

XTL BIOPHARMACEUTICALS LTD
Form 6-K
September 26, 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 September, 2017

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)

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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 first HALF 2017 FINANCIAL

results & provides CLINICAL and Operational UPDATE

RAANANA, Israel - (September 26, 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 second quarter ended June 30, 2017 and provided an update on the development program for its lead drug candidate hCDR1.

“The first half of 2017 included a number of accomplishments for XTL, 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. “Lupus has a large unmet clinical need, with few satisfactory treatment options and with recent failures in late stage clinical studies with the notable exception of the recent successful Phase 2 in Lupus Nephritis of Voclosporin being developed by Aurinia Pharmaceuticals. Toward that end, we raised more than \$5 million from new and existing investors. We also strengthened our Board of Directors with the addition of our largest shareholder, Mr. Alex Rabinovich, who participated in our latest fundraising. In addition, we unveiled additional preclinical data, which demonstrated the role of hCDR1 as a potential treatment for Sjögren’s syndrome (SS). 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. Finally, we strengthened the intellectual property of our lead asset, hCDR1, by filing a number of new patent applications on the dosing of our drug for lupus and for the treatment of SS.”

Clinical and Operational Update

The Company raised a total gross amount of approximately \$5.3 million during the first half of 2017 through a § public offering to US institutional investors and a private placement with existing investors. The transactions included the issuance of registered and unregistered ADSs and unregistered warrants to purchase ADSs.

§ The Company recently appointed Mr. Alex Rabinovitch as a member of the Company's board of directors. Mr. Rabinovitch is a leading investor in XTL holding over 18% of its outstanding shares.

§ 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 four pathogenic cytokines known to be involved in SS and lupus (including B-lymphocyte stimulator or BLyS), as well as upregulation of two immunosuppressive genes, one of which is a marker for activity of regulatory T cells. 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.

Three provisional patent applications have been filed with the U.S. Patent and Trademark Office for hCDR1 in the treatment of SS.

§ Based on hCDR1's well known mechanism of action and favorable safety profile, XTL can pursue an accelerated clinical development path for the treatment of Sjogren's syndrome.

§ 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.

§ On August 3, 2017, the Company had its Annual General Meeting of shareholders, pursuant to which the shareholders approved:

the re-appointment of Kesselman & Kesselman, Israel CPAs, a member firm of PricewaterhouseCoopers International Limited, as the Company's independent registered public accounting firm for the year ending December 31, 2017.

§ the election or reelection of Messrs. Alexander Rabinovitch, Dr. Jonathan Schapiro, Shlomo Shalev, Doron Turgeman and Dr. Dobroslav Melamed as directors in the Company.

the increase of the Company's authorized share capital by NIS 75,000,000, such that following the increase, the Company's authorized share capital shall equal NIS 145,000,000 divided into 1,450,000,000 ordinary shares, par value NIS 0.1 each.

§ the new employment terms of Mr. Joshua Levine, the Company's Chief Executive Officer, including issuance of 1,000,000 options to purchase 1,000,000 ordinary shares of the Company available through the Company's 2011 ESOP.

Financial Overview

XTL reported approximately \$6,325 thousand in cash and cash equivalents as of June 30, 2017, an increase of \$4,306 thousand since December 31, 2016. The Company plans to use these funds to advance the hCDR1 clinical program for the treatment of SLE and SS and to identify additional assets to add to the XTL portfolio. Currently, the Company has decided to minimize its expenses in connection with research and development of its product until additional funds will be raised in the future by issuing securities or through a collaboration arrangement with a potential partner.

Research and development expenses for the six months period ended June 30, 2017 were \$38 thousand compared to \$355 thousand for the corresponding period in 2016. During the six months period ended June 30, 2016, 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. Such development activities did not repeat during the six months

period ended June 30, 2017.

General and administrative expenses for the six months period ended June 30, 2017 were \$732 thousand compared to \$713 thousand for the corresponding period in 2016. The change resulted mainly from decreases in salaries and expenses relating to employees (including stock-based compensation expenses), investor relations and insurance costs, offset by amortization of certain costs that were previously capitalized as an asset.

Finance expenses, net for the six months period ended June 30, 2017, were \$1,595 thousand compared to finance income, net of \$14 thousand for the corresponding period in 2016. The difference is driven primarily by issuance costs related to the warrants granted to investors in the aforementioned fundraising transactions and revaluation of those warrants amounting to \$346 and \$1,268 thousand, respectively.

XTL reported an operating loss for the six months period ended June 30, 2017 of \$2,365 thousand, or \$0.006 per share, compared to \$1,054 thousand, or \$0.004 per share, for the corresponding period in 2016. The increased total net loss is driven primarily by the costs related to the issuance and revaluation of warrants offset by decreased spending on research and development, as described above.

XTL Biopharmaceuticals, Ltd. and Subsidiary

(USD in thousands)

Condensed Consolidated Statements of Financial Position - Selected Data

	As of	
	June 30,	
	2017	2016
Cash, cash equivalents	\$6,325	\$2,605
Other current assets	467	612
Non-current assets	380	1,120
Total assets	7,172	4,337
Current liabilities	382	258
Non-current liabilities	4,700	-
Share capital	13,182	6,624
Premium on shares, options and warrants	146,003	150,784
Reserve from transactions with non-controlling interests	20	111
Other comprehensive income	125	20
Accumulated deficit	(157,240)	(153,460)
Total shareholders' equity	\$2,090	\$4,079

XTL Biopharmaceuticals, Ltd. and Subsidiary*(USD in thousands, except per share amounts)*

Consolidated Statements of Comprehensive Loss - Selected Data

	For the six months ended	
	June 30,	
	2017	2016
Research and Development expenses	\$(38) \$(355
General and administrative expenses	(732) (713
Operating Loss	(770) (1,068
Finance income	24	19
Finance expenses	(1,619) (5
Finance income (expenses), net	(1,595) 14
Total loss	(2,365) (1,054
Other comprehensive income (loss):		
Items that may be reclassified to profit (loss):		
Changes in the fair value of available-for-sale financial assets	(38) 111
Other comprehensive income (loss)	(38) 111
Total comprehensive loss for the period	\$(2,403) \$(943
Basic and diluted loss per share (in U.S. dollars)	\$(0.006) \$(0.004
Weighted average number of issued ordinary shares	425,193,299	273,862,042

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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/A filed with the U.S. Securities and Exchange Commission on April 4, 2017.

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: September 26, 2017 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer