

XTL BIOPHARMACEUTICALS LTD  
Form 20-F  
March 30, 2017

**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, 2016

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

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Raanana 4365603, Israel

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(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 The Nasdaq Capital Market

one hundred Ordinary Shares, par value NIS 0.1

(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.

American Depositary Shares

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

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

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  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

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

US GAAP  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

**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 subsidiary. 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 and as of December 31, 2016, 2015, 2014, 2013 and 2012. We have derived the selected financial data for the fiscal years ended December 31, 2016, 2015 and 2014, and as of December 31, 2016 and 2015, 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”) We have derived the selected financial data for the fiscal years ended December 31, 2013 and 2012, and as of December 31, 2014, 2013 and 2012, from our audited consolidated financial statements not included in this report. 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. Consolidated Financial Statements.”



**Consolidated Statements of Comprehensive Loss:**

	Year ended December 31,				
	2016	2015	2014	2013	2012
	U.S Dollars in thousands (except for per share information)				
Research and development expenses	(443	) (578	) (278	) (82	) (92
General and administrative expenses	(1,270	) (1,419	) (1,744	) (1,329	) (2,448
Impairment of intangible assets	(848	) (1,604	) -	-	-
Other gains, net	-	(10	) -	1,059	802
Operating loss	(2,561	) (3,611	) (2,022	) (352	) (1,738
Finance income	23	4	10	65	57
Finance expenses	(7	) (15	) (107	) (6	) (7
Financial income (expenses), net	16	(11	) (97	) 59	50
Earnings (losses) from investment in associate	-	-	-	(845	) 569
Total loss from continuing operations	(2,545	) (3,622	) (2,119	) (1,138	) (1,119
Other comprehensive income (loss): Items that might be classified to profit or loss:					
Foreign currency translation adjustments	-	-	-	108	114
Reclassification of foreign currency translation adjustments to Other gains, net	-	-	-	(221	) -
Changes in the fair value of available-for-sale financial assets	163	-	-	-	-
Realized gain from sale available-for-sale financial assets	-	*)			
Total other comprehensive income	163	-	-	(113	) 114
Total comprehensive loss from continuing operations	(2,382	) (3,622	) (2,119	) (1,251	) (1,005
Total loss from discontinued operations	-	(689	) (746	) (2,575	) (623
Total comprehensive loss for the year	(2,382	) (4,311	) (2,865	) (3,826	) (1,628
Loss for the year attributable to:					

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Equity holders of the Company	(2,545	)	(4,313	)	(2,527	)	(2,476	)	(1,390	)
Non-controlling interests	-		2		(338	)	(1,237	)	(352	)
	(2,545	)	(4,311	)	(2,865	)	(3,713	)	(1,742	)
Total comprehensive loss for the year attributable to:										
Equity holders of the Company	(2,382	)	(4,313	)	(2,527	)	(2,589	)	(1,276	)
Non-controlling interests	-		2		(338	)	(1,237	)	(352	)
	(2,382	)	(4,311	)	(2,865	)	(3,826	)	(1,628	)
Basic and diluted loss from continuing and discontinued operations (in US dollars)										
From continuing operations	(0.009	)	(0.014	)	(0.009	)	(0.005	)	(0.005	)
From discontinued operations	-		(0.003	)	(0.002	)	(0.006	)	(0.001	)
Basic and diluted loss per share (in US dollars)	(0.009	)	(0.017	)	(0.011	)	(0.011	)	(0.006	)
Weighted average number of issued ordinary shares	274,035,533		263,730,467		231,224,512		223,605,181		217,689,926	

\*) – less than one thousand.

**Consolidated Statements of Financial Position Data:**

	As of December 31,				
	2016	2015	2014	2013	2012
	U.S Dollars in thousands				
Cash, cash equivalents and bank deposits	2,019	3,817	2,159	4,165	3,312
Working capital*	2,424	3,829	2,081	3,870	2,143
Total assets	3,017	5,323	5,644	8,015	11,086
Long term liabilities	-	-	-	11	13
Total shareholders' equity	2,687	4,887	4,660	6,265	7,353
Non-controlling interests	-	-	19	520	2,071

Working capital is calculated as current assets less liabilities.

**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 consolidated financial statements and related notes included elsewhere in this report, before you decide to purchase our ordinary shares or American Depositary Shares ("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 December 31, 2016, we had approximately \$2,019 thousand in cash, cash equivalents and bank deposits, working capital of approximately \$2,424 thousand and an accumulated deficit of approximately \$154,904 thousand. We have incurred continuing losses and depend on outside financing resources to continue our activities. Based on existing business plans, we estimate that our outstanding cash and cash equivalent balances will allow us to finance our activities for an additional period of at least 12 months from the date of this Report. In order to perform clinical trials aimed at developing our product until obtaining its marketing approval, we will need to raise additional financing by issuing securities. Should we fail to raise additional capital under terms acceptable to us, we will be required to reduce our development activities or sell or grant a sublicense to third parties to use all or part of our technologies.

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 and contract research organizations, 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;
- 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. We currently do not have any drug candidates pending approval with the Food and Drug Administration, or 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:

- obtaining regulatory approvals to commence a clinical trial;

- reaching agreement on acceptable terms with prospective CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;

- slower than expected rates of patient recruitment due to narrow screening requirements and competing clinical studies;

- the inability of patients to meet protocol requirements imposed by the FDA or other regulatory authorities;

- the need or desire to modify our manufacturing process;

- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and

- governmental or regulatory delays or “clinical holds” requiring suspension or termination of the trials.

Following the completion of a clinical trial, regulators may not interpret data obtained from pre-clinical and clinical tests of our drug candidates and technologies the same way that we do, which could delay, limit or prevent our receipt of regulatory approval. In addition, the designs of any clinical trials may not be reviewed or approved by the FDA prior to their commencement, and consequently the FDA could determine that the parameters of any studies are insufficient to demonstrate proof of safety and efficacy in humans. Failure to approve a completed study could also result from several other factors, including unforeseen safety issues, the determination of dosing, low rates of patient recruitment, the inability to monitor patients adequately during or after treatment, the inability or unwillingness of medical investigators to follow our clinical protocols, and the lack of effectiveness of the trials.

Additionally, the regulators could determine that the studies indicate the drugs may have serious side effects. In the U.S., this is called a black box warning, which is a type of warning that appears on the package insert for prescription drugs indicating that they may cause serious adverse effects. A black box warning means that medical studies indicate that the drug carries a significant risk of serious or even life-threatening adverse effects.

If the clinical trials fail to satisfy the criteria required, the FDA and/or other regulatory agencies/authorities may request additional information, including additional clinical data, before approval of marketing a product. Negative or inconclusive results or medical events during a clinical trial could also cause us to delay or terminate our development efforts. If we experience delays in the testing or approval process, or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates and technologies may be materially impaired.

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in clinical trials, even after achieving promising results in earlier trials. It may take us many years to complete the testing of our drug candidates and technologies, and failure can occur at any stage of this process.

Even if regulatory approval is obtained, our products and their manufacture will be subject to continual review, and there can be no assurance that such approval will not be subsequently withdrawn or restricted. Changes in applicable legislation or regulatory policies, or discovery of problems with the products or their manufacture, may result in the imposition of regulatory restrictions, including withdrawal of the product from the market, or result in increased costs to us.

***If third parties on which we will have to rely for clinical trials do not perform as contractually required or as we expect, we may not be able to obtain regulatory approval for or commercialize our products.***

We will have to depend on independent clinical investigators, and other third-party service providers to conduct the clinical trials of our drug candidates and technologies. We also may, from time to time, engage a clinical research organization for the execution of our clinical trials. We will rely heavily on these parties for successful execution of our clinical trials, but we will not control many aspects of their activities. Nonetheless, we are responsible for confirming that each of our clinical trials is conducted in accordance with the general investigational plan and protocol. Our reliance on these third parties that we do not control does not relieve us of our responsibility to comply with the regulations and standards of the FDA and/or other foreign regulatory agencies/authorities relating to good clinical practices. Third parties may not complete activities on schedule or may not conduct our clinical trials in accordance with regulatory requirements or the applicable trial's plans and protocols. The failure of these third parties to carry out their obligations could delay or prevent the development, approval and commercialization of our products, or could result in enforcement action against us.

***Our international clinical trials may be delayed or otherwise adversely impacted by social, political and economic factors affecting the particular foreign country.***

We may conduct clinical trials in different geographical locations. Our ability to successfully initiate, enroll and complete a clinical trial in any of these countries, or in any future foreign country in which we may initiate a clinical trial, are subject to numerous risks unique to conducting business in foreign countries, including:

- difficulty in establishing or managing relationships with clinical research organizations and physicians;
- different standards for the conduct of clinical trials and/or health care reimbursement;
- our inability to locate qualified local consultants, physicians, and partners;

the potential burden of complying with a variety of foreign laws, medical standards and regulatory requirements, including the regulation of pharmaceutical products and treatment; and

- general geopolitical risks, such as political and economic instability, and changes in diplomatic and trade relations.



Any disruption to our international clinical trial program could significantly delay our product development efforts.

***If the clinical data related to our drug candidates and technologies do not confirm positive early clinical data or preclinical data, our corporate strategy and financial results will be adversely impacted.***

Our drug candidates and technologies are in clinical stages. Specifically, our product candidate, hCDR1 is planned for and/or ready for advanced clinical studies. In order for our candidates to proceed to later stage clinical testing or marketing approval, they must show positive clinical results.

Preliminary results of pre-clinical, clinical observations or clinical tests do not necessarily predict the final results, and promising results in pre-clinical, clinical observations or early clinical testing might not be obtained in later clinical trials. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. Any negative results from future tests may prevent us from proceeding to later stage clinical testing or marketing approval, which would materially impact our corporate strategy, and our financial results may be adversely impacted.

***If we do not establish or maintain drug development and marketing arrangements with third parties, we may be unable to commercialize our drug candidates and technologies into products.***

We do not possess all of the capabilities to fully commercialize our drug candidates and technologies on our own. From time to time, we may need to contract with third parties to:

- assist us in developing, testing and obtaining regulatory approval for some of our compounds and technologies;
- manufacture our drug candidates; and
- market and distribute our products.

We can provide no assurance that we will be able to successfully enter into agreements with such third-parties on terms that are acceptable to us. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of

our drug development programs or seek to develop or commercialize our drug candidates and technologies independently, which could result in delays. Further, such failure could result in the termination of license rights to one or more of our drug candidates and technologies. Moreover, if these development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we may be unable to control whether such products will be scientifically or commercially successful.

***Even if we or our collaborative/strategic partners or potential collaborative/strategic partners receive approval to market our drug candidates, if our products fail to achieve market acceptance, we will never record meaningful revenues.***

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our product candidates will depend on a number of factors, including:

· perceptions by members of the health care community, including physicians, of the safety and efficacy of our products;

· the rates of adoption of our products by medical practitioners and the target populations for our products;

the potential advantages that our products offer over existing treatment methods or other products that may be developed;

- the cost-effectiveness of our products relative to competing products including potential generic competition;
- the availability of government or third-party pay or reimbursement for our products;

the side effects of our products which may lead to unfavorable publicity concerning our products or similar products; and

- the effectiveness of our and/or our partners' sales, marketing and distribution efforts.

Specifically, hCDR1, if successfully developed and commercially launched for the treatment of systemic lupus erythematosus, or SLE, and Sjogren's syndrome, or SS, on the one hand, will compete with both currently marketed and new products marketed by other companies. Health care providers may not accept or utilize any of our product candidates. Physicians and other prescribers may not be inclined to prescribe our products unless our products bring clear and demonstrable advantages over other products currently marketed for the same indications. Because we expect sales of our products to generate substantially all of our revenues in the long-term, the failure of our products to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

***If the third parties upon whom we rely to manufacture our products do not successfully manufacture our products, our business will be harmed.***

We do not currently have the ability to manufacture the compounds that we need to conduct our clinical trials and, therefore, rely upon, and intend to continue to rely upon, certain manufacturers to produce and supply our drug candidates for use in clinical trials and for future sales. In order to commercialize our products, such products will need to be manufactured in commercial quantities while adhering to all regulatory and other local requirements, all at an acceptable cost. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms, if at all.

If our contract manufacturers or other third parties fail to deliver our product candidates for clinical use on a timely basis, with sufficient quality, and at commercially reasonable prices, and we fail to find replacement manufacturers or sources, we may be required to delay or suspend clinical trials or otherwise discontinue development and production of our drug candidates.

Our contract manufacturers will be required to produce our clinical drug candidates under strict compliance with current Good Manufacturing Practices, or cGMP, in order to meet acceptable regulatory standards for our clinical trials. If such standards change, the ability of contract manufacturers to produce our drug candidates on the schedule we require for our clinical trials may be affected. In addition, contract manufacturers may not perform their obligations under their agreements with us or may discontinue their business before the time required by us to successfully produce and market our drug candidates. Any difficulties or delays in our contractors' manufacturing and supply of drug candidates could increase our costs, cause us to lose revenue or make us postpone or cancel clinical trials.

In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign or local governmental agencies to ensure strict compliance with, among other things, cGMP, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. No assurance can be given that our third-party manufacturers will comply with these regulations or other regulatory requirements now or in the future.

In the event that we are unable to obtain or retain third-party manufacturers, we will not be able to commercialize our products as planned. If third-party manufacturers fail to deliver the required quantities of our products on a timely basis and at commercially reasonable prices, our ability to develop and deliver products on a timely and competitive basis may be adversely impacted and our business, financial condition or results of operations will be materially harmed.

***If our competitors develop and market products that are less expensive, more effective or safer than our products, our revenues and results may be harmed and our commercial opportunities may be reduced or eliminated.***

The pharmaceutical industry is highly competitive. Our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our products. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are already commercialized or are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing safe, effective drugs, our products may not compete successfully with products produced by our competitors, who may be able to market their drugs more effectively.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields present substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop products that could render our technologies or our drug candidates obsolete or noncompetitive. Development of new drugs, medical technologies and competitive medical devices may damage the demand for our products without any certainty that we will successfully and effectively contend with those competitors.

***If we lose our key personnel or are unable to attract and retain additional personnel, our business could be harmed.***

As of March 30, 2017, we have 2 full-time employees, including our officers, and 5 part-time service providers. To successfully develop our drug candidates and technologies, we must be able to attract and retain highly skilled personnel, including consultants and employees. The retention of their services cannot be guaranteed. Our failure to retain and/or recruit such professionals might impair our performance and materially affect our technological and product development capabilities and our product marketing ability.

*Any acquisitions or in-licensing transactions we make may dilute your equity or require a significant amount of our available cash and may not be scientifically or commercially successful.*

As part of our business strategy, we may effect acquisitions or in-licensing transactions to obtain additional businesses, products, technologies, capabilities and personnel. If we complete one or more such transactions in which the consideration includes our ordinary shares or other securities, your equity may be significantly diluted. If we complete one or more such transactions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions and in-licensing transactions also involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology or personnel of the business;
- our inability to attract and retain management, key personnel and other employees necessary to conduct the business;

- our inability to maintain relationships with key third parties, such as alliance partners, associated with the business;

- exposure to legal claims for activities of the business prior to the acquisition;

- the diversion of our management's attention from our other drug development businesses; and

the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

In addition, the basis for completing the acquisition or in-licensing could prove to be unsuccessful as the drugs or processes involved could fail to be scientifically or commercially viable. We may also be required to pay third parties substantial transaction fees, in the form of cash or ordinary shares, in connection with such transactions.

If any of these risks occur, it could have an adverse effect on both the business we acquire or in-license and our existing operations.

***We face product liability risks and may not be able to obtain adequate insurance.***

The use of our drug candidates and technologies in clinical trials, and the sale of any approved products, exposes us to liability claims. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates and technologies or limit commercialization of any approved products.

We believe that we will be able to obtain sufficient product liability insurance coverage for our planned clinical trials. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for a product;

damage to our reputation;

inability to continue to develop a drug candidate or technology;

withdrawal of clinical trial volunteers; and

loss of revenues.

Consequently, a product liability claim or product recall may result in material losses.

### **Risks Related to Our Intellectual Property**

*Because all of our proprietary drug candidates and technologies are licensed to us by third parties, termination of these license agreements could prevent us from developing our drug candidates.*

We do not own any of our drug candidates and technologies. We have licensed the rights, patent or otherwise, to our drug candidates from third parties. We have licensed hCDR1 from Yeda Research and Development Company Ltd., or Yeda. We licensed a use patent for the use of rHuEPO from Yeda and Mor Research Applications Ltd., or Mor which we acquired from Bio-Gal Limited, or Bio-Gal.



These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed drugs and technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. While we have the right to defend patent rights related to our licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort. If we do not meet our obligations in a timely manner, or if we otherwise breach the terms of our agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates and technologies. From time to time, in the ordinary course of business, we may have disagreements with our licensors or collaborators regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development, collaboration and commercialization of our drug candidates, or could require or result in litigation or arbitration, which could be time-consuming and expensive.

***If we are unable to adequately protect our intellectual property, third parties may be able to use our technology, which could adversely affect our ability to compete in the market.***

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents and technologies against third-party challenges. As part of our business strategy, our policy is to actively file patent applications in the U.S. and internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and composition and improvements in each of these. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in force for only a short period following commercialization, thus reducing any advantage of the patent.

The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

Generally, patent applications in the U.S. are maintained in secrecy for a period of at least 18 months. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. We cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim compounds or technology also claimed by us, we may be required to challenge competing patent rights, which could

result in substantial cost, even if the eventual outcome is favorable to us. While we have the right to defend patent rights related to the licensed drug candidates and technologies, we are not obligated to do so. In the event that we decide to defend our licensed patent rights, we will be obligated to cover all of the expenses associated with that effort.

We also rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to protect our trade secrets or other proprietary information adequately. In addition, we share ownership and publication rights to data relating to some of our drug candidates and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to protect our proprietary information will be at risk.

***Litigation or third-party claims of intellectual property infringement could require us to spend substantial time, money and other resources defending such claims and adversely affect our ability to develop and commercialize our products.***

Third parties may assert that we are using their proprietary technology without authorization. In addition, third parties may have or obtain patents in the future and claim that our products infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected products could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all. In addition, any legal action against us that seeks damages or an injunction relating to the affected activities could subject us to monetary liability and/or require us to discontinue the affected technologies or obtain a license to continue use thereof.

In addition, there can be no assurance that our patents or patent applications or those licensed to us will not become involved in opposition or revocation proceedings instituted by third parties. If such proceedings were initiated against one or more of our patents, or those licensed to us, the defense of such rights could involve substantial costs and the outcome could not be predicted.

Competitors or potential competitors may have filed applications for, may have been granted patents for, or may obtain additional patents and proprietary rights that may relate to compounds or technologies competitive with ours. If patents are granted to other parties that contain claims having a scope that is interpreted to cover any of our products (including the manufacture thereof), there can be no assurance that we will be able to obtain licenses to such patents at reasonable cost, if at all, or be able to develop or obtain alternative technology.

#### ***Risks Related to our ADSs***

***We will need additional capital in the future. If additional capital is not available, we may not be able to continue to operate our business pursuant to our business plan or we may have to discontinue our operations entirely.***

Our net cash used in operating activities for the year ended December 31, 2016 was \$ 1,732 thousand. If we continue to use cash at this rate we will need significant additional financing, which we may seek to raise through, among other things, public and private equity offerings and debt financing. Any equity financings will likely be dilutive to existing

stockholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all.

***The ADSs are traded in small volumes, limiting ability to sell ADSs that represent ordinary shares at a desirable price, if at all.***

The trading volume of the ADSs has historically been low. Even if the trading volume of the ADSs increases, we can give no assurance that it will be maintained or will result in a desirable stock price. As a result of this low trading volume, it may be difficult to identify buyers to whom shareholders can sell ADSs in desirable volume and shareholders may be unable to sell your ADSs at an established market price, at a price that is favorable, or at all. A low volume market also limits shareholders' ability to sell large blocks of the ADSs at a desirable or stable price at any one time. Shareholders should be prepared to own the ADSs indefinitely.

***Our stock price can be volatile, which increases the risk of litigation and may result in a significant decline in the value of your investment.***

The trading price of the ADSs representing our ordinary shares is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

· developments concerning our drug candidates;

- announcements of technological innovations by us or our competitors;

- introductions or announcements of new products by us or our competitors;

- developments in the markets of the field of activities and changes in customer attributes;

announcements by us of significant acquisitions, in/out license transactions, strategic partnerships, joint ventures or capital commitments;

- changes in financial estimates by securities analysts;

actual or anticipated variations in interim operating results and near-term working capital as well as failure to raise required funds for the continued development and operations of the company;

- expiration or termination of licenses, patents, research contracts or other collaboration agreements;

- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

- failure to obtain orphan drug designation status for the relevant drug candidates in the relevant regions;

- increase in costs and lengthy timing of the clinical trials according to regulatory requirements;

- failure to increase awareness of our products;

- changes in reimbursement policy by governments or insurers in markets we operate or may operate in the future;

- any changes in the regulatory environment relating to our drug candidates;

- changes in the market valuations of similar companies; and

- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of the ADSs, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources even if we prevail in the litigation, all of which could seriously harm our business.

***Future issuances or sales of the ADSs could depress the market for the ADSs.***

Future issuances of a substantial number of the ADSs, or the perception by the market that those issuances could occur, could cause the market price of our ordinary shares or ADSs to decline or could make it more difficult for us to raise funds through the sale of equity in the future. Also, if we make one or more significant acquisitions in which the consideration includes ordinary shares or other securities, your portion of shareholders' equity in us may be significantly diluted.

***Concentration of ownership of our ordinary shares among our principal stockholders may prevent new investors from influencing significant corporate decisions.***

There are two shareholders (Mr. Alexander Rabinovitch, and Mr. David Bassa), who each beneficially hold more than 5% of our outstanding ordinary shares (approximately 26% cumulative, as of March 30, 2017). As a result, these persons, either acting alone or together, may have the ability to significantly influence the outcome of all matters submitted to our shareholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting alone or together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of our ordinary shares or ADSs.

Notwithstanding the aforesaid, in connection with Section 239 of the Israeli Companies Law that focuses on the number of votes required to appoint external directors, and in connection with Section 121(c) of the Israeli Companies Law that focuses on the number of votes required to authorize the Chairman of the Board in a company to act also as the Chief Executive Officer of such company, we will deem these three shareholders as controlling shareholders, for as long as such individuals are interested parties. In addition, any contractual arrangement as detailed in Section 270 (4) of the Israeli Companies Law with any of these three shareholders and/or their relatives will be presented for approval in accordance with the provisions of Section 275 of the Israeli Companies Law. In all of these situations, we will consider any of these three parties, who are not part of the transaction presented for approval, as individual interested parties in such transaction so that their vote will not be included in the quorum comprising a majority (50%) of the votes who are not interested parties in such transaction.

***Our ordinary shares and ADSs trade on two different markets, and this may result in price variations and regulatory compliance issues.***

ADSs representing our ordinary shares are listed for trading on the Nasdaq Capital Market, or Nasdaq, and our ordinary shares are traded on the TASE. Trading in our securities on these markets is made in different currencies and at different times, including as a result of different time zones, different trading days and different public holidays in the U.S. and Israel. Consequently, the effective trading prices of our securities on these two markets may differ. Any decrease in the trading price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

***Holders of our ordinary shares or ADSs who are U.S. citizens or residents may be required to pay additional income taxes.***

There is a risk that we will be classified as a passive foreign investment company, or PFIC, for certain tax years. If we are classified as a PFIC, a U.S. holder of our ordinary shares or ADSs representing our ordinary shares will be subject to special federal income tax rules that determine the amount of federal income tax imposed on income derived with respect to the PFIC shares. We will be a PFIC if either 75% or more of our gross income in a tax year is passive income or the average percentage of our assets (by value) that produce or are held for the production of passive income in a tax year is at least 50%. The risk that we will be classified as a PFIC arises because cash balances, even if held as working capital, are considered to be assets that produce passive income. Therefore, any determination of PFIC status will depend upon the sources of our income and the relative values of passive and non-passive assets, including goodwill. A determination as to a corporation's status as a PFIC must be made annually. We believe we may be a PFIC during 2015 and although we have not determined whether we will be a PFIC in 2016, or in any subsequent year, our operating results for any such years may cause us to be a PFIC. Although we may not be a PFIC in any one year, the PFIC taint remains with respect to those years in which we were or are a PFIC and the special PFIC taxation regime will continue to apply.

In view of the complexity of the issues regarding our treatment as a PFIC, U.S. shareholders are urged to consult their own tax advisors for guidance as to our status as a PFIC.



***As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic issuers.***

As a foreign private issuer, we will be permitted to follow certain home country corporate governance practices instead of those otherwise required under Nasdaq for domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition and function of the audit committee and other committees of our Board of Directors and certain general corporate governance matters. In addition, in certain instances we will follow our home country law, instead of the Nasdaq, which requires that we obtain shareholder approval for certain dilutive events, such as an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company. We comply with the director independence requirements of the Nasdaq, including the requirement that a majority of the Board of Directors be independent. Following our home country governance practices as opposed to the requirements that would otherwise apply to a United States company listed on Nasdaq may provide less protection than is accorded to investors under Nasdaq applicable to domestic issuers.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as domestic companies whose securities are registered under the Exchange Act.

***ADS holders are not shareholders and do not have shareholder rights.***

The Bank of New York Mellon, as depositary, executes and delivers the ADSs on our behalf. Each ADS is a certificate evidencing a specific number of ADSs. The ADS holders will not be treated as shareholders and do not have the rights of shareholders. The depositary will be the holder of the shares underlying the ADSs. Holders of the ADSs will have ADS holder rights. A deposit agreement among us, the depositary and the ADS holders, and the beneficial owners of ADSs, sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs. Our shareholders have shareholder rights prescribed by Israeli law. Israeli law and our Articles of Association, or Articles, govern such shareholder rights. The ADS holders do not have the same voting rights as our shareholders. Shareholders are entitled to our notices of general meetings and to attend and vote at our general meetings of shareholders. At a general meeting, every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote on a show of hands. Every shareholder present (in person or by proxy, attorney or representative) and entitled to vote has one vote per fully paid ordinary share on a poll. This is subject to any other rights or restrictions which may be attached to any shares. The ADS holders may instruct the depositary to vote the ordinary shares underlying their ADSs, but only if we ask the depositary to ask for

their instructions. If we do not ask the depository to ask for their instructions, the ADS holders are not entitled to receive our notices of general meeting or instruct the depository how to vote. The ADS holders will not be entitled to attend and vote at a general meeting unless they withdraw the ordinary shares from the depository. However, the ADS holders may not know about the meeting far enough in advance to withdraw the ordinary shares. If we ask for the ADS holders' instructions, the depository will notify the ADS holders of the upcoming vote and arrange to deliver our voting materials and form of notice to them. The depository will try, as far as is practical, subject to the provisions of the deposit agreement, to vote the shares as the ADS holders instruct. The depository will not vote or attempt to exercise the right to vote other than in accordance with the instructions of the ADS holders. We cannot assure the ADS holders that they will receive the voting materials in time to ensure that they can instruct the depository to vote their shares. In addition, there may be other circumstances in which the ADS holders may not be able to exercise voting rights.

The ADS holders do not have the same rights to receive dividends or other distributions as our shareholders. Subject to any special rights or restrictions attached to a share, the directors may determine that a dividend will be payable on a share and fix the amount, the time for payment and the method for payment (although we have never declared or paid any cash dividends on our ordinary stock and we do not anticipate paying any cash dividends in the foreseeable future). Dividends and other distributions payable to our shareholders with respect to our ordinary shares generally will be payable directly to them. Any dividends or distributions payable with respect to ordinary shares will be paid to the depositary, which has agreed to pay to the ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, after deducting its fees and expenses. The ADS holders will receive these distributions in proportion to the number of shares their ADSs represent. In addition, there may be certain circumstances in which the depositary may not pay to the ADS holders amounts distributed by us as a dividend or distribution.

***There are circumstances where it may be unlawful or impractical to make distributions to the holders of the ADSs.***

The deposit agreement with the depositary allows the depositary to distribute foreign currency only to those ADS holders to whom it is possible to do so. If a distribution is payable by us in New Israeli Shekels, the depositary will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, the ADS holders may lose some of the value of the distribution.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. This means that the ADS holders may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for the depositary to make such distributions available to them.

***Shareholders' percentage ownership in us may be diluted by future issuances of share capital, which could reduce their influence over matters on which shareholders vote.***

Issuances of additional shares would reduce shareholders' influence over matters on which our shareholders vote.

***We may fail to remain in compliance with the continued listing standards of the Nasdaq Capital Market and a delisting of our ADSs could make it more difficult for investors to sell their shares***

Our ADSs were approved for listing on Nasdaq in July 2013 where they continue to be listed. The listing standards of the Nasdaq provide that a company, in order to qualify for continued listing, must maintain a minimum share price of \$1.00 and satisfy standards relative to minimum shareholders' equity, minimum market value of publicly held shares and various additional requirements.

On November 8, 2016, Nasdaq informed the Company that it had failed to maintain a minimum bid price of \$1 per share for more than 30 consecutive business days. On February 28, 2017, the Company received notification from Nasdaq that it had regained compliance with this requirement. However, there is no guarantee that we will be able to maintain compliance with the minimum share price requirement or other applicable requirements.

If we fail to comply with Nasdaq's continued listing standards, we may be delisted and our ADSs will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board or OTCQX market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our ADSs could depress the price of our ADSs, substantially limit liquidity of our ADSs and materially adversely affect our ability to raise capital on terms acceptable to us, or at all.

Finally, delisting of our ADSs would likely result in our ADSs becoming a “penny stock” under the Securities Exchange Act. The principal result or effect of being designated a “penny stock” is that securities broker-dealers cannot recommend the shares but must trade it on an unsolicited basis. Penny stock rules require a broker-dealer, prior to a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document prepared by the SEC, which specifies information about penny stocks and the nature and significance of risks of the penny stock market. A broker-dealer must also provide the customer with bid and offer quotations for the penny stock, the compensation of the broker-dealer and sales person in the transaction, and monthly account statements indicating the market value of each penny stock held in the customer’s account. In addition, the penny stock rules require that, prior to a transaction in a penny stock not otherwise exempt from those rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s written agreement to the transaction. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for shares that become subject to those penny stock rules. Under such circumstances, shareholders may find it more difficult to sell, or to obtain accurate quotations, for our ADSs, and our ADSs would become substantially less attractive to certain purchasers such as financial institutions, hedge funds and other similar investors.

## **Risks Relating to Operations in Israel**

### *Conditions in the Middle East and in Israel may harm our operations.*

Our head executive office, our research and development facilities, as well as some of our planned clinical sites are or will be located in Israel. Our officers and most of our directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries. Any hostilities involving Israel or the interruption or curtailment of trade between Israel and its trading partners could adversely affect our operations and results of operations. In recent years, the hostilities involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. Our offices, located in Raanana, Israel, are within the range of the missiles and rockets that have been fired sporadically at Israeli cities and towns from Gaza and South Lebanon since 2006, with escalations in violence during which there were a substantially larger number of rocket and missile attacks aimed at Israel. In addition, since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria, Lebanon and Jordan which share common borders with Israel, and is affecting the political stability of those countries. This instability and any outside intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries, and may have the potential for causing additional conflicts in the region. In addition, Iran has threatened to attack Israel and is widely believed to be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, and various rebel militia groups in Syria. Additionally, a violent jihadist group named Islamic State of Iraq and Levant (IS or ISIL or ISIS) is involved in hostilities in Iraq, Syria and other countries and has been growing in influence. Although ISIL’s activities have not directly affected the political and economic conditions in Israel, ISIL’s

stated purpose is to take control of the Middle East, including Israel. Since September 2015, there has been an increase in terrorist attacks on Israeli civilians including shootings, stabbings and car rammings which has impacted the general feeling of personal safety in the country. These situations may potentially escalate in the future to more violent events which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions, could harm our results of operations and could make it more difficult for us to raise capital. Parties with whom we do business may decline to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary in order to meet our business partners face to face. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements. Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot assure you that this government coverage will be maintained. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, the State of Israel and Israeli companies have been subjected to an economic boycott. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business.

***Our results of operations may be adversely affected by inflation and foreign currency fluctuations.***

We hold most of our cash, cash equivalents and bank deposits in U.S. dollars. As we are located in Israel, a significant portion of our expenses are in New Israeli Shekels, or NIS, mainly due to payment to Israeli employees and suppliers. As a result, we could be exposed to the risk that the U.S. dollar will be devalued against the NIS or other currencies, and consequentially our financial results could be harmed. To protect against currency fluctuations we may decide to hold a significant portion of our cash, cash equivalents, bank deposits and marketable securities in NIS, as well as to enter into currency hedging transactions. These measures, however, may not adequately protect us from the adverse effects of inflation in Israel. In addition, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the New Israeli Shekel in relation to the U.S. dollar or that the timing of any devaluation may lag behind inflation in Israel.

***Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.***

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the holder of a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not

have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to those of our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.



***It may be difficult to enforce a U.S. judgment against us, our officers or our directors or to assert U.S. securities law claims in Israel.***

Service of process upon us, since we are incorporated in Israel, and upon our directors and officers, who reside outside the U.S., may be difficult to obtain within the U.S. In addition, because substantially all of our assets and most of our directors and officers are located outside the U.S., any judgment obtained in the U.S. against us or any of our directors and officers may not be collectible within the U.S. There is a doubt as to the enforceability of civil liabilities under the Securities Act or the Exchange Act pursuant to original actions instituted in Israel. Subject to particular time limitations and provided certain conditions are met, executory judgments of a U.S. court for monetary damages in civil matters may be enforced by an Israeli court.

***Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, employees may be entitled to seek compensation for their inventions irrespective of their agreements with us, which in turn could impact our future profitability.***

We generally enter into non-competition agreements with our employees and key consultants. These agreements prohibit our employees and key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

In addition, Chapter 8 to the Israeli Patents Law, 5727-1967, or the Patents Law, deals with inventions made in the course of an employee's service and during his or her term of employment, whether or not the invention is patentable, or service inventions. Section 134 of the Patents Law, sets forth that if there is no agreement which explicitly determines whether the employee is entitled to compensation for the service inventions and the extent and terms of such compensation, such determination will be made by the Compensation and Rewards Committee, a statutory committee of the Israeli Patents Office. As a result, it is unclear if, and to what extent, our research and development employees may be able to claim compensation with respect to our future revenue. As a result, we may receive less revenue from future products if such claims are successful, which in turn could impact our future profitability.

***Your rights and responsibilities as a shareholder will be governed by Israeli law which may differ in some respects from the rights and responsibilities of shareholders of U.S. companies.***

We are incorporated under Israeli law. The rights and responsibilities of the holders of our ordinary shares and ADSs are governed by our Articles of Association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S.-based corporations. In particular, a shareholder of an Israeli company has a duty to act in good faith toward the company and other shareholders and to refrain from abusing its power in the company, including, among other things, in voting at the general meeting of shareholders on matters such as amendments to a company's articles of association, increases in a company's authorized share capital, mergers and acquisitions and interested party transactions requiring shareholder approval. In addition, a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or to appoint or prevent the appointment of a director or executive officer in the company has a duty of fairness toward the company. There is limited case law available to assist us in understanding the implications of these provisions that govern shareholders' actions. These provisions may be interpreted to impose additional obligations and liabilities on holders of our ordinary shares and ADSs that are not typically imposed on shareholders of U.S. corporations.

## ITEM 4. INFORMATION ON THE COMPANY

### A. History and Development of XTL

We are a biopharmaceutical company engaged in the acquisition and development of pharmaceutical drugs for the treatment of autoimmune diseases. Our current drug development program is focused on the development of hCDR1 for the treatment of SLE and SS.

#### *Company Information and History*

Our legal and commercial name is XTL Biopharmaceuticals Ltd. We were established as a private company limited by shares under the laws of the State of Israel on March 9, 1993, under the name Xenograft Technologies Ltd. We re-registered as a public company on June 7, 1993, in Israel, and changed our name to XTL Biopharmaceuticals Ltd. on July 3, 1995. We commenced operations to use and commercialize technology developed at the Weizmann Institute, in Rehovot, Israel. Until 1999, our therapeutic focus was on the development of human monoclonal antibodies to treat viral, autoimmune and oncological diseases. Our first therapeutic programs focused on antibodies against the hepatitis B virus, interferon – and the Hepatitis C virus. Our current drug development program is currently focused on the treatment of SLE and SS.

In March 2009, we signed an asset purchase agreement to acquire the rights to develop rHuEPO for the treatment of Multiple Myeloma in exchange for the issuance of ordinary shares of XTL representing approximately 69.44% of our then issued and outstanding ordinary share capital at the issuance date. Under the agreement, we are obligated to pay 1% royalties on net sales of rHuEPO, as well as a fixed royalty payment in the total amount of \$350 thousand upon the success of Phase 2. Such payment of \$350 thousand mentioned above shall be made to Yeda upon the earlier of (i) six months from the successful completion of Phase 2 or (ii) the completion of a successful fundraising by XTL at any time after the completion of Phase 2 of at least \$2 million.

On January 7, 2014, the Company entered into a licensing agreement with Yeda to research, develop and commercialize hCDR1, a Phase II-ready asset for the treatment of Systemic Lupus Erythematosus ("SLE"), among other indications. The terms of the licensing agreement include, among other things, expense reimbursement for patent expenses payable in six installments (see below), certain milestone payments to Yeda, low single-digit royalties based on net sales, and additional customary royalties to the Office of the Chief Scientist.

Lupus is a debilitating disease affecting approximately five million people worldwide, according to the Lupus Foundation of America. hCDR1 is a peptide, short chains of amino acid monomers, and acts as a disease-specific treatment to m