



XTL BIOPHARMACEUTICALS REPORTS 2015 FINANCIAL RESULTS & PROVIDES CLINICAL AND OPERATIONAL UPDATE

RAANANA, ISRAEL - (March 31, 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 lupus, today announced financial results for the year ended December 31, 2015 and provided an update on the development program for its lead drug candidate hCDR1.

“2015 was a pivotal year for us, laying 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. We’re proud of having assembled a world class team of lupus experts at XTL. In the year ahead, we intend to execute on the advancement of hCDR1, which we believe holds tremendous promise for lupus patients currently in need of an effective treatment,” said Josh Levine, CEO of XTL.

Clinical and Operational Update

- XTL 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.
- XTL 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 clearly showed a statistically significant effect of a 0.5 mg dose of hCDR1 on the BILAG index.
- XTL joined the Lupus Foundation of America's Corporate Advisory Council. In 2015 XTL’s Scientific Advisor, Dr. Murray Urowitz of the University of Toronto University Health Network, provided the Lupus Foundation of America with an analysis of data from the Phase 2 clinical study of hCDR1 in the treatment of SLE.
- *Lupus Science & Medicine Journal* published results from the Phase 2b study on the safety and efficacy of hCDR1 for the treatment of SLE. The study showed that hCDR1 was safe, well tolerated, and met the secondary endpoint, BILAG, when treated with 0.5 mg dose of hCDR1.



- hCDR1 was granted a patent for pharmaceutical composition and manufacturing processes in Israel; and granted a patent for synthetic human peptides and pharmaceutical compositions for peptides in the treatment of SLE in Hungary.
- XTL appointed Dr. Daphna Paran, a world renowned expert in the treatment of lupus and an internal medicine and rheumatology specialist, as Medical Director.
- XTL received the European Medicines Agency's Small or Medium Sized Business Enterprise (SME) status in Europe, offering numerous benefits including fee reductions for pre and post marketing phases, scientific and procedural advice, and eligibility for funding and grants.
- XTL advanced its chemistry, manufacturing and controls (CMC) for hCDR1 through an agreement with CyDex Pharmaceuticals for the use of and supply of Captisol® and BioConnection for the production of hCDR1.

Financial Overview

XTL reported \$3.8 million in cash, cash equivalents and bank deposits as of December 31, 2015. Funds will be used to advance the hCDR1 clinical program for the treatment of SLE.

Research and development expenses for the year ended December 31, 2015 were \$578,000 compared with \$278,000 for 2014, reflecting increased investment in the hCDR1 clinical program and preparations for a Phase 2 clinical trial. General and administrative expenses for the year ended December 31, 2015 were \$1.4 million compared with \$1.7 million in 2014, reflecting the Company's continued efforts to reduce overhead costs and lower share-based compensation expenses.

XTL reported an operating loss for the year ended December 31, 2015 of \$3.6 million compared with \$2.0 million for 2014. The 2015 loss includes a \$1.6 million 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, 2015 of \$4.3 million or 0.017 per share, compared to \$2.9 million or 0.011 per share in 2014. Total net loss included a loss from discontinued operations of approximately \$689,000 in 2015 and \$746,000 in 2014.



XTL Biopharmaceuticals, Ltd. and Subsidiaries
(USD in thousands)

Consolidated Statements of Financial Position - Selected Data

	As of December 31,	
	2015	2014
Cash, Cash Equivalents and bank deposits	\$ 3,817	\$ 2,159
Other current assets	448	963
Non-current assets	1,058	2,522
Total assets	5,323	5,644
Total liabilities	\$ 436	\$ 965
Total shareholders' equity	4,887	4,660
Non-controlling interests	-	19

XTL Biopharmaceuticals, Ltd. and Subsidiaries
(USD in thousands, except per share amounts)
Consolidated Statements of Comprehensive Income - Selected Data

	Year ended December 31,	
	2015	2014
	Audited	
Research and development expenses	(578)	(278)
General and administrative expenses	(1,419)	(1,744)
Impairment of intangible assets	(1,604)	-
Other gains (losses), net	(10)	-
Operating loss	\$ (3,611)	\$ (2,022)
Finance income (expenses), net	\$ (11)	\$ (97)
Loss from continuing operations	\$ (3,622)	\$ (2,119)
Loss from discontinued operations	\$ (689)	\$ (746)
Total loss for the period	\$ (4,311)	\$ (2,865)
Loss for the period attributable to:		
Equity holders of the Company	(4,313)	(2,527)
Non-controlling interests from discontinued operations	2	(338)
	\$ (4,311)	\$ (2,865)
Basic and diluted loss per share (in U.S. dollars):		
From continuing operations	(0.014)	(0.009)
From discontinued operations	(0.003)	(0.002)
Loss per share for the period	\$ (0.017)	\$ (0.011)



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 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 a defect in 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 two 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.

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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 31, 2016.