XTL BIOPHARMACEUTICALS LTD
Form 20-F
March 31, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 20-F

(Mark One)

¨ REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

OR

¨ TRANSITIONAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

¨ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____to _____.

Commission file number: **000-36000**

XTL BIOPHARMACEUTICALS LTD.

(Exact name of registrant as specified in its charter)

Israel

(Jurisdiction of incorporation or organization)

5 HaCharoshet St.

Raanana 43656, Israel

(Address of principal executive offices)

Josh Levine

Chief Executive Officer

5 HaCharoshet St.

Raanana 4365603, Israel

Tel: +972-9-955-7080

Fax: +972-9-951-9708

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

American Depositary Shares, each representing twenty Ordinary Shares, par value NIS 0.1	The Nasdaq Capital Market
(Title of Class)	**(Name of each exchange on which registered)**

Securities registered or to be registered pursuant to Section 12(g) of the Act: None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report.

4,440,150 American Depositary Shares	273,525,799 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ¨ No x

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes ¨ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files.)

Yes ¨ No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act). (Check one):

Large accelerated filer ¨ Accelerated filer ¨ Non-accelerated filer x

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

¨ US GAAP x International Financial Reporting Standards as issued ¨ Other

by the International Accounting Standards Board

If "Other" has been check in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow.

Item 17 ¨ Item 18 ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ¨ No x

XTL BIOPHARMACEUTICALS LTD.

ANNUAL REPORT ON FORM 20-F

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Item 5. Operating and Financial Review and Prospects," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. In some instances, you can identify these forward-looking statements by words such as "anticipates," "believes," "estimates," "expects," "intends," "may," "plan," "potential," "will," "should," "would," or similar including their negatives. These forward-looking statements include, without limitation, statements relating to our expectations and beliefs regarding:

- fluctuations in the market price of our securities;
- the possibility that our securities could be delisted from Nasdaq or the Tel-Aviv Stock Exchange ("TASE");
- potential dilution to the holders of our securities as a result of future issuances of our securities;
- fluctuations in our results of operations;
- the accuracy of our financial forecasts in our drug development activity and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives;
- the timing and cost of the in-licensing, partnering and acquisition of new product opportunities;
- the timing of expenses associated with product development and manufacturing of the proprietary drug candidates that we have acquired - hCDR1 for the treatment of Lupus, rHuEPO for the treatment of Multiple Myeloma and those that may be in-licensed, partnered or acquired;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- other risks and uncertainties described in this report.

Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under "Item 3. Key Information-Risk Factors," "Item 4. Information on the Company," "Item 5. Operating and Financial Review and Prospects," and elsewhere in this report, as well as factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements.

Forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is filed. Therefore, you should not place undue reliance on any forward-looking statement as a prediction of future results. Forward-looking statements made in this report and the documents incorporated by reference are made as of the date of the respective documents, and we undertake no obligation to update them in light of new information or future results. Except as required by law, we assume no responsibility for updating any forward-looking statements.

PART I

Unless the context requires otherwise, references in this report to "XTL," the "Company," "we," "us" and "our" refer to XTL Biopharmaceuticals Ltd, an Israeli company and our consolidated subsidiaries. We have prepared our consolidated financial statements in United States, or US, dollars and in accordance with International Financial Reporting Standards, or IFRS. All references herein to "dollars" or "$" are to US dollars, and all references to "Shekels" or "NIS" are to New Israeli Shekels.

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not applicable

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The tables below present selected financial data for the fiscal years ended as of December 31, 2015, 2014, 2013, 2012 and 2011. We have derived the selected financial data for the fiscal years ended December 31, 2015, 2014 and 2013, and as of December 31, 2015 and 2014, from our audited consolidated financial statements, included elsewhere in this report and prepared in accordance with International Financial Reporting Standards ("IFRS") issued by the International Accounting Standards Board ("IASB"). You should read the selected financial data in conjunction with "Item 5. Operating and Financial Review and Prospects," "Item 8. Financial Information" and "Item 18. Financial Statements."

