

XTL BIOPHARMACEUTICALS LTD
Form 6-K
March 16, 2015

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, 2015

Commission File Number: **000-51310**

XTL Biopharmaceuticals Ltd.

(Translation of registrant's name into English)

85 Medinat Hayehudim St., Herzliya

Pituach, PO Box 4033,

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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): ☐

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes ☐ No ☒

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-N/A

Incorporation by Reference: This Form 6-K of XTL Biopharmaceuticals Ltd. dated March 16, 2015 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) filed by XTL Biopharmaceuticals Ltd. with the Securities and Exchange Commission on December 14, 2007, January 18, 2008, and October 28, 2008, respectively.

Annual Letter to Shareholders of XTL Biopharmaceuticals Ltd.

March 16, 2015

Dear Shareholders, Associates, and Friends:

As we begin the new year, I would like to take this opportunity to reflect on our progress in 2014 while also looking forward to continued success in 2015. I am very proud of our accomplishments throughout the year. We built a strong management team and strengthened our Board of Directors with the addition of four new members who have a wealth of knowledge in drug development and the capital markets that will help guide the Company forward. We remain focused on creating value for our shareholders with the development of our assets for Lupus and Multiple Myeloma.

Management and Board of Directors

At the start of 2014, the Company completed the transition to a new management team led by myself as Chief Executive Officer and David Kestenbaum as Chief Financial Officer. I was formerly the CEO of Proteologics Ltd. and a Senior Director at Teva Pharmaceuticals (“Teva”) and David was formerly the CFO of Colbar LifeScience, a division of Johnson & Johnson, and Unilever in Israel. During the year, we added four new directors with extensive drug development and capital markets experience to the Board. Dr. Jonathan Schapiro of Stanford University and Sheba Medical Center in Israel and Dr. Dobroslav Melamed, recently of SciVac/SciGen, both bring extensive drug development experience. Mr. Doron Turgeman and Mr. Shlomo Shalev both have strong financial backgrounds. I look forward to their contributions to the Company.

Acquisition and Development of hCDR1 for the Treatment of SLE

In early 2014, we in-licensed hCDR1, a Phase II-ready asset for the treatment of SLE (lupus). Lupus is a debilitating autoimmune disease and represents a large unmet medical need, with only one new treatment approved by the FDA in the past 50 years. A fourth quarter announcement by Eli Lilly that it discontinued development of a Phase III asset in this space further emphasized the unmet need and highlighted the significant opportunities for our hCDR1 asset and positions the Company to garner significant interest from clinicians, lupus patients and partners and will no doubt lead to “game changing” opportunities for us.

hCDR1 is a peptide that has a unique mechanism of action and has been published in more than 40 peer-reviewed papers. The drug has been administered to over 400 patients in two Phase I trials and a Phase II (PRELUDE) trial. The trials demonstrated that hCDR1 is well tolerated by patients and has a favorable safety profile. Although the Phase II trial did not achieve its primary efficacy endpoint, hCDR1 displayed encouraging results in its secondary clinical endpoint, the BILAG index. Following the Phase II PRELUDE trial, the FDA issued new guidelines and now recommends the BILAG index as a primary endpoint in future lupus trials. Given the FDA's recommendation and the positive findings with respect to the BILAG index, the Company is planning to discuss the results with the FDA and has been preparing for the initiation of a new clinical trial.

The Company has taken a number of steps to move the program forward:

We established a world-class Clinical Advisory Board to include Dr. Daniel Wallace of Cedars-Sinai Medical Center, a former President of the Lupus Foundation of America and operator of the largest lupus clinic in the US, Dr. Murray Urowitz of the University of Toronto and Toronto Western Hospital, who established the University of Toronto Lupus Clinic and the Lupus Databank Research Program and Dr. David Isenberg of University College London Hospitals who is, among other things, the author of the BILAG index.

We reached an agreement to transfer the Investigational New Drug application that was in place for the PRELUDE study to XTL.

We prepared a draft protocol for the planned trial with key opinion leaders.

We completed production of the peptide by Polypeptide, a CMO based in California.

We continue discussions with the FDA to explore our options in order to expedite the regulatory pathway.

Finally, we have held preliminary discussions with a number of potential partners/licensees as part of our partnering program.

Development of rHuEPO for the Treatment of Multiple Myeloma

Also during 2014, the Company initiated discussions with the FDA regarding the design of a Phase II clinical trial for rHuEPO for the treatment of multiple myeloma. The company owns a use patent and has obtained orphan drug designation for this application of the drug. The Phase II study is designed to demonstrate a significant survival benefit from the treatment of end-stage multiple myeloma patients with rHuEPO in a clinical setting. A dramatic survival benefit was demonstrated in a number of patients and results have been published in medical journals. The Company is concluding discussions with a leading pharmaceutical company for the supply of rHuEPO in the planned trial.

Shareholders and Fundraising

The Company filed a shelf registration statement with the United States Securities and Exchange Commission that became effective in April to raise the funds necessary to fund the next stage of development for our rHuEPO and

hCDR1 assets.

During the fourth quarter, Mr. Alex Rabinovich, our largest shareholder, increased his stake in XTL to 18.8% of issued and outstanding shares. He also announced an investment in InterCure, an XTL subsidiary, which effectively affords him control over an additional 2% of XTL shares held by InterCure. Mr. Rabinovich, an Israeli biotech investor, brings a wealth of knowledge and experience in the biotech industry. We appreciate his confidence in the management team and the direction we have taken the Company.

As we look ahead to 2015, we have a number of exciting opportunities that we believe will add value to the Company and, ultimately, to our shareholders. We plan to leverage these opportunities to raise the capital necessary to develop our clinical assets and strategically position the Company to partner, license or further develop these assets.

New Strategy

Spurred on by the developments of 2014, I would like to share a few highlights with you about our strategy for 2015. We will share the details of this strategy with you in a separate communication in the near future:

- Focus on our two main assets: hCDR1 for the treatment of SLE and rHuEPO for the treatment of multiple myeloma.

- Gain widespread awareness of the positive safety and efficacy data related to hCDR1 with the publication of the PRELUDE trial results.

- Engage with the FDA to expedite the development of hCDR1 including new approaches to regulatory issues.

- Take advantage of the renewed interest in potential therapies for lupus by identifying partnering opportunities for the development of hCDR1.

- Initiate a Phase II clinical study of rHuEPO for the treatment of multiple myeloma.

We are on the threshold of what we expect to be a very exciting year. We look forward to working with you, our team and our partners to leverage our assets and create value for our shareholders. We will continue to share news of our progress throughout the coming year.

Sincerely,

Josh Levine, CEO

About XTL Biopharmaceuticals 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. XTL is focused on late stage clinical development of drugs for the treatment of lupus, multiple myeloma and schizophrenia.

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.

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Cautionary Statement

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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 16, 2015 By: /s/ Josh Levine
Josh Levine
Chief Executive Officer