138)
Finance income (expenses), net	\$(233) \$(55) \$(47) \$(72) \$(97)
Loss from continuing operations	\$(1,486) \$(1,419) \$(443) \$(439) \$(2,119)
Loss from discontinued operations	\$(460) \$(620) \$- \$(129) \$ (746)
Total loss for the period	\$(1,946) \$(2,039) \$(443) \$(568) \$(2,865)
Loss for the period attributable to: Equity holders of the Company Non-controlling interests	(1,948) (1,759) (443) (510) (2,527) 2 (280) - (58) (338)
	\$(1,946) \$(2,039) \$(443) \$(568) \$(2,865)
Basic and diluted loss per share from continuing and discontinued operations (in U.S. dollars): From continuing operations	(0.006) (0.005) (0.002) (0.001) (0.009)
From discontinued operations	(0.002) (0.003) - (0.002) (0.002)
Loss per share for the period	\$(0.008) \$(0.008) \$(0.002) \$(0.003) \$(0.011)

XTL Biopharmaceuticals Ltd. 5 Hacharoshet Street, Raanana, 43656, Israel Page 3

Tel: +972 9 955 7080; email: <u>ir@xtlbio.com</u>

Edgar Filing: XT	_ BIOPHARMACEUTICALS	LTD - Form 6-K
------------------	----------------------	----------------

<u>About XTL Bio</u>	<u>pharmaceuticals</u>	Ltd.	("XTL"))

XTL Biopharmaceuticals Ltd., a biopharmaceutical company, focuses on the acquisition, development, and commercialization of pharmaceutical products for the treatment of unmet clinical needs. Currently, XTL is focused on late stage clinical development of its drug for the treatment of lupus.

XTL is a public company, traded on the Nasdaq Capital Market (NASDAQ: XTLB) and the Tel Aviv Stock Exchange (TASE: XTL). 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 Annual Report on Form 20-F as filed with the U.S. Securities and Exchange Commission on April 28 2015.

XTL Biopharmaceuticals Ltd.
5 Hacharoshet Street, Raanana, 43656, Israel Page 4
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: December 1, 2015 By: /s/ Josh Levine

Josh Levine

Chief Executive Officer