Consolidated Statements of Comprehensive income:

	Year ended December 31,				
	2015	2014	2013	2012	2011
	U.S Dollars in thousands				
Research and development expenses	(578)	(278)	(82)	(92)	(158)
General and administrative expenses	(1,419)	(1,744)	(1,329)	(2,448)	(1,078)
Impairment of intangible assets	(1,604)	-	-	-	-
Other gains, net	(10)	-	1,059	802	12
Operating loss	(3,611)	(2,022)	(352)	(1,738)	(1,224)
Finance income	4	10	65	57	24
Finance expenses	(15)	(107)	(6)	(7)	(7)
Financial income (expenses), net	(11)	(97)	59	50	17
Earnings (losses) from investment in associate	-	-	(845)	569	-
Total loss from continuing operations	(3,622)	(2,119)	(1,138)	(1,119)	(1,207)
Other comprehensive income (loss):					
Items that might be classified to profit or loss:					
Foreign currency translation adjustments	-	-	108	114	-
	-	-	(221)	-	-

Reclassification of foreign currency translation adjustments to Other gains, net					
Total other comprehensive income	-	-	(113)	114	-
Total comprehensive loss from continuing operations	(3,622)	(2,119)	(1,251)	(1,005)	(1,207)
Total loss from discontinued operations	(689)	(746)	(2,575)	(623)	-
Total comprehensive loss for the year	(4,311)	(2,865)	(3,826)	(1,628)	(1,207)
Loss for the year attributable to:					
Equity holders of the Company	(4,313)	(2,527)	(2,476)	(1,390)	(1,207)
Non-controlling interests	2	(338)	(1,237)	(352)	-
	(4,311)	(2,865)	(3,713)	(1,742)	(1,207)
Total comprehensive loss for the year attributable to:					
Equity holders of the Company	(4,313)	(2,527)	(2,589)	(1,276)	(1,207)
Non-controlling interests	2	(338)	(1,237)	(352)	-
	(4,311)	(2,865)	(3,826)	(1,628)	(1,207)
Basic and diluted loss from continuing and discontinued operations (in US dollars)					
From continuing operations	(0.014)	(0.009)	(0.005)	(0.005)	(0.006)
From discontinued operations	(0.003)	(0.002)	(0.006)	(0.001)	-
Basic and diluted loss per share (in US dollars)	(0.017)	(0.011)	(0.011)	(0.006)	(0.006)
Weighted average number of issued ordinary shares	263,730,467	231,224,512	223,605,181	217,689,926	201,825,645

Consolidated Statements of Financial Position Data:

	As of December 31,				
	2015	2014	2013	2012	2011
	U.S Dollars in thousands				
Cash, cash equivalents and bank deposits	3,817	2,159	4,165	3,312	1,495
Working capital	3,829	2,081	3,870	2,143	955
Total assets	5,323	5,644	8,015	11,086	4,073
Long term liabilities	-	-	11	13	-
Total shareholders' equity	4,887	4,660	6,265	7,353	3,444
Non-controlling interests	-	19	520	2,071	-

B. Capitalization And Indebtedness

Not applicable.

C. Reasons For Offer And Use Of Proceeds

Not applicable.

D. Risk Factors

Before you invest in our ordinary shares or American Depositary Shares, you should understand the high degree of risk involved. You should carefully consider the risks described below and other information in this report, including our financial statements and related notes included elsewhere in this report, before you decide to purchase our ordinary shares or ADSs. If any of the following risks actually occur, our business, financial condition and operating results could be adversely affected. As a result, the trading price of our ordinary shares or ADSs could decline and you could lose part or all of your investment.

Risks Related to Our Financial Position and Capital Requirements

We have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future in our drug development activity and may never become profitable.

You should consider our prospects in light of the risks and difficulties frequently encountered by development stage companies. We have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future. We have not yet commercialized any of our drug candidates or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, consummate out-licensing agreements, obtain regulatory approval for our drug candidates and technologies and successfully commercialize them.

We expect to continue to incur losses for the foreseeable future, and these losses will likely increase as we:

- initiate and manage pre-clinical development and clinical trials for our current and new product candidates;
- seek regulatory approvals for our product candidates;
- implement internal systems and infrastructures;
- seek to license additional technologies to develop;
- hire management and other personnel; and
- progress product candidates towards commercialization.

If our product candidates fail in clinical trials or do not gain regulatory clearance or approval, or if our product candidates do not achieve market acceptance, we may never become profitable. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our inability to achieve and then maintain profitability would negatively affect our business, financial condition, results of operations and cash flows. Moreover, our prospects must be considered in light of the risks and uncertainties encountered by an early-stage company and in highly regulated and competitive markets, such as the biopharmaceutical market, where regulatory approval and market acceptance of our products are uncertain. There can be no assurance that our efforts will ultimately be successful or result in revenues or profits.

We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of December 31, 2015, we had approximately $3,817 thousand in cash, cash equivalents and bank deposits, working capital of approximately $3,829 thousand and an accumulated deficit of approximately $152,487 thousand. As of December 31, 2015, we had sufficient cash and cash commitments to fund operations based on existing business plans, for at least the next twelve months. We have expended and believe that we will continue to expend significant operating and capital expenditures for the foreseeable future developing our product candidates. These expenditures will include, but are not limited to, costs associated with research and development, manufacturing, conducting preclinical experiments and clinical trials, contracting with contract manufacturing organizations ("CMOs") and research organizations ("CROs"), hiring additional management and other personnel and obtaining regulatory approvals, as well as commercializing any products approved for sale. Because the outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates and any other future product. In addition, other unanticipated costs may arise. As a result of these and other factors currently unknown to us, we will require additional funds, through public or private equity or debt financings or other sources, such as strategic partnerships and alliances and licensing arrangements. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. A failure to fund these activities may harm our growth strategy, competitive position, quality compliance and financial condition.

Our future capital requirements depend on many factors, including:

- the number and characteristics of products we develop;
- the scope, progress, results and costs of researching and developing our product candidates and conducting preclinical and clinical trials;
- the timing of, and the costs involved in, obtaining regulatory approvals;
- the cost of commercialization activities if any are approved for sale, including marketing, sales and distribution costs;
- the cost of manufacturing any product candidate we successfully commercialize;
- our ability to establish and maintain strategic partnerships, licensing, supply or other arrangements and the financial terms of such agreements;

- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;

- hCDR1 patent expiration in 2024 and failure to obtain patent term extension, expand patent protection or obtain data exclusivity in the U.S. and Europe;

- rHuEPO patent expiration in 2019 and failure to retain orphan drug designation in the U.S. or obtain orphan drug designation in Europe;

- the costs of in-licensing further patents and technologies.

- the cost of development of in-licensed technologies

- the timing, receipt and amount of sales of, or royalties on, any future products;

- the expenses needed to attract and retain skilled personnel; and

- any product liability or other lawsuits related to existing and/or any future products.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other research and development activities for our product candidates or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates or any future products.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of private and public equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of existing shareholders will be diluted, and the terms may include liquidation or other preferences that adversely affect shareholder rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring debt, making capital expenditures or declaring dividends. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to Our Drug Development Business

We have not yet commercialized any products or technologies, and we may never become profitable.

We have not yet commercialized any products or technologies, and we may never be able to do so. We do not know when or if we will complete any of our product development efforts, obtain regulatory approval for any product candidates incorporating our technologies or successfully commercialize any approved products. Even if we are successful in developing products that are approved for marketing, we will not be successful unless these products gain market acceptance for appropriate indications at favorable reimbursement rates. The degree of market acceptance of these products will depend on a number of factors, including:

the timing of regulatory approvals in the countries, and for the uses, we seek;

the competitive environment;

the establishment and demonstration in the medical community of the safety and clinical efficacy of our products and their potential advantages over existing therapeutic products;

our ability to enter into strategic agreements with pharmaceutical and biotechnology companies with strong marketing and sales capabilities;

the adequacy and success of distribution, sales and marketing efforts; and

the pricing and reimbursement policies of government and third-party payors, such as insurance companies, health maintenance organizations and other plan administrators.

Physicians, patients, third-party payors or the medical community in general may be unwilling to accept, utilize or recommend, and in the case of third-party payors, cover any of our products or products incorporating our technologies. As a result, we are unable to predict the extent of future losses or the time required to achieve profitability, if at all. Even if we successfully develop one or more products that incorporate our technologies, we may not become profitable.

If we are unable to successfully complete our clinical trial programs for our drug candidates, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete clinical trials depends in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate at which we are able to collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases and stages as we are studying. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis.

We have limited experience in conducting and managing clinical trials necessary to obtain regulatory approvals. If our drug candidates and technologies do not receive the necessary regulatory approvals, we will be unable to commercialize our products.

We have not received, and may never receive, regulatory approval for commercial sale for hCDR1 or rHuEPO. We currently do not have any drug candidates pending approval with the Food and Drug Administration (“FDA”) or with regulatory authorities of other countries. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. In order to obtain FDA approval to market a new drug product, we or our potential partners must demonstrate proof of safety and efficacy in humans. To meet these requirements, we and/or our potential partners will have to conduct “adequate and well-controlled” clinical trials.

Clinical development is a long, expensive and uncertain process. Clinical trials are very difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. The commencement and rate of completion of clinical trials may be delayed by many factors, including: