UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

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

☒ 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

☐ TRANSITION 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
Date of event requiring this shell company report _____

Commission file number 001-35773

RedHill Biopharma Ltd.
(Exact name of Registrant as specified in its charter)

N/A
(Translation of Registrant's name into English)

Israel
(Jurisdiction of incorporation or organization)

21 Ha'arba'a Street, Tel Aviv 64739, Israel
(Address of principal executive offices)

Ori Shilo, Deputy Chief Executive Officer Finance and Operations
21 Ha'arba'a Street, Tel Aviv 64739, Israel
Tel: 972-3-541-3131; Fax: 972-3-541-3144
(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.

Title of class	Name of each exchange on which registered
American Depositary Shares, each representing ten Ordinary Shares (1)	Nasdaq Capital Market
Ordinary Shares, par value NIS 0.01 per share (2)	Nasdaq Capital Market

(1) Evidenced by American Depositary Receipts.
(2) Not for trading, but only in connection with the listing of the American Depositary Shares.

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

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None

(Title of Class)

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: 127,114,294

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 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 (§232.405 of this chapter) 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:

U.S. GAAP ☐

International Financing Reporting Standards as issued by the International Accounting

Standards Board ☒
Other ☐

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

Item 17 [ ] Item 18 [ ]

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and, as such, may elect to comply with certain reduced public company reporting requirements.

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Unless the context otherwise requires, all references to "RedHill," "we," "us," "our," the "Company" and similar designations refer to RedHill Biopharma Ltd. The term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar", "US$" or "$" refer to U.S. dollars, the lawful currency of the U.S. Our functional and presentation currency is the U.S. dollar. Unless otherwise indicated, U.S. dollar amounts herein (other than amounts originally receivable or payable in dollars) have been translated for the convenience of the reader from the original NIS amounts at the representative rate of exchange as of February 22, 2016 ($1 = NIS 3.907). The dollar amounts presented should not be construed as representing amounts that are receivable or payable in dollars or convertible into dollars, unless otherwise indicated. Foreign currency transactions in currencies other than the U.S. dollar are translated in this Annual Report into U.S. dollars using exchange rates in effect at the date of the transactions.

All references to the term "therapeutic candidates" include both pharmaceuticals and programs related to their development, such as diagnostics and devices.

FORWARD-LOOKING STATEMENTS

Some of the statements under the sections entitled "Item 3. Key Information — Risk Factors," "Item 4. Information on the Company," "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report may include forward looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. In addition, the sections of this Annual Report entitled "Item 4. Information on the Company" contain information obtained from independent industry and other sources that we have not been independently verified. You should not put undue reliance on any forward-looking statements. Unless we are required to do so under U.S. federal securities laws or other applicable laws, we do not intend to update or revise any forward-looking statements.

Factors that could cause our actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to

- the initiation, timing, progress and results of our research, manufacturing, preclinical studies, clinical trials, and other therapeutic candidate development efforts, as well as the extent and number of additional studies that we may be required to conduct;
- our ability to advance our therapeutic candidates into clinical trials or to successfully complete our preclinical studies or clinical trials;
- our receipt of regulatory clarity and approvals for our therapeutic candidates, and the timing of other regulatory filings and approvals;
- the research, manufacturing, clinical development, commercialization, and market acceptance of our therapeutic candidates;
- our ability to establish and maintain corporate collaborations;
- our ability to acquire products approved for marketing in the U.S. that achieve commercial success and build our own marketing and commercialization capabilities;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in research, manufacturing, preclinical studies or clinical trials;
- the implementation of our business model, strategic plans for our business and therapeutic candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing upon the intellectual property rights of others;
- estimates of our expenses, future revenues capital requirements and our need for additional financing;
- competitive companies, technologies and our industry; and
- the impact of the political and security situation in Israel on our business.

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 following table sets forth our selected financial data, which is derived from our financial statements prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board, or IFRS. We have derived the selected financial data as of December 31, 2015 and 2014 and for the years ended December 31, 2015, 2014 and 2013 from our audited financial statements included elsewhere in this Annual Report on Form 20-F. We have derived the selected financial data as of December 31, 2011, 2012, and 2013 and for the years ended December 31, 2012 and 2011 from our audited financial statements not included in this Annual Report. You should read this selected financial data and other information provided in this Annual Report in conjunction with, and is qualified in its entirety by, our historical financial information including "Item 5. Operating and Financial Review and Prospects" and our financial statements and related notes appearing elsewhere in this Annual Report.

	Year ended December 31				
	2015	**2014**	**2013**	**2012**	**2011**
Statement of Comprehensive Loss					
Revenues	3	7,014	12	16	23
Cost of Revenue	-	1,050	-	-	-
Research and development expenses, net	17,771	12,700	8,100	6,455	5,414
General and administrative expenses	4,134	4,011	2,684	2,601	2,482
Other (income) expenses	100	(100)	-	-	-
Operating loss	22,002	10,647	10,772	9,040	7,873
Financial income	1,124	319	158	197	570
Financial expenses	212	383	14	1,483	8,200
Financial (income) expenses, net	(912)	64	(144)	1,286	7,630
Loss and comprehensive loss	21,090	10,711	10,628	10,326	15,503
Loss per ordinary share (in U.S. dollars)					
Basic	0.19	0.12	0.17	0.20	0.32
Diluted	0.19	0.13	0.17	0.20	0.32
Weighted average number of ordinary shares used in computing loss per ordinary share	110,813,742	86,610,126	62,379,171	52,595,128	48,087,362
Weighted average number of ordinary shares used in computing diluted loss per share	111,714,566	87,222,188	62,379,171	52,595,128	48,087,362

	As of December 31				
	2015	**2014**	**2013**	**2012**	**2011**
Balance Sheet Data					
Cash and short term investments	58,138	22,945	12,113	18,365	18,647
Working capital	54,996	24,299	10,186	17,485	18,223
Total assets	66,828	28,856	14,340	20,096	20,186
Total liabilities	6,751	3,845	2,415	1,078	1,399
Accumulated deficit	(61,944)	(42,218)	(33,260)	(23,887)	(15,209)
Equity	60,077	25,011	11,925	19,018	18,787

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

You should carefully consider the risks we describe below, in addition to the other information set forth elsewhere in this Annual Report, including our financial statements and the related notes beginning on page F-1, before deciding to invest in our ordinary shares or our American Depositary Shares. These material risks could adversely impact our results of operations, possibly causing the trading price of our ordinary shares and American Depositary Shares to decline, and you could lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

We are a clinical development-stage biopharmaceutical company with a history of operating losses. We expect to incur additional losses in the future and may never be profitable.

We are a clinical development-stage biopharmaceutical company. Since our incorporation in 2009, we have been focused primarily on the development and acquisition of late clinical-stage therapeutic candidates. All of our therapeutic candidates are in the clinical development stage, and, except for RIZAPORT™ which has been approved for marketing in Germany but has yet to be marketed, none has been approved for marketing or is being marketed or commercialized. Most of our therapeutic candidates require additional clinical trials before we can obtain the regulatory approvals in order to initiate commercial sales. We have incurred losses since inception, principally as a result of research and development and general and administrative expenses in support of our operations. We experienced net losses of approximately $21.1 million in 2015 and $10.7 million in 2014. As of December 31, 2015, we had an accumulated deficit of approximately $61.9 million. We may incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our therapeutic candidates. Our ability to generate revenue and achieve profitability depends mainly upon our ability, alone or with others, to successfully develop our therapeutic candidates, obtain the required regulatory approvals in various territories and commercialize our therapeutic candidates. We may be unable to achieve any or all of these goals with regard to our therapeutic candidates. As a result, we may never be profitable or achieve significant and/or sustained revenues.

Our limited operating history makes it difficult to evaluate our business and prospects.

We have a limited operating history and our operations to date have been limited primarily to acquiring and in-licensing therapeutic candidates, research and development, raising capital and recruiting scientific and management personnel and third party partners. Except with respect to RHB-106 and related rights, which is out-licensed to Valeant Pharmaceuticals International, Inc. (Valeant), and with respect to RIZAPORT™, for which we have received marketing approval in Germany, we have not yet demonstrated an ability to commercialize or obtain regulatory approval for any of our therapeutic candidates. Consequently, any predictions about our future performance may not be accurate, and you may not be able to fully assess our ability to complete development and/or commercialize our therapeutic candidates, obtain regulatory approvals, or achieve market acceptance or favorable pricing for our therapeutic candidates.

Our current working capital is not sufficient to complete our research and development with respect to all of our therapeutic candidates. We will need to raise additional capital to achieve our strategic objectives of acquiring, developing and commercializing therapeutic candidates, and our failure to raise sufficient capital would significantly impair our ability to fund our operations, develop our therapeutic candidates, attract development and/or commercial partners and retain key personnel.

We have funded our operations primarily through public and private offerings of our securities. We plan to fund our future operations through commercialization and out-licensing of our therapeutic candidates and raising additional capital. As of December 31, 2015, we had cash and short-term investments of approximately $58.1 million, and as of December 31, 2014, we had cash and short term investments of approximately $22.9 million. These amounts are not sufficient to complete the research and development of all of our therapeutic candidates, and accordingly we may need to raise additional capital in the coming year.

To date, our business generated limited revenues. As we plan to continue expending substantial funds in research and development, including clinical trials, as well as to acquire additional products, we will need to raise additional capital in the future through either debt or equity financing or pursuant to development or commercialization agreements with third parties with respect to particular therapeutic candidates. However, we cannot be certain that we will be able to raise capital on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We may have difficulty raising needed capital or securing a development or commercialization partner in the future as a result of, among other factors, our lack of revenues from commercialization of the therapeutic candidates, as well as the inherent business risks associated with our company, our therapeutic candidates and present and future market conditions. In addition, global and local economic conditions may make it more difficult for us to raise needed capital or secure a development or commercialization partner in the future and may impact our liquidity. If we are unable to obtain future financing or obtain sufficient future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research, development or commercialization programs for our therapeutic candidates, any of which may have material adverse effect on our business, financial condition and results of operations. Moreover, to the extent we are able to raise capital through the issuance of debt or equity securities, it could result in substantial dilution to existing shareholders.

Our long-term capital requirements are subject to numerous risks.

Our long term capital requirements are expected to depend on many potential factors, including:

- the number of therapeutic candidates in development;
- the regulatory clarity and path of each of our therapeutic candidates;
- the progress, success and cost of our clinical trials and research and development programs including manufacturing;
- the identification and acquisition of additional therapeutic candidates;
- the costs, timing and outcome of regulatory review and obtaining regulatory clarity and approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of manufacturing, developing sales, marketing and distribution channels;
- our ability to successfully commercialize our therapeutic candidates, including through securing commercialization agreements with third parties and favorable pricing and market share or through securing our own commercialization capabilities; and
- our consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

Risks Related to Our Business and Regulatory Matters

If we and/or our commercialization partners are unable to obtain FDA and/or other foreign regulatory authority clarity and approval for our therapeutic candidates, we and/or our commercialization partners will be unable to commercialize our therapeutic candidates.

To date, we have not marketed, distributed or sold any therapeutic candidate or other product. Currently, we have eight therapeutic candidates, which includes one therapeutic candidate (RP101) for which we have an option to acquire, in various programs and clinical development stages, "RHB-105" for the eradication of *H. pylori* infection; "RHB-104" for the treatment of Crohn's disease and potentially other diseases; "RHB-106" (out-licensed to Valeant) for bowel preparation; BEKINDA™ (RHB-102) for acute gastroenteritis and gastritis, irritable bowel syndrome with diarrhea (IBS-D) and for the prevention of chemotherapy and radiotherapy induced nausea and vomiting; YELIVA™ (ABC294640), a sphingosine kinase-2 (SK2) selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal indications; MESUPRON® targeting gastrointestinal and other solid tumor cancers; "RP101" (currently subject to an option-to-acquire by us) targeting pancreatic and other gastrointestinal cancers; and "RIZAPORT™" (RHB-103) for the treatment of acute migraine headaches. Our therapeutic candidates are subject to extensive governmental laws, regulations and guidelines relating to development, clinical trials, manufacturing and commercialization of drugs. Other than RIZAPORT™ which has received marketing approval to date only in Germany, we may not be able to obtain marketing approval for any of our therapeutic candidates in a timely manner or at all.

Any material delay in obtaining, or the failure to obtain, required regulatory clarity and approvals will increase our costs and materially and adversely affect our ability to generate future revenues. Any regulatory approval to market a therapeutic candidate may be subject to limitations on the indicated uses for marketing the therapeutic candidate or may impose restrictive conditions of use, including cautionary information, thereby limiting the size of the market for the therapeutic candidate. We also are, and will be, subject to numerous regulatory requirements from both the U.S. Food and Drug Administration (FDA) and foreign state agencies that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. Moreover, approval by one regulatory authority does not ensure approval by other regulatory authorities in separate jurisdictions. Each jurisdiction may have different approval processes and may impose additional testing, development and manufacturing requirements for our therapeutic candidates than other jurisdictions. Additionally, the FDA or other foreign regulatory bodies may change their approval policies or adopt new laws, regulations or guidelines in a manner that materially delays or impairs our ability to obtain the necessary regulatory approvals or our ability to commercialize our therapeutic candidates.

Clinical trials and related non-clinical studies may involve a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We and/or commercialization partners will not be able to commercialize our therapeutic candidates without completing such trials.

We have limited experience in conducting and managing the clinical trials that are required to commence commercial sales of our therapeutic candidates. Clinical trials and related non-clinical studies are expensive, complex, can take many years and have uncertain outcomes. We cannot predict whether we, independently or through third parties, will encounter problems with any of the completed, ongoing or planned clinical trials that will cause delays, including suspension of a clinical trial, delay of data analysis or release of the final report. The clinical trials of our therapeutic candidates may take significantly longer to complete than is estimated. Failure can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could materially delay or prevent commercialization of our current or future therapeutic candidates.

In connection with the clinical trials for our therapeutic candidates and other therapeutic candidates that we may seek to develop in the future, either on our own or through licensing or partnering agreements, we face various risks and uncertainties, including but not limited to:

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in receiving import or other government approvals to ensure appropriate drug supply;
- delays in obtaining institutional review board and other regulatory approvals to commence a clinical trial;
- expiration of clinical trial material before or during our trials as a result of degradation of, or other damage to, the clinical trial material;
- negative or inconclusive results from clinical trials;
- the FDA or other foreign regulatory authorities may disagree with the number, design, size, conduct or implementation of our clinical studies;
- the FDA or other foreign regulatory authorities may require us to conduct additional clinical trials and/or studies;
- inability to monitor patients adequately during or after treatment;
- problems with investigator or patient compliance with the trial protocols;
- a therapeutic candidate may not prove safe or efficacious; there may be unexpected or even serious adverse events and side effects from the use of a therapeutic candidate;
- the results with respect to any therapeutic candidate may not confirm the positive results from earlier preclinical studies or clinical trials;
- the results may not meet the level of statistical significance required by the FDA or other foreign regulatory authorities;
- the results may justify only limited and/or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of a therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates; and
- changes to the current regulatory requirements related to clinical trials which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory approvals.

A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after seeing promising results in earlier clinical trials. As such, despite the results reported in earlier clinical trials of our therapeutic candidates, we do not know if the clinical trials we conduct will demonstrate adequate efficacy and safety sufficient to obtain regulatory approval to market our therapeutic candidates. If any of the clinical trials of any therapeutic candidate do not produce favorable results, our ability to obtain regulatory approval for the therapeutic candidate may be adversely impacted, which will have a material adverse effect on our business, financial condition and results of operations.

If we do not establish collaborations for our therapeutic candidates or otherwise raise substantial additional capital, we will likely need to alter our development and any commercialization plans.

Our drug development programs and the potential commercialization of our therapeutic candidates will require additional cash to fund expenses. As such, our strategy includes either selectively partnering or collaborating with multiple pharmaceutical and biotechnology companies to assist us in furthering development and/or potential commercialization of our therapeutic candidates, in whole or in part, in some or all jurisdictions or through securing our own commercialization capabilities. Although we are currently aware of numerous potential new third party partners for the development or commercialization of our therapeutic candidates, we may not be successful in entering into new collaborations with third parties on acceptable terms, or at all. In addition, if we fail to negotiate and maintain suitable development and/or commercialization agreements or otherwise raise substantial additional capital to secure our own commercialization capabilities, we may have to limit the size or scope of our activities or we may have to delay one or more of our development or commercialization programs. Any failure to enter into development or commercialization agreements with respect to the development, marketing and commercialization of any therapeutic candidate or failure to develop, market and commercialize such therapeutic candidate independently will have an adverse effect on our business, financial condition and results of operations.

Any collaborative arrangements that we have established or may be established may not be successful or we may otherwise not realize the anticipated benefits from these collaborations, including our out-license of RHB-106. We do not control third parties with whom we have or may have collaborative arrangements, and we rely on them to achieve results which may be significant to us. In addition, any future collaborative arrangements may place the development and commercialization of our therapeutic candidates outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

Each of our collaborative arrangements requires us to rely on external consultants, advisors, and experts for assistance in several key functions, including clinical development, manufacturing, regulatory, market research, intellectual property and commercialization. We do not control these third parties, but we rely on them to achieve results which may be significant to us. To date, we have out-licensed one of our therapeutic candidates, RHB-106 and related rights to Valeant. We do not control Valeant, but we rely on Valeant to clinically develop and commercialize the product based on the license agreement.

Relying upon collaborative arrangements to develop and commercialize our therapeutic candidates, such as our out-license of RHB-106 and related rights, subjects us to a number of risks, including but not limited to:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our therapeutic candidates;
- should a collaborator fail to comply with applicable laws, rules, or regulations when performing services for us, we could be held liable for such violations;
- our collaborators may experience financial difficulties or changes in business focus;
- our collaborators' partners may fail to secure adequate commercial supplies of our therapeutic candidates upon marketing approval, if at all;
- our collaborators' partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business or business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate developed either independently or in collaboration with others, including our competitors; and
- collaborative arrangements are often terminated or allowed to expire, which could delay the development and may increase the cost of developing our therapeutic candidates.

If any of these scenarios materialize, they could have an adverse effect on our business, financial condition or results of operations.

We may not be successful in acquiring products and/or companies that own the rights to FDA-approved products (approved for marketing in the U.S.) that achieve commercial success or building our own marketing and commercialization capabilities.

Part of our strategy is to identify and acquire rights to products that have been approved for marketing in the U.S. Specifically, we seek to acquire rights to products that are already commercialized in the U.S., which would enable us to commercialize such products independently and build our own marketing and commercialization capabilities. However, there can be no assurance as to our ability to identify and acquire rights to such products, in particular those with a therapeutic focus on GI, inflammation and/or cancer. If we are not successful in acquiring any such products, we may not be able to build our own marketing and commercialization capabilities. This may limit our ability to commercialize our products on our own or require us to contract with third party commercialization partners which may not be on commercially favorable terms and which may result in additional commercialization and marketing expenses.

In addition, there can be no assurance as to our ability to accurately or consistently identify products approved for marketing in the U.S. that will achieve commercial success or that we will successfully commercialize these products in the U.S.

We may encounter difficulties successfully expanding our operations to build our own marketing and commercialization capabilities.

To build our own marketing and commercialization capabilities, we would need to expand our development, regulatory, manufacturing, marketing and sales capabilities and to increase our personnel to accommodate sales, including establishing a direct sales force and a complete commercial team. Expanding our operations would also impose significant added responsibilities on our management. We must be able to manage our independent commercialization efforts effectively; hire, train and integrate additional management, development, administrative and sales and marketing personnel; improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure and adversely affect our research and development activities. We may also not have sufficient funds to finance the hiring of the additional personnel and the expansion of our marketing and commercialization activities. If we are not able to effectively expand our operations to build our own marketing and commercialization capabilities, our revenues and growth may be adversely affected, which will have a material adverse effect on our business, financial condition and results of operations.

We have no history of independently commercializing therapeutic candidates and may have difficulty commercializing products on our own.

We have no prior experience in commercializing therapeutic candidates on our own, which may materially increase marketing and sales expenses. There can be no assurance we will successfully commercialize our products or the products we acquire.

In addition, many companies, both public and private, including well-known pharmaceutical companies and smaller niche-focused companies, are currently distributing drug products that directly compete with the therapeutic candidates that we may seek to commercialize. Many of these companies have significantly greater financial, marketing and sales experience and resources than us. As a result, our competitors may be more successful than we are in commercializing their products to consumers.

We rely on third parties to conduct our clinical trials and related non-clinical studies and those third parties may not perform satisfactorily, including but not limited to failing to meet established deadlines for the completion of such clinical trials.

We currently do not have the ability to independently conduct clinical trials and related non-clinical studies for our therapeutic candidates, and we rely on third parties, such as contract research organizations, medical institutions, contract laboratories, development and commercialization partners, clinical investigators and independent study monitors to perform these functions. Our reliance on these third parties for clinical development activities reduces our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have, in the ordinary course of business, entered into agreements with such third parties, other than with respect to RHB-106 and related rights, which we have out-licensed to Valeant, we continue to be responsible for confirming that each of our clinical trials is conducted in accordance with its general investigational plan and protocol. Moreover, the FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. Our reliance on third parties does not relieve us of these responsibilities and requirements. To date, we believe our contract research organizations and other similar entities with which we are working have performed well. However, if these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them or perform such functions independently. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial and additional costs. Accordingly, we may be materially delayed in obtaining regulatory approvals for our therapeutic candidates and may be materially delayed in our efforts to successfully commercialize our therapeutic candidates for targeted diseases.

In addition, our ability to bring our therapeutic candidates to market depends on the quality and integrity of data that we present to regulatory authorities in order to obtain marketing authorizations. Although we attempt to audit and control the quality of third party data, we cannot guarantee the authenticity or accuracy of such data, nor can we be certain that such data has not been fraudulently generated.

If third parties do not manufacture our therapeutic candidates with sufficient quality, in sufficient quantities, in the required timeframe, and at an acceptable cost, clinical development and commercialization of our therapeutic candidates would be delayed.

We do not currently own or operate manufacturing facilities, and we rely, and expect to continue to rely, on third parties to manufacture clinical and commercial quantities of our therapeutic candidates. Our reliance on third parties includes our reliance on them for quality assurance related to regulatory compliance. Our current and anticipated future reliance upon others for the manufacture of our therapeutic candidates may adversely affect our future profit margins, if any, and our ability to develop therapeutic candidates and commercialize any therapeutic candidates on a timely and competitive basis.

We may not be able to maintain our existing or future third-party manufacturing arrangements on acceptable terms, if at all. If for some reason our manufacturers do not perform as agreed or expected, we may be required to replace them. Although we are not substantially dependent upon our existing manufacturing agreements since we could replace them with other third party manufacturers, we may incur added costs and delays in identifying, engaging, qualifying and training any such replacements.

We rely on third-party-contract vendors to manufacture and supply us with high quality APIs (or active pharmaceutical ingredients) in the quantities we require on a timely basis.

We currently do not manufacture any APIs ourselves. Instead, we rely on third-party vendors for the manufacture and supply of our APIs that are used to formulate our therapeutic candidates. While there are many potential API suppliers in the market, if these suppliers are incapable or unwilling to meet our current or future needs on acceptable terms or at all, we could experience a delay in obtaining regulatory approval for our therapeutic candidates or conducting additional clinical trials of our therapeutic candidates and incur additional costs.

For example, our supplier of raw materials for RIZAPORT™ has been sending updates to the FDA regarding progress of corrective actions in regard to compliance issues at its manufacturing facility and subsequently invited the FDA for re-inspection, which are independent of us and not specific to RIZAPORT™. Although the supplier is working to solve its compliance issues and although we are working to ensure continued supply of the necessary raw materials for RIZAPORT™ regardless of the outcome of its compliance discussions, our ability to obtain FDA approval for RIZAPORT™ may be delayed until we are able to secure a compliant source of API, and successfully manufacture new batches with the new API.

While there may be several alternative suppliers of API on the market, we have yet to conclude extensive investigations into the quality or availability of their APIs. As a result, we can provide no assurances that supply sources will not be interrupted from time to time. Changing API suppliers or finding and qualifying new API suppliers can be costly and take a significant amount of time. Many APIs require significant lead time to manufacture. There can also be challenges in maintaining similar quality or technical standards from one manufacturing batch to the next.

If we are not able to find stable, affordable, high quality, or reliable supplies of our APIs, we may not be able to produce enough supplies of our therapeutic candidates, which could materially adversely affect our business, financial condition or results of operations.

We anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our therapeutic candidates.

To date, our therapeutic candidates have been manufactured in relatively small quantities for preclinical testing and clinical trials as well as for other regulatory purposes by third-party manufacturers. If the FDA or other regulatory agencies approve any of our therapeutic candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved therapeutic candidates. These manufacturers may not be able to successfully increase the manufacturing capacity for any of our approved therapeutic candidates in a timely or economic manner, or at all. Significant scale-up of manufacturing may require additional validation studies, which the FDA or other foreign regulatory agencies must review and approve. If they are unable to successfully increase the manufacturing capacity for a therapeutic candidate, or we are unable to establish our own manufacturing capabilities or secure replacement manufacturers, the commercial launch of any approved products may be delayed or there may be a shortage in supply.

We and our third-party manufacturers are, and will be, subject to regulations of the FDA and other foreign regulatory authorities.

We and our contract manufacturers are, and will be, required to adhere to laws, regulations and guidelines of the FDA or other foreign regulatory authorities setting forth current good manufacturing practices. These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates. We and our manufacturers may not be able to comply with applicable laws, regulations and guidelines. We and our manufacturers are and will be subject to unannounced inspections by the FDA, state regulators and similar foreign regulatory authorities outside the United States (U.S.). Our failure, or the failure of our third-party manufacturers, to comply with applicable laws, regulations and guidelines could result in the imposition of sanctions on us, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our therapeutic candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates, and materially and adversely affect our business, financial condition and results of operations.

Even if we obtain regulatory approvals, our therapeutic candidates will be subject to ongoing regulatory review. If we fail to comply with continuing U.S. and applicable foreign laws, regulations and guidelines, we could lose those approvals, and our business may be seriously harmed.

Even if our therapeutic candidates receive regulatory approval, we or our commercialization partners, as applicable, will be subject to ongoing reporting obligations, including pharmacovigilance, and the therapeutic candidates and the manufacturing operations will be subject to continuing regulatory review, including inspections by the FDA or other foreign regulatory authorities. The results of this ongoing review may result in the withdrawal of a therapeutic candidate from the market, the interruption of the manufacturing operations and/or the imposition of labeling and/or marketing limitations. Since many more patients are exposed to drugs following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the therapeutic candidate. As we develop our product candidates, we may also periodically discuss with the FDA certain clinical, regulatory and manufacturing matters and our views may, at times, differ from those of the FDA. For example, the FDA may seek to regulate our therapeutic candidates that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's claimed effect. If the FDA raises questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in such combination drug products, we may be required to provide additional information, which may include the results of additional preclinical studies or clinical trials. If we are required to conduct additional clinical trials or other testing of our product candidates, we may face substantial additional expenses, be delayed in obtaining marketing approval for our product candidates or may never obtain marketing approval.

In addition, the manufacturer and the manufacturing facilities that we or our commercialization partners use to produce any therapeutic candidate will be subject to periodic review and inspection by the FDA and other foreign regulatory authorities. Later discovery of previously unknown problems with any therapeutic candidate, manufacturer or manufacturing process, or failure to comply with rules and regulatory requirements, may result in actions, including but not limited to the following:

- restrictions on such therapeutic candidate, manufacturer or manufacturing process;
- warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the therapeutic candidate from the market;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications that we or our commercialization partners submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our therapeutic candidates;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

If we, or our commercialization partners, suppliers, third party contractors or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we or our commercialization partners may lose marketing approval for any of our therapeutic candidates if any of our therapeutic candidates are approved, resulting in decreased or lost revenue from milestones, product sales or royalties.

Modifications to our therapeutic candidates, or to any other therapeutic candidates that we may acquire or develop in the future, may require new regulatory clearances or approvals or may require us or our development and/or commercialization partners, as applicable, to recall or cease marketing of these therapeutic candidates until clearances are obtained.

Modifications to our therapeutic candidates, after they have been approved for marketing, if at all, or to any other pharmaceutical product or medical device that we may acquire or develop in the future, may require new regulatory clearance or approvals, and, if necessitated by a problem with a marketed product, may result in the recall or suspension of marketing of the previously approved and marketed product until clearances or approvals of the modified product are obtained. The FDA and other foreign regulatory authorities require pharmaceutical products and device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplement or clearance. A manufacturer may determine in conformity with applicable laws, regulations and guidelines that a modification may be implemented without pre-clearance by the FDA or other foreign regulatory authorities. However, the FDA or other foreign regulatory authorities can review a manufacturer's decision and may disagree. The FDA or other foreign regulatory authorities may also on their own initiative determine that a new clearance or approval is required. If the FDA or other foreign regulatory authorities require new clearances or approvals of any pharmaceutical product for which we or our partners, including development and/or commercialization partners previously received marketing approval, we or our partners, including development and/or commercialization partners may be required to recall such therapeutic candidate and to stop marketing the therapeutic candidate as modified, which could require us or our partners, including development and/or commercialization partners to redesign the therapeutic candidate and may cause a material adverse effect on our business, financial condition and results of operations.

We depend on our ability to identify and in-license or acquire therapeutic candidates to achieve commercial success, including products approved for marketing in the U.S.

Our eight therapeutic candidates were all acquired by us from or licensed to us by third parties, other than RP101 for which we have an option to acquire. We evaluate internally and with external consultants each therapeutic candidate. However, there can be no assurance as to our ability to accurately or consistently identify therapeutic candidates that are likely to achieve commercial success, specifically therapeutic candidates that have been approved for marketing in the U.S. In addition, even if we identify additional therapeutic candidates that are likely to achieve commercial success, there can be no assurance as to our ability to in-license or acquire such therapeutic candidates under favorable terms or at all.

We compete with other entities for some of our in-license or acquisition opportunities.

As part of our overall strategy, we pursue opportunities to in-license or acquire therapeutic candidates. We may compete for in-license and acquisition opportunities with other, established and well-capitalized companies. As a result, we may be unable to in-license or acquire additional therapeutic candidates at all or on favorable terms. Our failure to further in-license or acquire therapeutic candidates in the future may materially hinder our ability to grow and could materially harm our business, financial condition and results of operations.

If we cannot meet our obligations under our acquisition or in-license agreements or we cannot renegotiate our obligations, or if other events occur that are not within our control such as bankruptcy of a licensor, we could lose the rights to our therapeutic candidates and/or experience delays in developing and/or commercializing our therapeutic candidates, or incur additional costs, which could have a material adverse effect on our business.

We acquired our rights to three of our therapeutic candidates, RHB-105, RHB-104 and RHB-106, from a third party pursuant to an asset and purchase agreement. In addition, we in-licensed our rights to four other therapeutic candidates, BEKINDA™, YELIVA™, MESUPRON® and RIZAPORT™ pursuant to license agreements in which we received exclusive perpetual licenses to certain patent rights and know-how related to these therapeutic candidates. We have also obtained an option-to-acquire for RP101. These agreements require us to make payments and satisfy various performance obligations in order to maintain our rights and licenses with respect to these therapeutic candidates. If we do not meet our obligations under these agreements, or if other events occur that are not within our control such as the bankruptcy of a licensor, we could lose the rights to our therapeutic candidates, experience delays in developing and/or commercializing our therapeutic candidates and/or incur additional costs, any of which could have a material adverse effect on our business, financial condition and results of operations. In addition, our agreement with IntelGenx Corp. requires us to renegotiate certain provisions of the agreement in the event the agreed-to budget is exceeded by a certain amount. In the event we are required to renegotiate this agreement, there is no guarantee that we will agree upon new terms promptly, or at all, which could delay the development and/or commercialization of RIZAPORT™. Moreover, if we elect not to exercise the option-to-acquire RP101, the term of which was extended in 2015 under the option agreement for an additional 12 month period, we may lose all of our rights in relation to RP101.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under these agreements in a timely manner and/or if other events occur that are not within our control, such as the bankruptcy of a licensor, which impacts our ability to prosecute certain patent applications and maintain certain issued patents licensed to us, we could lose the rights to our therapeutic candidates which could have a material adverse effect on our business, financial condition and results of operations. We manage a large portfolio of patents and may decide to discontinue maintaining certain patents in certain territories for various reasons, such as a current belief that the commercial market for the therapeutic candidate will not be large or that there is a near-term patent expiration that may reduce the value of the therapeutic candidate. In the event we discontinue maintaining such patents, we may not be able to enforce rights for our therapeutic candidates or protect our therapeutic candidates from competition in those territories.

Our business could suffer if we are unable to attract and retain key employees.

The loss of the services of members of senior management or other key personnel could delay or otherwise adversely impact the successful completion of our planned clinical trials or the commercialization of our therapeutic candidates or otherwise affect our ability to manage our company effectively and to carry out our business plan. These key personnel are Dror Ben-Asher, our chief executive officer, and Reza Fathi PhD, our senior vice president for research and development. We do not maintain key-man life insurance. Although we have entered into employment or consultancy agreements with all of the members of our senior management team, members of our senior management team may resign at any time. High demand exists for senior management and other key personnel in the pharmaceutical industry. There can be no assurance that we will be able to continue to retain and attract such personnel.

Our growth and success also depend on our ability to attract and retain additional highly qualified scientific, technical, business development, marketing, managerial and finance personnel. We experience intense competition for qualified personnel, and the existence of non-competition agreements between prospective employees and their former employers may prevent us from hiring those individuals or subject us to liability from their former employers. In addition, if we elect to independently commercialize any therapeutic candidate or if we acquire rights to therapeutic candidates which are already approved for marketing and/or are already commercialized, we will need to build and expand our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. If we cannot attract and retain sufficiently qualified suitable employees on acceptable terms, we may not be able to develop and commercialize competitive therapeutic candidates. Further, any failure to effectively integrate new personnel could materially prevent us from successfully growing our company.

We face several risks associated with international business.

We operate our business in multiple international jurisdictions. Such operations could be materially affected by changes in foreign exchange rates, capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to, our therapeutic candidates, as well as by political unrest, unstable governments and legal systems and inter-governmental disputes. Any of these changes could materially adversely affect our business.

Risks Related to Our Industry

Even if our therapeutic candidates receive regulatory approval or do not require regulatory approval, they may not become commercially viable products.

Except for RIZAPORT™, which has been approved for marketing in Germany but has yet to be marketed, none of our therapeutic candidates has been approved for marketing or is being marketed or commercialized. Even if our therapeutic candidates are approved for commercialization, they may not become commercially viable products. For example, if we or our commercialization partners receive regulatory approval to market a therapeutic candidate, approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions which could materially and adversely affect the marketability and profitability of the therapeutic candidate. In addition, a new therapeutic candidate may appear promising at an early stage of development or after clinical trials but never reach the market, or it may reach the market but not result in sufficient product sales, if any. A therapeutic candidate may not result in commercial success for various reasons, including but not limited to:

- difficulty in large-scale manufacturing, including yield and quality;
- low market acceptance by physicians, healthcare payors, patients and the medical community as a result of lower demonstrated clinical safety or efficacy compared to other products, prevalence and severity of adverse side effects, or other potential disadvantages relative to alternative treatment methods;
- insufficient or unfavorable levels of reimbursement from government or third-party payors, such as insurance companies, health maintenance organizations and other health plan administrators;
- infringement on proprietary rights of others for which we or our commercialization partners have not received licenses;
- incompatibility with other therapeutic candidates;
- other potential advantages of alternative treatment methods and competitive forces that may make it more difficult for us to penetrate a particular market segment, if at all;
- ineffective marketing and distribution support;
- lack of significant competitive advantages over existing products on the market;
- lack of cost-effectiveness or unfavorable pricing compared to other alternatives available on the market;
- inability to establish collaborations with third party commercialization partners on acceptable terms, or at all, and our inability or unwillingness for cost or other reasons to commercialize the therapeutic candidates on our own; or
- timing of market introduction of competitive products.

Physicians, various other health care providers, patients, payors or the medical community in general may be unwilling to accept, utilize or recommend any of our approved therapeutic candidates. If we are unable, either on our own or through third parties, to manufacture, commercialize and market our proposed formulations or therapeutic candidates when planned, or to develop commercially viable therapeutic candidates, we may not achieve any market acceptance or generate revenue.

The market for our therapeutic candidates is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs and new treatments which may be developed by others could impair our ability to maintain and grow our business and remain competitive.

The pharmaceutical and biotechnology industry is highly competitive, and we face significant competition from many pharmaceutical, biopharmaceutical and biotechnology companies that are researching and marketing products designed to address the indications for which we are currently developing therapeutic candidates or for which we may develop therapeutic candidates in the future. There are various other companies that currently market, are in the process of developing or may develop in the future products that address all of the indications or diseases treated by our therapeutic candidates. For information regarding our competition, see Item 4. “Information on the Company – B. Business Overview – Our Therapeutic Candidates.”

New drug delivery mechanisms, drug delivery technologies, new drugs and new treatments that have been developed or that are in the process of being developed or will be developed by others may render our therapeutic candidates noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our therapeutic candidates. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, human resources and budgets than we do, as well as substantially more marketing, manufacturing, financial and managerial resources. These entities represent significant competition for us. Acquisitions of, or investments in, competing pharmaceutical or biotechnology companies by large corporations could increase such competitors’ financial, marketing, manufacturing and other resources.

The potential widespread acceptance of therapies that are alternatives to ours may limit market acceptance of our formulations or therapeutic candidates, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medications or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our therapeutic candidates to receive widespread acceptance if commercialized.

We could be adversely affected if healthcare reform measures substantially change the market for medical care or healthcare coverage in the U.S.

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) and on March 30, 2010, the President signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of health care, and conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients. Through the law making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made in order to extend medical benefits to those who lack insurance coverage. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services and drugs. This legislation is one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and is expected to have meaningful ramifications on tens of millions of citizens in the U.S. This legislation is expected to impact the scope of healthcare insurance, the insurance refunds from the insurance companies and possibly also on the costs of medical products. Additionally, the Healthcare Reform Law's provisions are designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. Through modified reimbursement rates and other incentives, the U.S. government is requiring that providers identify the most cost-effective services, supplies and pharmaceuticals. This environment has caused changes in the purchasing habits of providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. To the extent that our therapeutic candidates may at some point be reimbursable by U.S. federal government programs, this attention may result in our therapeutic candidates being chosen less frequently or the pricing being substantially lowered. However, the effect of the legislation is difficult to predict and, at this stage, we are unable to estimate the full extent of the direct and/or indirect impact of the legislation on us.

These structural changes could entail modifications to the existing system of private payors and government programs (such as Medicare, Medicaid and State Children's Health Insurance Program), creation of a government-sponsored healthcare insurance source, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, such as those we and our development and/or commercialization partners are currently developing. If reimbursement for our approved therapeutic candidates, if any, is substantially reduced in the future, or rebate obligations associated with them are substantially increased, our business could be materially and adversely impacted.

Extending medical benefits to those who currently lack coverage will likely result in substantial cost to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care. Cost of care could be reduced by decreasing the level of reimbursement for medical services or products (including those therapeutic candidates currently being developed by us or our development and/or commercialization partners), or by restricting coverage (and, thereby, utilization) of medical services or products. In either case, a reduction in the utilization of, or reimbursement for, any therapeutic candidate for which we receive marketing approval in the future could have a materially adverse effect on our financial performance.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the healthcare reform legislation as constitutional. However, the Supreme Court held that the legislation improperly required the states to expand their Medicaid programs to cover more individuals. As a result, the states have a choice as to whether they will expand the numbers of individuals covered by their respective state Medicaid programs. Some states have determined that they will not expand their Medicaid programs and will develop other cost saving and coverage measures to provide care to currently uninsured residents. Many of these efforts to date have included the institution of Medicaid managed care programs. The manner in which these cost saving measures are implemented could have a materially adverse effect on our financial performance. Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. We cannot predict the impact on our business of future legal challenges to the healthcare reform legislation or other changes to the current laws and regulations.

If third-party payors do not adequately reimburse customers for any of our therapeutic candidates that are approved for marketing, they might not be purchased or used, and our revenues and profits will not develop or increase.

Our revenues and profits will depend heavily upon the availability of adequate reimbursement for the use of our approved therapeutic candidates, if any, from governmental or other third-party payors, both in the U.S. and in foreign markets. Reimbursement by a third-party payor may depend upon a number of factors, including but not limited to the third-party payor's determination that the use of an approved therapeutic candidate is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining reimbursement approval for a therapeutic candidate from each government or other third-party payor is a time-consuming and costly process that could require us or our development and/or commercialization partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our therapeutic candidates to each payor. Even when a payor determines that a therapeutic candidate is eligible for reimbursement, the payor may impose coverage limitations that preclude payment for some uses that are approved by the FDA or other foreign regulatory authorities. Reimbursement rates may vary according to the use of the therapeutic candidate and the clinical setting in which it used, may be based on payments allowed for lower-cost products that are already reimbursed, may be incorporated into existing payments for other products or services, and may reflect budgetary constraints and/or imperfections in Medicare, Medicaid or other data used to calculate these rates.

In the U.S., there have been, and we expect that there will continue to be, federal and State proposals to constrain expenditures for medical products and services, which may affect payments for our therapeutic candidates in the U.S. In addition, there is a growing emphasis on comparative effectiveness research, both by private payors and by government agencies. To the extent other drugs or therapies are found to be more effective than our products, payors may elect to cover such therapies in lieu of our products and/or reimburse our products at a lower rate. We believe that legislation that reduces reimbursement for our therapeutic candidates could adversely impact how much or under what circumstances healthcare providers will prescribe or administer our therapeutic candidates, if approved. This could materially and adversely impact our business by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market our therapeutic candidates, if approved. At this stage, we are unable to estimate the extent of the direct and/or indirect impact of any such federal and State proposals.

Furthermore, the Centers for Medicare and Medicaid Services frequently change product descriptors, coverage policies, product and service codes, payment methodologies and reimbursement values. Third-party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and both the Centers for Medicare and Medicaid Services and other third-party payors may have sufficient market power to demand significant price reductions.

We are subject to additional federal and state laws and regulations relating to our business, and our failure to comply with those laws could have a material adverse effect on our results of operations and financial conditions.

In the event that we were to market products in the U.S., we would be subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct or will conduct our business. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;
- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or family member has a financial relationship with the entity providing the designated health service, unless an exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers.

Further, the recently enacted Healthcare Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity can now be found guilty of fraud or an anti-kickback violation without actual knowledge of the statute or specific intent to violate it. In addition, the Healthcare Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act. Possible sanctions for violation of these anti-kickback laws include monetary fines, civil and criminal penalties, exclusion from Medicare, Medicaid and other government programs and forfeiture of amounts collected in violation of such prohibitions. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our reputation, business, results of operations and financial condition.

The Healthcare Reform Law also imposes reporting requirements on certain medical device and pharmaceutical manufacturers, among others, to make annual public disclosures of certain payments and other transfers of value to physicians and teaching hospitals and ownership or investment interests held by physicians or their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not reported. Manufacturers were required to begin data collection on August 1, 2013 and report such data to CMS by March 31 each year. CMS made the data publicly available on its searchable database beginning in September 2014.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians for marketing, medical directorships, and other purposes. Some states, such as California, Massachusetts and Vermont, mandate implementation of corporate compliance programs, along with the tracking and reporting of gifts, compensation and other remuneration to physicians, and some states limit or prohibit such gifts.

The scope and enforcement of these laws is uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, results of operations, and financial condition. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

We could be exposed to significant drug product liability claims which could be time consuming and costly to defend, divert management attention and adversely impact our ability to obtain and maintain insurance coverage.

The clinical trials that we conduct, and the testing, manufacturing, marketing and commercial sale of our therapeutic candidates, involve and will involve an inherent risk that significant liability claims may be asserted against us. We currently have a product liability policy that includes coverage for our clinical trials. Should we decide to seek additional insurance against such risks before our product sales commence, there is a risk that such insurance will be unavailable to us, or if it can be obtained at such time, that it will be available at an unaffordable cost. Even if we obtain insurance, it may prove inadequate to cover claims and/or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our therapeutic candidates, regardless of their outcome, could require us to spend significant time and money in litigation or to pay significant settlement amounts or judgments. Any successful product liability or other claim may prevent us from obtaining adequate liability insurance in the future on commercially desirable or reasonable terms. An inability to obtain sufficient insurance coverage at an acceptable cost or otherwise to protect against potential product liability claims could prevent or inhibit the commercialization of our products and therapeutic candidates. A product liability claim could also significantly harm our reputation and delay market acceptance of our therapeutic candidates.

Global economic conditions may make it more difficult for us to commercialize our therapeutic candidates.

The pharmaceutical industry, like other industries and businesses, continues to face the effects of the challenging economic environment. Patients experiencing the effects of the challenging economic environment, including high unemployment levels and increases in co-pays, may switch to generic products, delay treatments, skip doses or use other less effective treatments to reduce their costs. Challenging economic conditions in the U.S. include the demands by payors for substantial rebates and formulary restrictions limiting access to brand-name drugs. In addition, in Europe and in a number of emerging markets there are government-mandated reductions in prices for certain pharmaceutical products, as well as government-imposed access restrictions in certain countries. All of the aforesaid may make it more difficult for us to commercialize our therapeutic candidates.

Our business involves risks related to handling regulated substances which could severely affect our ability to conduct research and development of our therapeutic candidates.

In connection with our or our development and/or commercialization partners' research and clinical development activities, as well as the manufacture of materials and therapeutic candidates, we and our development and/or commercialization partners are subject to federal, State and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and waste. We and our development and/or commercialization partners may be required to incur significant costs to comply with environmental and health and safety regulations in the future. Our research and clinical development, as well as the activities of our manufacturing and commercialization partners, both now and in the future, may involve the controlled use of hazardous materials, including but not limited to certain hazardous chemicals. We cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources.

Risks Related to Intellectual Property

We may be unable to adequately protect or enforce our rights to intellectual property, causing us to lose valuable rights. Loss of patent rights may lead us to lose market share and anticipated profits.

Our success depends, in part, on our ability, and the ability of our commercialization partners to obtain patent protection for our therapeutic candidates, maintain the confidentiality of our trade secrets and know how, operate without infringing on the proprietary rights of others and prevent others from infringing our proprietary rights.

We try to protect our proprietary position by, among other things, filing U.S., European, and other patent applications related to our therapeutic candidates, inventions and improvements that may be important to the continuing development of our therapeutic candidates.

Because the patent position of pharmaceutical companies involves complex legal and factual questions, we cannot predict the validity and enforceability of patents with certainty. Our issued patents and the issued patents of our commercialization partners may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

Patent rights are territorial; thus, the patent protection we do have will only extend to those countries in which we have issued patents. Even so, the laws of certain countries do not protect our intellectual property rights to the same extent as do the laws of the U.S. and the European Union. Competitors may successfully challenge our patents, produce similar drugs or products that do not infringe our patents, or produce drugs in countries where we have not applied for patent protection or that do not respect our patents. Furthermore, it is not possible to know the scope of claims that will be allowed in published applications and it is also not possible to know which claims of granted patents, if any, will be deemed enforceable in a court of law.

After the completion of development and registration of our patents, third parties may still manufacture and/or market therapeutic candidates in infringement of our patent protected rights. Such manufacture and/or market of our therapeutic candidates in infringement of our patent protected rights is likely to cause us damage and lead to a reduction in the prices of our therapeutic candidates, thereby reducing our anticipated profits.

In addition, due to the extensive time needed to develop, test and obtain regulatory approval for our therapeutic candidates, any patents that protect our therapeutic candidate may expire early during commercialization. This may reduce or eliminate any market advantages that such patents may give us. Following patent expiration, we may face increased competition through the entry of generic products into the market and a subsequent decline in market share and profits.

In addition, in some cases we may rely on our licensors to conduct patent prosecution, patent maintenance or patent defense on our behalf. Therefore, our ability to ensure that these patents are properly prosecuted, maintained, or defended may be limited, which may adversely affect our rights in our therapeutic candidates. Any failure by our licensors or development partners to properly conduct patent prosecution, patent maintenance or patent defense could materially harm our ability to obtain approval or commercialization of the products, thereby materially reducing our anticipated profits.

If we are unable to protect the confidentiality of our trade secrets or know-how, such proprietary information may be used by others to compete against us.

In addition to filing patents, we generally try to protect our trade secrets, know-how and technology by entering into confidentiality or non-disclosure agreements with parties that have access to it, such as our development and/or commercialization partners, employees, contractors and consultants. We also enter into agreements that purport to require the disclosure and assignment to us of the rights to the ideas, developments, discoveries and inventions of our employees, advisors, research collaborators, contractors and consultants while we employ or engage them. However, these agreements can be difficult and costly to enforce or may not provide adequate remedies. Any of these parties may breach the confidentiality agreements and willfully or unintentionally disclose our confidential information, or our competitors might learn of the information in some other way. The disclosure to, or independent development by, a competitor of any trade secret, know-how or other technology not protected by a patent could materially adversely affect any competitive advantage we may have over any such competitor.

To the extent that any of our employees, advisors, research collaborators, contractors or consultants independently develop, or use independently developed, intellectual property in connection with any of our projects, disputes may arise as to the proprietary rights to this type of information. If a dispute arises with respect to any proprietary right, enforcement of our rights can be costly and unpredictable and a court may determine that the right belongs to a third party.

Legal proceedings or third-party claims of intellectual property infringement and other challenges may require us to spend substantial time and money and could prevent us from developing or commercializing our therapeutic candidates.

The development, manufacture, use, offers for sale, sale or importation of our therapeutic candidates may infringe on the claims of third-party patents or other intellectual property rights. The nature of claims contained in unpublished patent filings around the world is unknown to us and it is not possible to know which countries patent holders may choose for the extension of their filings under the Patent Cooperation Treaty, or other mechanisms. We may also be subject to claims based on the actions of employees and consultants with respect to the usage or disclosure of intellectual property learned at other employers. The cost to us of any intellectual property litigation or other infringement proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation or defense of intellectual property litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may also absorb significant management time. Consequently, we are unable to guarantee that we will be able to manufacture, use, offer for sale, sell or import our therapeutic candidates in the event of an infringement action.

In the event of patent infringement claims, or to avoid potential claims, we may choose or be required to seek a license from a third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we were able to obtain a license, the rights may be non-exclusive, which could potentially limit our competitive advantage. Ultimately, we could be prevented from commercializing a therapeutic candidate or be forced to cease some aspect of our business operations if, as a result of actual or threatened patent infringement or other claims, we are unable to enter into licenses on acceptable terms. This inability to enter into licenses could harm our business significantly.

We may be subject to other patent-related litigation or proceedings that could be costly to defend and uncertain in their outcome.

In addition to infringement claims against us, we may in the future become a party to other patent litigation or proceedings before regulatory agencies, including interference or re-examination proceedings filed with the U.S. Patent and Trademark Office or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our therapeutic candidates, as well as other disputes regarding intellectual property rights with development and/or commercialization partners, or others with whom we have contractual or other business relationships. Post-issuance oppositions are not uncommon and we, our development and/or commercialization partners will be required to defend these opposition procedures as a matter of course. Opposition procedures may be costly, and there is a risk that we may not prevail which could harm our business significantly.

Risks Related to our Ordinary Shares and American Depositary Shares.

We may be a "passive foreign investment company" for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors.

While the determination of passive foreign investment company, or PFIC, status is fact specific, and generally cannot be made until the close of the taxable year in question, based on the value and composition of our assets, we may be a PFIC for U.S. federal income tax purposes for our current taxable year and future taxable years. A non-U.S. corporation will be considered a PFIC for any taxable year if either (1) at least 75% of its gross income for such year is passive income or (2) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during such year) is attributable to assets that produce or are held for the production of passive income. Because the value of our assets for purposes of this determination will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs. A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). If we are a PFIC for any taxable year during which a U.S. Holder (as defined in "Taxation—U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies") holds ordinary shares or ADSs, the U.S. Holder may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of an interest charge with respect to such gain and certain dividends and (iii) compliance with certain reporting requirements. Each U.S. Holder is strongly urged to consult its own tax advisor regarding these issues. See "Item 10. Additional Information – E. Taxation – Foreign Exchange Regulations – Passive Foreign Investment Companies."

The market price of our Ordinary Shares and our ADSs are subject to fluctuation, which could result in substantial losses by our investors.

The stock market in general and the market price of our Ordinary Shares on the TASE and our American Depository Shares on The NASDAQ in particular, are subject to fluctuation, and changes in the price of our securities may be unrelated to our operating performance. The market price of our Ordinary Shares on the TASE and the market price of our American Depository Shares on The NASDAQ have fluctuated in the past, and we expect they will continue to do so. The market price of our Ordinary Shares and ADSs are and will be subject to a number of factors, including but not limited to:

- announcements of technological innovations or new therapeutic candidates by us or others;
- announcements by us of significant acquisitions, strategic partnerships, in-licensing, out-licensing, joint ventures or capital commitments;
- expiration or terminations of licenses, research contracts or other development or commercialization agreements;
- public concern as to the safety of drugs we, our development or commercialization partners or others develop;
- the volatility of market prices for shares of biotechnology companies generally;
- success or failure of research and development projects;
- departure of key personnel;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our Ordinary Shares or ADSs are covered by analysts;
- changes in government regulations or patent decisions;
- developments by our development and/or commercialization partners; and
- general market conditions and other factors, including factors unrelated to our operating performance.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of our Ordinary Shares and result in substantial losses by our investors.

Additionally, market prices for securities of biotechnology and pharmaceutical companies historically have been very volatile. The market for these securities has from time to time experienced significant price and volume fluctuations for reasons unrelated to the operating performance of any one company. In the past, following periods of market volatility, shareholders have often instituted securities class action litigation. If we were involved in securities litigation, it could have a substantial cost and divert resources and attention of management from our business, even if we are successful.

Future sales of our Ordinary Shares or ADSs could reduce the market price of our Ordinary Shares and ADSs.

All of our outstanding Ordinary Shares are registered and available for sale in Israel. In addition, as of February 22, 2016, we had non-tradable warrants to purchase an aggregate of 4,183,496 Ordinary Shares and non-tradable warrants to purchase an aggregate of 357,896 ADSs (each representing 10 Ordinary Shares) and options to purchase 20,511,338 Ordinary Shares under our 2010 Stock Option Plan. Substantial sales of our Ordinary Shares or ADSs, or the perception that such sales may occur in the future, including sales of shares issuable upon the exercise of options and warrants, may cause the market price of our Ordinary Shares or ADSs to decline. Moreover, the issuance of shares underlying our options and warrants will also have a dilutive effect on our shareholders, which could further reduce the price of our Ordinary Shares and ADSs on their respective exchanges.

Our Ordinary Shares and our ADSs are traded on different markets and this may result in price variations.

Our Ordinary Shares have been traded on the TASE since February 2011, and our ADSs have been listed on The NASDAQ since December 27, 2012. Trading in our securities on these markets take place in different currencies (U.S. dollars on The NASDAQ and New Israeli Shekels, or NIS, on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the U.S. and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

There has been a limited market for our ADSs. We cannot ensure investors that an active market will continue or be sustained for our ADSs on The NASDAQ, and this may limit the ability of our investors to sell our ADSs in the U.S.

In the past, there was limited trading in our ADSs, and there is no assurance that an active trading market of our ADSs will continue or will be sustained. Limited or minimal trading in our ADSs has in the past, and may in the future, lead to dramatic fluctuations in market price and investors may not be able to liquidate their investment at all or at a price that reflects the value of the business.

While our ADSs began trading on The NASDAQ in December 2012, we cannot assure you that we will maintain compliance with all of the requirements for our ADSs to remain listed. Additionally, there can be no assurance that trading of our ADSs on such market will be sustained or desirable.

We have incurred additional increased costs as a result of the listing of our ADSs on The NASDAQ, and we may need to devote substantial time and resources to new compliance initiatives and reporting requirements.

As a public company in the U.S., we incur additional significant accounting, legal and other expenses as a result of the listing of our securities on both The NASDAQ and the Tel-Aviv Stock Exchange. These include costs associated with the reporting requirements of the Securities and Exchange Commission and the requirements of The NASDAQ Market Rules, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act. These rules and regulations have increased our legal and financial compliance costs, introduced new costs such as investor relations, travel costs, stock exchange listing fees and shareholder reporting, and made some activities more time consuming and costly. Any future changes in the laws and regulations affecting public companies in the U.S. and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the Market Rules of The NASDAQ, as well as applicable Israeli reporting requirements, will result in increased costs to us as we respond to such changes. These laws, rules and regulations could make it more difficult and costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers and may require us to pay more for such positions.

Since we are an "emerging growth company," as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes Oxley Act (and the rules and regulations of the SEC thereunder). We will remain an emerging growth company until the earliest of: (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the date of the first sale of our Ordinary Shares pursuant to an effective registration statement (in our case, December 31, 2018); (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act of 1934, as amended, which would occur if the market value of our Ordinary Shares held by non-affiliates is $700 million or more as of the last business day of our most recently completed fiscal quarter. When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with such reporting requirements. We cannot predict or estimate the amount of additional costs we may incur as a result of complying with these additional reporting requirements.

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

As a foreign private issuer, we are permitted to follow certain home country corporate governance practices instead of those otherwise required under The NASDAQ Capital Market Rules for domestic issuers. For instance, we follow home country practice in Israel with regard to, among other things, composition of the board of directors, which does not require that a majority of a company's board of directors be independent, director nomination procedure and quorum at shareholders' meetings. In addition, we follow our home country law, instead of The NASDAQ Capital Market Rules, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, 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. Following our home country governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on The NASDAQ may provide less protection than is accorded to investors under The Market Rules of The NASDAQ Capital Market applicable to domestic issuers.

In addition, as a foreign private issuer, we are exempt from the rules and regulations under the United States Securities Exchange Act of 1934, as amended, 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 United States Securities Exchange Act of 1934, as amended. In addition, we are not required under the United States Securities Exchange Act of 1934, as amended, to file annual, quarterly and current reports and financial statements with the Securities and Exchange Commission as frequently or as promptly as domestic companies whose securities are registered under the United States Securities Exchange Act of 1934, as amended.

We may fail to maintain effective internal controls over financial reporting, which may adversely affect investor confidence in our company and, as a result, may affect the value of our Ordinary Shares and ADSs.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. Pursuant to the JOBS Act, we are classified as an "emerging growth company," and we are exempt from certain reporting requirements, including the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act. Under this exemption, our auditor will not be required to attest to and report on management's assessment of our internal controls over financial reporting during a five year transition period commencing in 2013.

Our management report regarding our internal control over financial reporting must include, among other things, disclosure of any material weaknesses identified by our management in our internal control over financial reporting. The continuous process of strengthening our internal controls and complying with Section 404 is complicated and time-consuming.

We have documented and tested our internal control systems and procedures in order for us to comply with the requirements of Section 404. While our assessment of our internal control over financial reporting resulted in our conclusion that as of December 31, 2015, our internal control over financial reporting was effective, we cannot predict the outcome of our testing in future periods. If we fail to maintain the adequacy of our internal controls, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting. Failure to maintain effective internal control over financial reporting could result in investigation or sanctions by regulatory authorities, and could have a material adverse effect on our operating results, investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our Ordinary Shares and ADSs to decline.

We currently do not anticipate paying cash dividends, and accordingly, investors must rely on the appreciation in our ADSs for any return on their investment.

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Therefore, the success of an investment in our ADSs will depend upon any future appreciation in their value. There is no guarantee that our ADSs will appreciate in value or even maintain the price at which our investors have purchased their securities.

Investors in our ADSs may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, investors in our ADSs may not receive dividends or other distributions on our Ordinary Shares and may not receive any value for them, if it is illegal or impractical to make them available to investors in our ADSs.

The depositary for the ADSs has agreed to pay to investors in our ADSs the cash dividends or other distributions it or the custodian receives on Ordinary Shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. Investors in our ADSs will receive these distributions in proportion to the number of Ordinary Shares such ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act of 1933, as amended, but that are not properly registered or distributed under an applicable exemption from registration. In addition, conversion into U.S. dollars from foreign currency that was part of a dividend made in respect of deposited Ordinary Shares may require the approval or license of, or a filing with, any government or agency thereof, which may be unobtainable. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, Ordinary Shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, Ordinary Shares, rights or anything else to holders of ADSs. In addition, the depositary may deduct from such dividends or distributions its fees and may withhold amounts on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that investors in our ADSs may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, investors in our ADSs may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to investors in our ADSs. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the depositary to exercise their rights as shareholders of our company.

Holders of our ADSs do not have the same rights of our shareholders and may only exercise the voting rights with respect to the underlying Ordinary Shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law, the minimum notice period required to convene a shareholder meeting is no less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of our ADSs may not receive sufficient notice of a shareholders' meeting to permit them to withdraw their Ordinary Shares to allow them to cast their vote with respect to any specific matter. In addition, the depositary and its agents may not be able to send voting instructions to holders of our ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depositary to extend voting rights to holders of our ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depositary to vote their ADSs. Furthermore, the depositary and its agents are not responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of our ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as an American Depositary Share holder, they are not able to call a shareholders' meeting.

The depositary for our ADSs gives us a discretionary proxy to vote our Ordinary Shares underlying ADSs if a holder of our ADSs does not vote at shareholders' meetings, except in limited circumstances, which could adversely affect their interests.

Under the deposit agreement for the ADSs, the depositary gives us a discretionary proxy to vote our Ordinary Shares underlying ADSs at shareholders' meetings if a holder of our ADSs does not vote, unless:

- we have instructed the depositary that we do not wish a discretionary proxy to be given;
- we have informed the depositary that there is substantial opposition as to a matter to be voted on at the meeting; or
- a matter to be voted on at the meeting would have a material adverse impact on shareholders.

The effect of this discretionary proxy is that a holder of our ADSs cannot prevent our Ordinary Shares underlying such ADSs from being voted, absent the situations described above, and it may make it more difficult for holders of our ADSs to influence the management of our company. Holders of our Ordinary Shares are not subject to this discretionary proxy.

Risks Related to our Operations in Israel

We conduct our operations in Israel and therefore our results may be adversely affected by political, economic and military instability in Israel and the region.

We are incorporated under the laws of the State of Israel, our principal offices are located in central Israel and some of our officers, employees and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors. Any hostilities involving Israel or the interruption or curtailment of trade within Israel or between Israel and its trading partners could adversely affect our operations and results of operations and could make it more difficult for us to raise capital. During the summer of 2014, Israel was engaged in an armed conflict with Hamas in Gaza, which involved missile strikes against civilian targets in various parts of Israel and negatively affected business conditions in Israel. In addition, recent political uprisings and conflicts in various countries in the Middle East, including Egypt and Syria, are affecting the political stability of those countries. It is not clear how this instability will develop and how it will affect the political and security situation in the Middle East. This instability has raised concerns regarding security in the region and the potential for armed conflict. In addition, it is widely believed that Iran, which has previously threatened to attack Israel, has been stepping up its efforts to achieve nuclear capability. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza and Hezbollah in Lebanon. Additionally, the Islamic State of Iraq and Levant (ISIL), a violent jihadist group, is involved in hostilities in Iraq and Syria and have 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. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy in general and us in particular. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations. For example, any major escalation in hostilities in the region could result in a portion of our employees being called up to perform military duty for an extended period of time. Parties with whom we do business have sometimes declined to travel to Israel during periods of heightened unrest or tension, forcing us to make alternative arrangements when necessary. 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.

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, or if maintained, will be sufficient to compensate us fully for damages incurred. 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.

The State of Israel and Israeli companies have been subject to economic boycotts. These restrictions and boycotts may have an adverse impact on our operating results, financial condition or the expansion of our business.

Our operations may be disrupted as a result of the obligation of management or personnel to perform military service.

Many of our employees in Israel, including members of our senior management, perform up to one month, and in some cases more, of annual military reserve duty until they reach the age of 45 or older and, in the event of a military conflict, may be called to active duty. There have also been periods of significant call-ups of military reservists, and it is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by the absence of a significant number of our employees. Such disruption could materially adversely affect our business, financial condition and results of operations.

Because a certain portion of our expenses is incurred in currencies other than the U.S. dollar, our results of operations may be harmed by currency fluctuations and inflation.

Our reporting and functional currency is the U.S. dollar. Most of the royalty payments from our agreements with our development and/or commercialization partners are payable in U.S. dollars, and we expect our revenues from future licensing agreements to be denominated mainly in U.S. dollars or in Euros. We pay a substantial portion of our expenses in U.S. dollars; however, a portion of our expenses, related to salaries of the employees in Israel and payment to part of the service providers in Israel and other territories, are paid in NIS and in other currencies. In addition, a portion of our financial assets is held in NIS and in other currencies. As a result, we are exposed to the currency fluctuation risks. For example, if the NIS strengthens against the U.S. dollar, our reported expenses in U.S. dollars may be higher. In addition, if the NIS weakens against the U.S. dollar, the U.S. dollar value of our financial assets held in NIS will decline.

Provisions of our 2010 Option Plan, Israeli law and our articles of association may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, or an acquisition of a significant portion of our shares, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Our 2010 Option Plan provides that all options granted by us will be fully accelerated upon a "takeover" of the Company. A "takeover" is defined in our 2010 Option Plan as an event in which any person, entity or group that was not an "interested party", as defined in the Israeli Securities Law – 1968, on the date of the initial public offering of our securities on the TASE, shall become a "controlling shareholder". A "controlling shareholder" for these purposes means a controlling shareholder as defined in the Israel Securities Law, 1968. See "Item 6. Directors, Senior Management and Employees – E. Share Ownership – Option Plan" for a description of interested parties under the Israeli Securities Law – 1968.

The Israeli Companies Law, 1999, or the Israeli Companies Law, regulates mergers, requires tender offers for acquisitions of shares or voting rights 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, a majority of each class of securities of the target company must approve a merger. Moreover, the Israeli Companies Law provides that certain purchases of securities of a public company are subject to tender offer rules. As a general rule, the Israeli Companies Law prohibits any acquisition of shares or voting power in a public company that would result in the purchaser holding 25% or more, or more than 45% of the voting power in the company, if there is no other person holding 25% or more, or more than 45% of the voting power in a company, respectively, without conducting a special tender offer. The Israeli Companies Law further provides that a purchase of shares or voting power of a public company or a class of shares of a public company, which will result in the purchaser's holding 90% or more of the company's shares, class of shares or voting rights, is prohibited unless the purchaser conducts a full tender offer for all of the company's shares or class of shares. The purchaser will be allowed to purchase all of the company's shares or class of shares (including those shares held by shareholders who did not respond to the offer), if either (i) the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, or (ii) the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class. The shareholders, including those who indicated their acceptance of the tender offer (except if otherwise detailed in the tender offer document), may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition. At the request of an offeree of a full tender offer which was accepted, the court may determine that the consideration for the shares purchased under the tender offer was lower than their fair value and compel the offeror to pay to the offerees the fair value of the shares. Such application to the court may be filed as a class action.

In addition, the Israeli Companies Law provides for certain limitations on a shareholder that holds more than 90% of the company's shares, or class of shares.

Pursuant to our articles of association, the size of our board of directors shall be no less than 5 persons but no more than seven, excluding at least two external directors. The directors, except for our external directors, are divided into three classes, as nearly equal in number as possible. At each annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three year term that expires at the annual general meeting held in the third year following such election. This process continues indefinitely. Such provisions of our articles of association make it more difficult for a third party to effect a change in control or takeover attempt that our management and board of directors oppose.

Furthermore, Israeli tax considerations may, in certain circumstances, make potential transactions unappealing to us or to some of our shareholders. 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, or an acquisition of a significant portion of our shares, even if such an acquisition or merger would be beneficial to us or to our shareholders. See "Item 10. Additional Information - B. Memorandum and Articles of Association."

It may be difficult to enforce a U.S. judgment against us and our officers and directors in Israel or the U.S., or to serve process on our officers and directors.

We are incorporated in Israel. Most of our executive officers and directors reside outside of the U.S., and all of our assets and most of the assets of our executive officers and directors are located outside of the U.S.. Therefore, a judgment obtained against us or most of our executive officers and our directors in the U.S., including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the U.S. and may not be enforced by an Israeli court. It may also be difficult for you to affect service of process on these persons in the U.S. or to assert U.S. securities law claims in original actions instituted in Israel.

The obligations and responsibilities of our shareholders are governed by Israeli law which may differ in some respects from the obligations and responsibilities of shareholders of U.S. companies. Israeli law may impose obligations and responsibilities on a shareholder of an Israeli company that are not imposed upon shareholders of corporations in the U.S.

We are incorporated under Israeli law. The obligations and responsibilities of the holders of our Ordinary Shares are governed by our articles of association and Israeli law. These obligations and responsibilities differ in some respects from the obligations 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 responsibilities on holders of our Ordinary Shares that are not typically imposed on shareholders of U.S. corporations.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful shareholder claims against us and may reduce the amount of money available to us.

The Israeli Companies Law and our articles of association permit us to indemnify our directors and officers for acts performed by them in their capacity as directors and officers. The Israeli Companies Law provide that a company may not exempt or indemnify a director or an office holder nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of (a) a breach by the director or officer of his duty of loyalty, except for insurance and indemnification where the director or officer acted in good faith and had a reasonable basis to believe that the act would not prejudice the company; (b) a breach by the director or officer of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence; (c) any act or omission done with the intent to derive an illegal personal benefit; or (d) any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director. Our Articles of Association provide that the Company may exempt or indemnify a director or an office holder to the maximum extent permissible under law. See "Item 6. Directors, Senior Management and Employees – C. Board Practices - Corporate Governance Practices - Exemption, Insurance and Indemnification of Directors and Officers."

We have issued letters of indemnification to our directors and officers, pursuant to which we have agreed to indemnify them in advance for any liability or expense imposed on or incurred by them in connection with acts they perform in their capacity as a director or officer, subject to applicable law. The amount of the advance indemnity is limited to the higher of 25% of our then shareholders' equity, per our most recent annual financial statements, or $5 million.

Our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their duties as directors by shifting the burden of such losses and expenses to us. Although we have obtained directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to who may choose to bring a claim against our company. These provisions and resultant costs may also discourage us from bringing a lawsuit against directors and officers for breaches of their duties, and may similarly discourage the filing of derivative litigation by our shareholders against the directors and officers even though such actions, if successful, might otherwise benefit our security holders.

ITEM 4. INFORMATION ON THE COMPANY

A. History and Development of the Company

Our legal and commercial name is RedHill Biopharma Ltd. The company was incorporated on August 3, 2009 and was registered as a private company limited by shares under the laws of the State of Israel. Our principal executive offices are located at 21 Ha'arba'a Street, Tel Aviv, Israel and our telephone number is 972-3-541-3131.

In February 2011, we completed our initial public offering in Israel, pursuant to which we issued 14,302,300 ordinary shares, and 7,151,150 tradable Series 1 Warrants to purchase 7,151,150 ordinary shares for aggregate gross proceeds of approximately $14 million. On December 27, 2012, we completed the listing of our ADSs on The Nasdaq Capital Market. Our ordinary shares are traded on the Tel Aviv Stock Exchange under the symbol "RDHL," and our ADSs are traded on The Nasdaq Capital Market under the symbol "RDHL".

Our capital expenditures for the years ended December 31, 2015, 2014 and 2013 were $14,000, $70,000 and $14,000, respectively. Our current capital expenditures involve equipment and leasehold improvements.

B. Business Overview

We are a biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases and cancer. From inception to the end of the period covered by this Annual Report, we have invested a total of $6.1 million on in-licensing and acquisitions of therapeutic candidates and related technologies.

Depending on the specific development program, our therapeutic candidates are designed to exhibit greater efficacy, provide improvements over existing drugs by improving their safety profile, reducing side effects, lowering the number of administrations, using a more convenient administration form and/or providing a cost advantage. Where applicable, we intend to seek FDA approval for the commercialization of certain of our therapeutic candidates through the alternative Section 505(b)(2) regulatory path under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, and in corresponding regulatory paths in other foreign jurisdictions. Our current pipeline consists of eight late clinical development therapeutic candidates, including one therapeutic candidate (RP101) for which we have an option to acquire.

We generate our pipeline of therapeutic candidates by identifying, rigorously validating and in-licensing or acquiring products that are consistent with our products strategy and that we believe exhibit a relatively high probability of therapeutic and commercial success. With the exception of RIZAPORT™ which was approved for marketing in Germany, our therapeutic candidates have not yet been approved for marketing and, to date, our therapeutic candidates have not generated meaningful sales. We intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements with pharmaceutical companies on a global and territorial basis. We also evaluate, on a case by case basis, co-development and similar arrangements and the independent commercialization of our therapeutic candidates in the U.S.

Our Strategy

Our goal is to become a significant player in the development of pharmaceuticals for the treatment of inflammatory and gastrointestinal (GI) diseases and cancer.

Key elements of our strategy are to:

- Identify and acquire rights to products from pharmaceutical companies that have encountered cash flow or operational problems or that decide to divest one or more of their products for various reasons. Specifically, we seek to acquire rights to and develop products that are intended to treat pronounced clinical needs, have patent or other protections, and have target markets totaling tens of millions to billions of dollars. Additionally, we seek to acquire rights to and develop products based on different technologies designed to reduce our dependency on any specific product technology. We identify such opportunities through our broad network of contacts and other sources in the pharmaceutical field.
- Identify and acquire rights to products that have been approved for marketing in the U.S from pharmaceutical companies that are interested in divesting one or more of their products. Specifically, we seek to acquire rights to products that are already commercialized in the U.S., preferably with a therapeutic focus on GI, inflammation and/or cancer, which would enable us to commercialize such products independently and build our own marketing and commercialization capabilities. We identify such opportunities through our broad network of contacts and other sources in the pharmaceutical field.
- Enhance existing pharmaceutical products, including broadening their range of indications, or launching innovative and advantageous pharmaceutical products based on existing active ingredients. Because there is a large knowledge base regarding existing products, the preclinical, clinical and regulatory requirements needed to obtain marketing approval for enhanced formulations are relatively well- defined. In particular, clinical trial designs, inclusion criteria and endpoints previously accepted by regulators may sometimes be re-used. In addition to reducing costs and time to market, we believe that targeting therapeutics with proven safety and efficacy profiles provides us a better prospect of clinical success.
- Where applicable, utilize the FDA's 505(b)(2) regulatory pathway to potentially obtain more timely and efficient approval of our formulations of previously approved products. Under the 505(b)(2) process, we are able to seek FDA approval of a new dosage form, strength, route of administration, formulation, dosage regimen, or indication of a pharmaceutical product that has previously been approved by the FDA. This process enables us to partially rely on the FDA findings of safety and/or efficacy for previously approved drugs, thus avoiding the duplication of costly and time-consuming preclinical and various human studies. See "Government Regulations and Funding - Section 505(b)(2) New Drug Applications."
- Cooperate with third parties to develop and/or commercialize therapeutic candidates in order to share costs and leverage the expertise of others.

Our eight current clinical stage therapeutic candidates include "RHB-105", "RHB-104", "BEKINDA™", "RHB-106", "Yeliva™", "MESUPRON®", "RP101" (subject to an option to acquire) and "RIZAPORT™" and related research and development programs, the most advanced of which are described below.

Our Therapeutic Candidates

Summary

A summary of our therapeutic candidates' select programs is provided below:

Name of Product	Relevant Indication	Potential Advantages Over Most Existing Treatments	Development Stage	Rights to the Product
RHB-105	*H. pylori* infection	Improved efficacy, potential to overcome bacterial resistance; all-in-one pill	First Phase III study in the U.S. successfully completed	Acquired all rights to the product, worldwide and exclusive
RHB-104	Crohn's disease	Novel mechanism of action and improved clinical benefit (targeting suspected underlying cause of Crohn's disease)	First Phase III study in N. America, Israel, Australia, New Zealand and Europe ongoing	Acquired all rights to the product, worldwide and exclusive
RHB-104	Multiple sclerosis (MS)	Oral formulation and novel mechanism of action	Phase IIa proof of concept study in Israel ongoing	Acquired all rights to the product, worldwide and exclusive

RHB-104	Rheumatoid arthritis (RA)	Oral formulation targeting suspected underlying cause of RA and systemic lupus erythematosus	TBD	Acquired all rights to the product, worldwide and exclusive
BEKINDA™	Oncology support anti-emetic	Reduced number of drug administrations, improved compliance and adherence	MAA pursued in Europe. Additional data required for U.S. oncology support program	Worldwide, exclusive license
BEKINDA™	Gastroenteritis/gastritis	No other approved 5HT-3 antagonist for this indication, improved compliance and adherence	Phase III ongoing in gastroenteritis and gastritis in the U.S.	Worldwide, exclusive license
BEKINDA™	IBS-D	Potential 5-HT3 antagonist with improved safety while maintaining efficacy, for broader use in the indication	Phase II in the U.S. planned to be initiated in the coming weeks	Worldwide, exclusive license
RHB-106	Bowel preparation	Oral pill, avoid severe bad taste of chemical solutions, no known nephrotoxicity issues	Licensed to Valeant Pharmaceuticals (which acquired Salix Pharmaceuticals, Inc.)	Worldwide rights licensed to Valeant Pharmaceuticals
YELIVA™	Oncology; advanced solid tumors	Oral administration, first-in-class sphingosine kinase-2 (SK2) selective inhibitor, with anti-inflammatory and anti-cancer activities.	Phase I study in the U.S. completed	Worldwide, exclusive license
YELIVA™	Refractory or relapsed diffuse large B-Cell lymphoma (DLBCL), including patients with virus-induced (e.g., KSHV- or EBV-associated) lymphoma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities.	Phase I/IIa study in the U.S. initiated	Worldwide, exclusive license
YELIVA™	Refractory or relapsed multiple myeloma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities.	Phase Ib/II study planned	Worldwide, exclusive license
YELIVA™	Oncology support, prevention of radiation -associated mucositis in the treatment of head and neck cancer.	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities.	Phase II study planned	Worldwide, exclusive license
MESUPRON®	Gastrointestinal and other solid tumors	Oral administration; new non-cytotoxic approach to cancer therapy inhibiting both tumor invasion and metastasis	Completed two Phase II studies; Pre-clinical studies ongoing	Worldwide exclusive license; excludes China, Hong Kong, Taiwan and Macao
RP101	Pancreatic and other cancers	Oral administration; may prevent chemoresistance, thus maintaining sensitivity of the tumor to chemotherapy and potentially enhancing patient survival	Completed a Phase II study; Pre-clinical studies ongoing	Option to acquire the worldwide exclusive rights to RP101 for all indications, other than to the pancreatic cancer indication in South Korea
RIZAPORT™	Acute migraine	Oral thin film formulation; Avoids exacerbation of nausea, administered without water, ease of use, convenient portability and discrete carriage and use	NDA filed and accepted, Complete Response Letter (CRL) received and response is being prepared; European marketing application approved in Germany	Worldwide, exclusive license and co-development
Combination against Ebola virus	Ebola virus disease	Efficacy and safety	Nonclinical research collaboration with a U.S. government agency ongoing	All worldwide rights to the product

RHB-105

RHB-105 is intended for the eradication of *H. pylori* bacterial infection in the gastrointestinal tract. RHB-105 is a combination of three approved drug products – omeprazole, which is a proton pump inhibitor (prevents the secretion of hydrogen ions necessary for digestion of food in the stomach), and amoxicillin and rifabutin which are antibiotics. RHB-105 is administered to patients orally.

Chronic infection with *H. pylori* irritates the mucosal lining of the stomach and small intestine. The original discovery of the *H. pylori* bacteria and its association with peptic ulcer disease warranted the Nobel Prize in 2005. *H. pylori* infection has since been associated with a variety of outcomes which include: dyspepsia (non-ulcer or functional), peptic ulcer disease (duodenal ulcer and gastric ulcer), primary gastric B-cell lymphoma, vitamin B12 deficiency, iron deficiency anemia and gastric cancer.

Gastric cancer is the second most frequent cancer worldwide and is associated with a poor prognosis (five-year survival rate of only 10-15% in patients with advanced disease). Almost all gastric cancer is now known to be attributable to *H. pylori* infection, and *H. pylori* eradication seems to either eliminates, stabilizes, or reduces risk for progression to gastric cancer, depending upon the severity and extent of damage present when the *H. pylori* infection is cured.

RHB-105 was granted Qualified Infectious Disease Product (QIDP) designation by the FDA in November 2014. The QIDP designation was granted under the FDA's Generating Antibiotic Incentives Now (GAIN) Act, which is intended to encourage development of new antibiotic drugs for the treatment of serious or life-threatening infections that have the potential to pose a serious threat to public health. The granted QIDP designation allows us to benefit from Fast-Track development status with an expedited development pathway for RHB-105 and Priority Review status which potentially provides shorter review time by the FDA of a future potential marketing application. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity on top of the standard exclusivity period for a total of eight years.

RHB-105 is targeting a significantly broader indication than that of existing *H. pylori* therapies, as a first line treatment of *H. pylori* infection regardless of ulcer status.

As noted above, we acquired the rights to RHB-105 pursuant to an agreement with Giaconda Limited. See "– Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106."

Competition and Market

The most common treatments of *H. pylori* type bacteria combine clarithromycin or metronidazole antibiotics with amoxicillin and a proton pump inhibitor. Such current standard of care treatments fail in approximately 30% of the patients due to the development of antibiotic resistance, based on reports by Prof. David Y. Graham, MD, *et al.* published in Nature Clinical Practice Gastroenterology & Hepatology in 2008 and in Gut in 2010. The potential advantage of RHB-105 over these drugs (such as PrevPac® of Takeda Pharmaceuticals NA and Pylera® of Actavis) was shown in a Phase II study comprising of 130 subjects, in which a different formulation of RHB-105, using the same antibiotic ingredients and a similar proton pump inhibitor, was shown to eradicate *H. pylori* in over 90% of treated patients who failed previous eradication attempts using standard of care treatments, as published in the 2006 study report by Dr. T.J. Borody, et. al. in Alimentary Pharmacology & Therapeutics. Furthermore, top-line results from a Phase III study conducted by us demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105 in 118 dyspepsia patients with confirmed *H. pylori* infection.

We estimate that there are approximately three million *H. pylori* infected patients present with first time dyspeptic symptoms per annum in the U.S., based on a 2007 report by Colin W. Howden, MD, *et. al.* published in The American Journal of Managed Care and a 2005 report by Nicholas J. Talley, MD, et al. published in The American Journal of Gastroenterology. Based on this figure, combined with the current price of current branded treatments, we estimate the potential global and U.S. market for RHB-105 at approximately $4.83 billion and $1.45 billion, respectively.

Clinical Development

A Phase II clinical trial in Australia was completed with a different formulation of RHB-105, using the same antibiotic ingredients and a similar proton pump inhibitor. A first Phase III trial in the U.S. was completed in 2015. Top line data showed 89.4% eradication of *H. pylori* with *RHB-105* therapy while open-label standard-of-care yielded an *H. pylori* eradication of rate of 63% in placebo subjects. The full clinical study report is expected to be available in the first quarter of 2016. We intend to meet with the FDA to discuss the further clinical development path towards marketing approval of RHB-105 through the 505(b)(2) regulatory path.

Professor David Y. Graham, MD, from Baylor College of Medicine, Houston, Texas, served as the lead investigator of the first Phase III clinical trial of RHB-105.

The following chart summarizes the clinical trial history and status of RHB-105:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Number of subjects of the trial	Nature and status of the trial	Schedule
-	Phase IIa	Examining the product's effectiveness in treating *H. pylori* infections in patients for whom standard of care had failed to treat the infection	Center for Digestive Disease, Australia	130	The trial was performed and indicated that the treatment is effective for bacteria patients for whom standard of care had failed to treat the infection	Completed in 2005
-	Comparative Bioavailability	Comparing the bioavailability of RHB-105 to the bioavailability of an equivalent dose of commercially available active ingredients	Algorithme Pharma Canada	16	Successfully completed	Completed in 2013
ERADICATE Hp	Phase III	Examining the effectiveness, safety and pharmacokinetics of the final formulation	13 sites in the US	Up to 118	Successfully completed	Completed in 2015; Final results expected in Q1 2016
TBD	Phase III	Assess the safety and efficacy of RHB-105 as compared to active comparator	TBD	TBD	Planned for initiation in Q3 2016	TBD

An additional Phase III study comparing RHB-105 to current therapy is planned to be undertaken following completion of the ERADICATE Hp study. Supplemental studies may be required as part of the RHB-105 global development program and regulatory strategy.

We cannot predict with certainty our development costs, and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements."

RHB-104

RHB-104 is intended to treat Crohn's disease, which is a serious inflammatory disease of the gastrointestinal system that may cause severe abdominal pain and bloody diarrhea, malnutrition and potentially life-threatening complications.

RHB-104 is a patented combination of clarithromycin, clofazimine and rifabutin, three generic antibiotic ingredients, in a single capsule. The compound was developed to treat *Mycobacterium avium paratuberculosis* (MAP), infections in Crohn's disease. According to a 2007 article in *The Lancet Infectious Diseases* by Feller *et. al.*, which contains a meta-analysis of 18 published scientific and clinical trials, Crohn's disease patients are seven times more likely to be infected with MAP than non-Crohn's patients.

To date, Crohn's disease has been considered to be an autoimmune disease, but the exact pathological mechanism is unclear. Dr. Robert J. Greenstein suggested in *The Lancet Infectious Diseases*, 2003 that Crohn's disease is caused by MAP, the same organism responsible for a major cause of disease in animal agriculture production, domestic and wild animals. This hypothesis is supported by an expanding number of scientific and clinical studies published in peer reviewed journals since a National Institute of Allergy and Infectious Diseases conference that focused on MAP in Crohn's disease took place in 1998. Specific genetic loci like NOD2 have been implicated in the pathogenesis of Crohn's disease with mutations in NOD2 suspected of leading to defective recognition of MAP and increased compensatory immune activation in patients with Crohn's disease.

In 2011, we obtained FDA "Orphan Drug" status for RHB-104 for the treatment of Crohn's disease in the pediatric population. See "– Government Regulations and Funding Orphan Drug Designation."

The formulation for RHB-104 is presently complete and manufacturing of the all-in-one capsules for our clinical trials is currently in process. Stability testing of the clinical trial material is ongoing.

We acquired the rights to RHB-104, RHB-105 and RHB-106 pursuant to an asset purchase agreement with Giaconda Limited, a publicly traded Australian company. See "– Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106."

A diagnostic technology enabling the identification of the presence of MAP bacterial DNA in patients was developed and patented by Professor Saleh Naser of the University of Central Florida in Orlando. On September 15, 2011, we entered into an agreement with the University of Central Florida Research Foundation, Inc., pursuant to which we acquired the exclusive rights in this patented diagnostic test. See "– Acquisition and License Agreements – License Agreement related to RHB-104."

On February 12, 2012, we entered into an agreement with Q Squared Solutions LLC (f/k/a Quest Diagnostics Ltd.) (Q Squared) to develop a commercial diagnostic test for detecting the presence of MAP bacterial DNA in the blood based upon the rights we acquired from the University of Central Florida Research Foundation, Inc. Additional intellectual property covering other aspects of MAP detection was licensed from the University of Minnesota in December 2014 in order to potentially enhance our ability to detect MAP. On January 29, 2015, we announced that, together with Q Squared, we concluded a pre-submission meeting with the FDA regarding the development path of a commercial companion diagnostic test for the detection of MAP in Crohn's disease patients. We initiated a study of Crohn's disease patients to assess the clinical utility of the companion diagnostic test during the third quarter of 2015.

Market

According to GlobalData, a provider of market intelligence for the pharmaceutical sector, there were approximately 1.38 million diagnosed cases of Crohn's disease in the 10 major markets in 2015. This number of diagnosed cases is expected to increase to 1.48 million by 2022.

The MAP bacterium is suspected of being a major factor in causing the inflammatory symptoms of Crohn's disease patients. According to a study by Bull TJ, *et. al.* in 2003 in *Journal of Clinical Microbiology*, MAP was detected in 92% of Crohn's disease patients evaluated in the study. According to a 2014 report by EvaluatePharma, a leading market intelligence and information resource, the market of drug treatments for Crohn's disease was estimated to exceed $5.7 billion worldwide in 2015. The report also estimates that the worldwide market for drug treatment of Crohn's disease will exceed $6 billion in 2017.

Competition

Unlike drugs on the market for the treatment of Crohn's disease, which are immunosuppressive agents, RHB-104 is intended to address the suspected cause of the disease, MAP bacterial infection. To the best of our knowledge, there are no drugs approved for marketing that target infections of MAP bacteria in Crohn's disease patients.

Currently available drugs on the market for the treatment of Crohn's disease offer only symptomatic relief, the effects of which are largely temporary and accompanied by numerous adverse effects. A summary of these side effects described by Dr. Carol Nacy *et. al.* in a report from the American Academy of Microbiology published in June 2007 is included in the following chart (except with respect to 5-Aminosalicylates (5-ASA) as indicated below).

Drug Family	**Example of Drug from the Family**	**Effect**	**Common Side Effects**
5-Aminosalicylates (5-ASA)	Mesalamine	Possible efficacy in inducing remission in limited subgroups of patients with mild to moderate CD (Feldman PA *et. al.*. Clin Colon Rectal Surg. 2007 Nov; 20(4): 269–281), although no longer recommended (Sandborn WJ Gastroenterology 2014;147:702–705)	Side effects include headache, nausea , bloating, abdominal pain cramping loss of appetite vomiting rash, fever, diarrhea, decrease sperm count and rarely kidney injury (Crohn's & Colitis Foundation of America)
Corticosteroids	Prednisone	Relatively good effectiveness, for some patients only	Headaches, swinging moods, muscle and bone weakness, heart failure, diabetes and risk of infections

Immunomodulatory drugs	6-Mercaptopurine Methotrexate Azathioprine	High effectiveness, but only for a limited time and for some patients	Suppresses the immune system causing risks of infection or even cancer, negative side effects on the liver, kidneys and blood
Biological agents –Anti-TNF-α and other monoclonal antibody drugs. TNF (Tumor Necrosis Factor) is a component of the immune system.	Infliximab Adalimumab Certolizumab pegol Vedolizumab	Administered intravenously (IV) or subcutaneously every 1-8 weeks. Effective for some patients (30-40%). Effectiveness decreases over time	Suppresses a central component of the immune system. Risk of infectious diseases, cancer and damage to the nervous system

We may also be exposed to potentially competitive products which may be under development to treat Crohn's disease, including new anti-TNFα and other biological therapies. Additionally, a clinical trial is being conducted by Valeant with the antibiotic rifaximin (Xifaxan®) for the treatment of Crohn's disease.

Clinical Development

In the Phase III clinical trial in Australia, sponsored by Pharmacia and published by Professor Warwick Selby *et al.* in 2007 in the medical journal *Gastroenterology*, the primary objectives were to evaluate the ratio of patients with recurrent symptoms of the disease following initial induction of remission with 16 weeks of treatment. Subjects were subsequently assessed at 52, 104 and 156 weeks. The main secondary objective was the percentage of patients who achieved clinical remission at 16 weeks. Although the study did not meet the main objective of showing a difference in relapse rate with long-term treatment, there was a statistically significant difference between the treatment groups in the percentage of subjects in remission at week 16. Professor Marcel Behr and Professor James Hanley from McGill University published a re-analysis of the study in *The Lancet Infectious Diseases* in June 2008, based on the intent-to-treat (ITT) principle, and found that there was a significant statistical advantage for the active therapy over the placebo throughout the period of administration that disappeared once the active therapy was discontinued.

We are currently conducting our first Phase III clinical trial in North America, Israel, Australia, New Zealand, Poland and other countries with RHB-104 (MAP US) as well as preparing a planned second clinical trial in Europe. These trials, based on the analysis and data from a Phase III trial conducted in Australia with the RHB-104 active ingredients in a different formulation, are designed as a Phase III trial for Crohn's disease patients. The Map U.S. trial commenced in October 2013. We plan to increase the number of clinical sites of the MAP U.S. trial, currently ongoing from 100 to 120, and expect to include new sites mainly in Europe.

The MAP US trial of RHB-104 is being led by Professor David Y. Graham, MD, of Baylor College of Medicine, Houston, Texas, U.S., while the second Phase III clinical trial of RHB 104, in Europe (MAP Europe), will be led by Professor Colm O'Morain, MD, of Meath and Adelaide Hospital, Dublin, Ireland.

In October 2012, we entered into an agreement with our Canadian service provider which, in turn, entered into a back-to-back agreement with a Canadian manufacturer to complete the manufacturing and supply of RHB-104 for our clinical trials. In addition, we entered into an additional manufacturing agreements directly with the Canadian manufacturer.

In June 2011, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with PharmaNet Canada Inc. for the provision of clinical trial services for the RHB-104 adult studies in North America and Europe. PharmaNet was subsequently acquired by inVentiv Health and our agreements were transferred to inVentiv. See "– Master Service Agreements with Canadian service provider" and see also "– Clinical Services Agreement related to RHB-104."

Subsequent to our discussions with the FDA for approval to conduct the North American trial based upon an Investigative New Drug (IND) approved by the FDA on July 18, 2007, we made a number of changes to the original protocol. On August 29, 2012, we revised the IND filed by Giaconda with the submission of a new Phase III protocol to the FDA, and after 30 days, the IND became effective. Based upon the response from the FDA on issues relating to the clinical study, additional changes have been made, and will be made, to the clinical study in North America and Israel and other countries. A further amendment to the protocol was submitted to the FDA on December 23, 2014 responding to recommendations from the investigators and to expedite recruitment in the study.

Approximately 270 Crohn's disease patients are currently expected to participate in the MAP US trial. Half of the patients will receive RHB-104 and half will receive a placebo drug over a period of approximately six months to determine efficacy, with an additional six month follow-up period to further investigate maintenance of efficacy and safety. A Clinical Trial Application (CTA) for MAP EU Study has been submitted in Europe and approved by three countries to date.

The following chart summarizes the clinical trial history and status of RHB-104 and its earlier individual active agents:

Clinical trial author/design-nation	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
Borody 2002	Phase IIa	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	12	Performed	Completed in 2002
Borody 2005	Phase II	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	52	Performed	Completed in 2005
Selby	Phase III	Examining the effect of the treatment with the product on Crohn's disease patients	20 clinical centers in Australia	213	The trial was performed and indicated promising improvement rates, although it did not meet the main trial objective, as defined	Published in 2007
Biovail PK study 2007	PK Study	Optimize the formulation of RHB-104 on a PK basis.	Toronto, Ontario	24	Trial compared two formulations to determine the optimum formulation for RHB-104	Completed in 2007
MAP US	Phase III	Assess the safety and efficacy of RHB-104 in Crohn's disease patients	US, Canada. Israel, Australia, New Zealand and Europe	270	Phase III trial in North America and Israel and other countries has commenced	First patient entered study in Q3 2013
MAP EU	Phase III)	Assess the safety and efficacy of RHB-104 in Crohn's disease patients	Europe and potential other countries	To be determined	Under examination	
Food Effect Study	PK Study	Determine the effect of food on the bioavailability of RHB-104 in healthy volunteers	Algorithme Pharma, Canada	84	Completed	Completed in 2014
Drug-Drug Interaction Study	PK Study	To assess the net pharmacokinetic effect of multiple doses of RHB-104 on CYP3A4 enzymes in healthy volunteers	Algorithme Pharma, Canada	36	Ended	Ended in 2014

Supplemental studies will be required as part of the RHB-104 global development program and regulatory strategy.

We cannot predict with certainty our development costs, and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements."

Multiple Sclerosis Indication of RHB-104

We have performed several preclinical studies, including studies in an experimental autoimmune encephalomyelitis (EAE) mouse model of MS, to investigate the potential impact of RHB-104 in treating MS. The first preclinical study measured cytokine production (biomarkers of inflammation) and demonstrated that the RHB-104 treatment led to a significant reduction of pro-inflammatory cytokine concentrations of IL-6 and TNF, which are associated with inflammation and MS, compared to the control group. The second preclinical study measured the efficacy of RHB-104 as prophylactic therapy, and the treatment with RHB-104 demonstrated a significant reduction in the inflammatory area and level of demyelination, compared with the control group. The third preclinical study measured relapses, demonstrating RHB-104's efficacy in significantly reducing the incidence of relapse compared with the control group. Following these preclinical studies, we are conducting a Phase IIa proof of concept clinical trial at two sites in Israel. This clinical trial was initiated in June 2013 with interim top-line results expected during the first quarter of 2016.

MS is an inflammatory, demyelinating, and neurodegenerative disease of the central nervous system of uncertain etiology that exhibits characteristics of both infectious and autoimmune pathology. There is a growing consensus in the medical community that a dysregulated immune system plays a critical role in the pathogenesis of MS.

The following chart summarizes the development history and status of RHB-104-MS:

Trial name	Development phase	Purpose of the trial	Clinical trial sites	Planned number of subjects of the trial	Nature and status of the trial	Schedule
Experimental Autoimmune Encephalomyelitis (EAE) Mouse T-cell Function Study	Pre-Clinical	Measure cytokine production as a measure of inflammation in EAE mice treated with RHB-104 vs. negative controls	-			Completed 2012
Experimental Autoimmune Encephalomyelitis (EAE) Prophylaxis Study	Pre-Clinical	Scoring EAE severity in mice treated prophylactically with RHB-104 vs. negative controls	-			Completed 2012
Experimental Autoimmune Encephalomyelitis (EAE) Relapse Study	Pre-Clinical	Scoring EAE severity in mice treated with RHB-104 vs. negative and positive controls	-			Completed 2012
Lipopolysaccharide (LPS)-induced cytokine production study	Pre-Clinical	Measure LPS induced cytokine production in C57BL/6 mice treated with RHB-104 vs. negative and positive controls	-			Completed 2013
CEASE-MS	Phase IIa	Proof of concept study to assess the safety and efficacy of RHB-104 in Relapsing Remitting MS	Israel	16-18	In process	Interim top-line results expected in Q1 2016

Additional trials will be required as part of the RHB-104 MS global development program and regulatory strategy.

We cannot predict with certainty our development costs and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements."

BEKINDA™ (RHB-102)

BEKINDA™ is a once-daily controlled release oral formulation of ondansetron, a leading member of the family of 5HT-3 serotonin receptor inhibitors. We are developing two dose strength products, a 24 mg dose and a 12 mg dose. They are being developed for use in the following indications, the first two of which are novel indications for ondansetron targeting large potential markets and the third is an existing indication of ondansetron and therefore targets a smaller potential market:

1) Gastroenteritis and gastritis - 24 mg strength
2) Irritable Bowel Syndrome with Diarrhea (IBS-D) - 12 mg strength
3) Prevention of chemotherapy and radiotherapy induced nausea and vomiting (oncology support) – 24 mg strength

BEKINDA™ utilizes a technology called CDT® that uses salts to provide an extended release of ondansetron. The CDT® platform enables extended drug release (*i.e.*, measured rate of introduction of active drug) at a relatively low manufacturing cost.

In March 2014, we entered into a License Agreement with Temple University to secure direct rights to patents related to BEKINDA™. Previously, these rights were licensed to us from SCOLR Pharma Inc, which announced that they had ceased business operations in 2013. See "– Acquisition and License Agreements – License Agreement for BEKINDA™".

Gastroenteritis and Gastritis Indication of BEKINDA™

Acute gastroenteritis/gastritis is an inflammation of the mucus membranes of the gastrointestinal tract, most commonly caused by a viral infection. Symptoms of gastroenteritis/gastritis include nausea, vomiting, diarrhea and abdominal pain. Gastroenteritis/gastritis is a major cause of emergency room visits, particularly for pediatrics. If approved, BEKINDA™ could potentially decrease the number of emergency room visits of patients suffering from acute gastroenteritis, by offering them an effective and long lasting treatment which can be taken in the comfort of their home.

Competition and Market

A single dose of BEKINDA™ is intended to treat nausea and vomiting over a time window of approximately 24 hours. This is potentially advantageous for acute gastroenteritis and gastritis patients as it is intended to provide them with relief from nausea and vomiting symptoms for a full 24-hour period with a single oral tablet, thus avoiding the need to take additional drugs (tablets) during the day or receiving intravenously administered drugs. BEKINDA™ could also potentially reduce the burden on health systems by reducing visits to emergency departments.

If BEKINDA™ is approved for the treatment of acute gastroenteritis and gastritis, it could potentially hold substantial advantages over existing treatments. To the best of our knowledge, if approved, BEKINDA™ will be the only 5-HT3 serotonin receptor inhibitor indicated for the treatment of acute gastroenteritis and gastritis, whereas most treatments used today are not indicated or approved for this condition. If approved, BEKINDA™ could be prescribed by primary care physicians to patients early on, thus potentially preventing emergency room visits, dehydration and the need to provide IV fluids.

BEKINDA™ is targeting an annual potential worldwide market estimated to exceed $650 million, based on Graves S. Nancy, Acute Gastroenteritis, Prim Care Clin Office Pract 40 (2013) 727–741 and Company analysis.

To the best of our knowledge, there are no other 5-HT3 serotonin receptor inhibitors indicated or currently being developed for this indication. Patients presenting at hospitals with gastroenteritis and gastritis are often treated with antiemetic drugs, off label, including 5-HT3 serotonin receptor inhibitors, primarily in IV administration, which are not indicated or approved for this condition.

Clinical Development

We have initiated a randomized, double-blind, placebo controlled, parallel group Phase III trial (GUARD study) that is conducted in up to 30 clinical sites in the U.S. and is expected to enroll 320 adults and children over the age of 12 who suffer from acute gastroenteritis/gastritis. Patients are randomized to receive either BEKINDA™ or a placebo. The primary endpoint for the trial is the absence of vomiting, need for rescue medications or IV hydration from 30 minutes through 24 hours after the first dose of study medication. Secondary endpoints include, among others, frequency of vomiting, severity and time to resolution of nausea and time to resumption of normal activities. Top-line results from the BEKINDA™ GUARD Phase III trial are expected during the second half of 2016.

The lead investigator for the Phase III study is Dr. Robert A. Silverman, MD, MS, Associate Professor at the Hofstra North Shore-LIJ School of Medicine and an emergency medicine specialist.

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
GUARD Study	Phase III	Randomized double blind placebo controlled Phase III study in gastroenteritis and gastritis	Up to 12 sites in the U.S.	320	Evaluating the safety and efficacy of BEKINDA™ in gastroenteritis and gastritis	Top line date expected in H2 2016

Following prior discussions with the FDA and the UK Medicines and Healthcare Products Regulatory Agency (MHRA), the study is intended to support potential future submissions of marketing applications in both the U.S. and Europe in this indication.

If approved for this indication, BEKINDA™ could be the only 5-HT3 antagonist approved to treat gastritis and gastroenteritis. We expect that would potentially allow BEKINDA™ to capture a large segment of the potential market in this indication.

We cannot predict with certainty our development costs and they may be subject to changes. See “Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements.”

Irritable Bowel Syndrome with Diarrhea (IBS-D) Indication of BEKINDA™

Irritable bowel syndrome (IBS) is a multifactorial disorder marked by recurrent abdominal pain or discomfort and altered bowel function. It affects between 10 and 20 percent of the population in the developed world, about one-third of whom have IBS associated with diarrhea (IBS-D). Certain factors that alter gastrointestinal function can contribute to IBS symptoms, including stress, prior gastroenteritis, changes in the gut microbiome, and bile acids and short-chain fatty acids, which may stimulate serotonin (5-HT) release and increase colonic permeability and motility. (Source: http://www.mayoclinic.org/medical-professionals/clinical-updates/digestive-diseases/better-agents-needed-irritable-bowel-syndrome-diarrhea).

In preliminary studies, ondansetron has demonstrated activity in IBS-D (Garsed K, Chernova J, Hastings M, *et al*. *Gut* Published Online First December 12, 2013). Unlike alosetron (a currently approved 5-HT3 antagonist in IBS-D), ondansetron has not been noted to cause ischemic colitis (FDA labeling for Lotronex® (alosetron), 2010; FDA labeling for Zofran® (ondansetron), 2014).

BEKINDA™ is a bimodal release formulation of ondansetron. It provides an initial release similar to immediate release ondansetron and then extended release over 24 hours. Because of its extended release properties, and once daily dosing we believe it is a promising candidate for treatment of IBS-D.

Competition and Market

Irritable bowel syndrome is one of the most common gastrointestinal disorders, and irritable bowel syndrome with diarrhea is the most common subtype of IBS in the U.S., according to a report by GlobalData, a provider of market intelligence for the pharmaceutical sector.

According to reports by Saito YA. *et al* published in 2002 in The American Journal of Gastroenterology and by Lovell RM *et al*., published in 2012 in Clinical Gastroenterology and Hepatology, it is estimated that at least 30 million Americans may suffer from IBS. According to GlobalData, worldwide over approximately 40% of the cases of IBS will be of the IBS-D subtype.

According to a 2015 report from EvaluatePharma, a provider of market intelligence for the pharmaceutical sector, the U.S. potential market for IBS-D treatments is estimated to reach approximately $1.3 billion in 2020.

To the best of our knowledge, there is one other 5-HT3 serotonin receptor inhibitor indicated for this indication – alosetron (currently marketed by Prometheus Laboratories Inc., Actavis plc and Roxane Laboratories). However, alosetron is approved only for the treatment of IBS in women with severe chronic IBS-D and is under a restricted prescribing program due to potential severe side effects. The active ingredient in BEKINDA™, ondansetron, is approved by the U.S. FDA as an oncology support antiemetic and has a good safety profile. Therefore, we believe that BEKINDA™, if approved, has the potential to be the preferred 5-HT3 serotonin receptor inhibitor treatment for patients suffering from IBS-D. To the best of our knowledge, the patent for alosetron (Lotronex®) expired in November 2015. According to GlobalData, the U.S. sales of Lotronex® exceeded $60 million in 2015.

To the best of our knowledge, the main competitor for BEKINDA™ for the treatment of IBS-D is Xifaxan® (Rifaximin) marketed in the U.S. by Valeant. Xifaxan® is an antibiotic treatment which was approved for the treatment of IBS-D in May 2015. Xifaxan® was previously approved in the U.S. for the treatment of hepatic encephalopathy and traveler's diarrhea. According to a report by GlobalData, it is believed that Xifaxan® exerts its therapeutic effects in patients with IBS by treating intestinal bacteria overgrowth. Xifaxan® is administered orally at a dose of 550 mg three times daily for two weeks in the treatment of IBS-D patients. According to a GlobalData analysis, due to the chronic nature of IBS, physicians may have safety concerns associated with the long-term use of antibiotics, such as the induction of antibiotic resistance and imbalance in the intestinal flora. According to a report by EvaluatePharma, the worldwide annual sales of Xifaxan® for the treatment of IBS-D are estimated to exceed $920 million by 2020. To the best of our knowledge, an oral version of Aloxi® was approved in August 2008 in the U.S., but is not currently marketed in the U.S.

Viberzi® (eluxadoline) is another new drug approved for the treatment of IBS-D in May 2015. Viberzi® is a locally-acting mu-opioid receptor agonist and a delta-opioid receptor antagonist marketed in the U.S. by Ironwood Pharmaceuticals and Allergan plc. According to a report by EvaluatePharma, the worldwide sales of Viberzi® are estimated to reach $470 million in 2020.

To the best of our knowledge, the most advanced treatment for IBS-D currently in development for the U.S. market is ibodutant, developed by A. Menarini Industrie Farmaceutiche Riunite Srl. Ibodutant is an oral tachykinin NK2 receptor antagonist, Ibodutant is currently undergoing a Phase III study for the treatment of women with IBS-D.

Clinical Development

We are conducting a randomized, double-blind, placebo controlled, Phase II trial that will be conducted in up to 12 clinical sites in the U.S. and is expected to enroll 120 adults over the age of 18 who suffer from IBS-D. Patients will be randomized to receive either BEKINDA™ 12 mg daily or a placebo.

The primary endpoint for the trial is the proportion of patients in each treatment group with response in stool consistency on study drug as compared to baseline. Response is defined as per FDA guidelines for the indication. Additional endpoints will be analyzed including:

- Proportion of patients in each treatment group who are pain responders, per FDA guidance definition
- Proportion of patients in each treatment group who are overall responders, per FDA guidance definition
- Differences between treatment groups in
    - Abdominal pain
    - Abdominal discomfort
    - Frequency of defecation
    - Incidence and severity of adverse events

IBS-D Phase II trial is expected to be initiated during the first quarter of 2016.

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
TBD	Phase II	Randomized double blind placebo controlled phase II study in IBS-D	Up to 12 sites in the U.S.	120	Evaluating the safety and efficacy of BEKINDA™ 12 mg in IBS-D	Expected to be initiated in Q1 2016

We cannot predict with certainty our development costs and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements.

Oncology Support Indication of BEKINDA™

Competition and Market

Chemotherapy-induced nausea and vomiting (CINV) is among the most severe symptoms cited by cancer patients receiving chemotherapy. CINV negatively impacts health-related quality of life following moderately and highly emetogenic chemotherapy (MEC and HEC) while leading to increased resource use and costs. BEKINDA™ (ondansetron) belongs to the family of 5-HT3 serotonin receptor inhibitors, which account for a substantial market share of CINV treatments. According to a report from EvaluatePharma, a provider of market intelligence for the pharmaceutical sector, the worldwide sales of 5-HT3 serotonin receptor inhibitors for CINV are estimated to exceed $479 million in 2016.

To the best of our knowledge, the main competitors of BEKINDA™ are other 5-HT3 serotonin receptor inhibitors. This class of medication includes the active ingredient ondansetron (the generic drug marketed in the U.S. under the trade name Zofran®, originally produced by GlaxoSmithKline). Additional first-generation generic drugs from the same family contain the active ingredient granisetron (marketed in the U.S. under the name Kytril®, produced by Hoffman-La Roche Ltd.) or the active ingredient dolasetron (marketed in the U.S. under the name of Anzemet®, produced by Sanofi-Aventis Group). In addition, second-generation drugs containing the active ingredient palonosetron are still under patent and marketed in the U.S. under the brand names Aloxi® and Akynzeo® by Eisai Pharmaceuticals Inc., or Eisai.

Ondansetron became generic in the U.S. in December 2006. The drug is available in the U.S. in the form of oral tablet, ODT, oral soluble film, oral solution and intravenous (IV) formulations.

Granisetron and dolasetron are additional first-generation generic drugs from the same family of 5-HT3 serotonin receptor inhibitors. The generic drugs containing these active ingredients are available both orally and intravenously and by transdermal patch. Additionally, Heron Therapeutics is developing Sustol®, a long-acting formulation of granisetron for the prevention of both acute and delayed CINV associated with moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC). To the best of our knowledge, a U.S. New Drug Application (NDA) for Sustol® is currently under review by the FDA. Sustol® is administered by injection.

BEKINDA™ is planned to be delivered orally, in tablet form. Oral administration is expected to allow self-administration by patient, without the need for a clinical setting, thus potentially saving patient travel time to the clinic or hospital and reducing health care professional work load, which we believe will lower its cost relative to currently available intravenous (IV) alternatives.

Aloxi® is a second-generation drug from the same family of inhibitors. To the best of our knowledge, it is currently administered only intravenously in the U.S. Akynzeo®, is a fixed combination capsule comprised of oral palonosetron (the API in Aloxi®) and netupitant (NK1), and is the first orally available 5-HT3 and NK1 combination product to reach the market. Akynzeo® was approved by the FDA in October 2014 for prevention of acute and delayed nausea and vomiting following chemotherapy and is marketed by Eisai Inc. in the U.S. Both Aloxi® and Akynzeo® have longer duration of action in the body and are the only drugs in this family that were approved for use with an indication of nausea and vomiting prevention for more than 24 hours from the chemotherapy treatment (delayed onset). This means that the drugs continue to be effective from the time of their administration for more than the ensuing 24 hours. The price of these drugs is significantly higher than Zofran® and is estimated at approximately $480 per treatment with Aloxi® IV and approximately $560 per capsule of Akynzeo®, according to www.goodrx.com.

A single dose of BEKINDA™ is anticipated to prevent chemotherapy or radiotherapy-induced nausea and vomiting over a time window of approximately 24 hours. This effectiveness period is significantly longer than the effective time of Zofran® 8 mg, which is indicated to be administered several times a day. This is potentially advantageous for cancer patients undergoing chemotherapy and radiation treatments that would prefer to avoid the need to take additional drugs (tablets) during the day after the treatment, when they may suffer attacks of nausea and vomiting.

The potential advantages of BEKINDA™ compared to Aloxi®, the first of the only two drugs that have a relatively long-term effect (beyond 24 hours, as stated above), are the delivery method and price. Aloxi® is a drug that in the U.S. is delivered intravenously and costs approximately $480 per dose according to www.goodrx.com. BEKINDA™ is planned to be delivered orally, in tablet form. Oral administration is expected to allow self-administration by patient, without the need for a clinical setting, thus saving patient travel time to the clinic or hospital and reducing health care professional work load, significantly lowering its cost relative to currently available IV alternatives, including Aloxi®.

The potential advantage of BEKINDA™ compared to Akynzeo®, the second drug to have long-term effect, is the price. Akynzeo® is priced at approximately $560 per capsule according to www.goodrx.com. We estimate that the high price of Akynzeo® provides sufficient margins for BEKINDA™ to be priced significantly lower than Akynzeo® and potentially capture a large segment of the market at a premium price to the generic ondansetron tablets that need to be taken multiple times per day.

To the best of our knowledge, there are several plans to develop new products in the area of nausea and vomiting prevention, including the development of a product that directly competes with BEKINDA™, for controlled release of ondansetron, based on a different technology of controlled release developed by Eurand N.V. and now owned by Allergan Plc. To the best of our knowledge, this product completed Phase II trials and according to GlobalData, a provider of market intelligence for the pharmaceutical sector, the development program for this drug is currently inactive.

Clinical Development

We completed two comparative bioavailability studies of BEKINDA™ given once daily as compared to approved regimens of Zofran® 8 mg tablets given in multiple doses per day, a food-effect study and a comparative bioavailability study of BEKINDA™ given once daily as compared to Zofran® 16 mg suppository, which is approved in major territories in the EU.

In order to carry out pharmacokinetic trials for BEKINDA™, in November 2011 we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with Algorithme Pharma Inc., a Canadian clinical research organization specializing in the performance of clinical trials. Algorithme Pharma Inc. performed the clinical trial described below for BEKINDA™. See " Master Service Agreement with 7810962 Canada Inc."

The following chart summarizes the pharmacokinetic trial history and status of BEKINDA™:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Number of subjects of the trial	Nature and status of the trial	Schedule
PK Program	Comparative Bioavailability	Four PK studies of BEKINDA™	Algorithme Pharma, Canada	Total of 80 healthy volunteers	To support marketing applications in EU and US in oncology support	Completed in 2014

In light of the positive results of the clinical pharmacokinetic studies, we submitted a Marketing Authorization Application (MAA) in Europe for chemotherapy and radiotherapy-induced nausea and vomiting in December 2014 and have received an extension to respond to comments from MHRA until Feb 2016 following which we recently decided to withdraw the MHRA MAA and initiated discussions for potential MAA submission in other EU member states. Accordingly, we recently met with the French Agence Nationale de Sécurité du Médicament (ANSM) to seek further guidance about the potential path to approval in the EU for the oncology support indications. In the U.S., the FDA feedback in 2015 indicated that additional clinical efficacy data is required to support a U.S. New Drug Application (NDA) with BEKINDA™ for oncology support indications under the 505(b)(2) regulatory path. Further development for oncology support indications will be decided as more feedback is received from additional EU member states and data from the ongoing and planned efficacy studies of BEKINDA™ for gastroenteritis and gastritis and IBS-D becomes available.

We cannot predict with certainty our development costs and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements."

RHB-106

RHB-106 is a tablet intended for the preparation and cleansing of the gastrointestinal tract prior to the performance of abdominal procedures, including diagnostic tests such as colonoscopy, barium enema or virtual colonoscopy, as well as surgical interventions, such as laparotomy.

As noted above, we acquired the rights to RHB-106 pursuant to an agreement with Giaconda Limited. See "– Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106."

On February 27, 2014, we entered into a licensing agreement with Salix Pharmaceuticals, Ltd. (Salix), which was later acquired by Valeant Pharmaceuticals International, Inc., or Valeant, by which Salix licensed the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation and rights to other purgative developments. Pursuant to this agreement, we received an upfront payment of $7 million and are entitled to an additional potential $5 million in subsequent milestone payments. In addition, as part of the terms of the agreement, Salix agreed to pay us tiered royalties on net sales of RHB-106, ranging from the low single-digits up to low double-digits. See "– Acquisition and License Agreements – Exclusive License Agreement with Valeant Pharmaceuticals International, Inc."

Competition and Market

According to a report by EvaluatePharma, the worldwide market of laxative products intended for cleansing the gastrointestinal system was estimated to reach approximately $1.3 billion in 2016.

To the best of our knowledge, the main competitors for RHB-106 are gastrointestinal cleansing products based on polyethylene glycol (PEG 3350). These products are delivered in the form of a water-soluble powder, and require users to drink between 2-4 liters of solution before performance of the gastroenterological procedure. In addition to the need to drink considerable amounts of solution, a common side effect that raises difficulties with users is the accompanying harsh and unpleasant taste leading to potential difficulties with patient compliance. RHB-106 offers the potential for improved patient compliance because it is tasteless and eliminates the need for drinking liters of poor tasting electrolyte solution. RHB-106 also potentially has an advantage compared to currently available tablet products in the field, in that it does not contain sodium phosphate, an active ingredient linked with a risk of nephrotoxicity.

An additional product, called PrepoPik™ in the U.S., is manufactured by Ferring Pharmaceuticals and received FDA approval on July 17, 2012. The product, marketed under the name PicoPrep™ in other countries, is based on an active chemical ingredient called sodium picosulfate, the same active ingredient used in RHB-106. This product is intended to be used for clearing the gastrointestinal system and it is given in the form of a water-soluble powder and requires drinking quantities of fluids.

Products administered in the form of tablets or capsules that were released on the market in the U.S., such as OsmoPrep® and Visicol® (produced by Valeant), are based on a chemical substance called sodium phosphate. In December 2008, the FDA published a severe warning against the use of these products due to rare but severe side effects linked to kidney damage. As a consequence of this development, the FDA required in 2008 that oral sodium phosphate products carry a severe warning (black box label). As announced by Salix Pharmaceuticals Inc. (now Valeant), following the black box warning received from the FDA, sales in 2009 of these products declined by 39% compared to 2008.

A leading product among the PEG 3350 family of products is MoviPrep®, marketed by Valeant in the U.S. and by Norgine B.V. in Europe. It requires drinking about 2 liters of solution, and some users report it has an unpleasant taste. The potential advantage of RHB-106 over the current competitor products of the PEG 3350 type (such as MoviPrep®), as well as over PicoPrep™, is that it is tasteless, permits the patient to drink any clear liquid with the product and spares the patient the exposure to the harsh tastes that may accompany these products. RHB-106 also does not fall under the black box warning against nephrotoxicity issued by the FDA in December 2008 with respect to currently marketed sodium phosphate capsule preparations.

Salix Pharmaceuticals, Inc. (now Valeant), which acquired a worldwide exclusive license to RHB-106 and other purgative developments from us, estimated in its 2014 Investor Day that the peak year revenue from their encapsulated bowel prep would reach approximately $280 million.

Clinical Development

Following the acquisition of Salix Pharmaceuticals by Valeant, we received confirmation, in July 2015, that Valeant is continuing the development of RHB-106.

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical site	Number of subjects of the trial	Nature and status of the trial	Performance schedule
-	Phase IIa	Comparison of the product's effectiveness and safety with an existing products	Center for Digestive Disease, Australia	60	Performed	Completed in 2005

YELIVA™ (ABC294640)

YELIVA™ is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) selective inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple inflammatory, gastrointestinal (GI) and oncology indications.

YELIVA™ inhibits SK2, a lipid kinase that catalyzes formation of the lipid signaling molecule sphingosine 1-phosphate (S1P). S1P promotes cancer growth, and proliferation and pathological inflammation, including TNFα signaling and other inflammatory cytokine production. Specifically, by inhibiting the SK2 enzyme, YELIVA™ blocks the synthesis of S1P which regulates fundamental biological processes such as cell proliferation, migration, immune cell trafficking and angiogenesis, and is also involved in immune-modulation and suppression of innate immune responses from T cells.

On March 31, 2015, we entered into an exclusive worldwide license agreement with Apogee Biotechnology Corporation (Apogee), pursuant to which Apogee granted us the exclusive worldwide development and commercialization rights to ABC294640 (which we then renamed to YELIVA™) and additional intellectual property for all indications. Under the terms of the agreement, we agreed to pay Apogee an upfront payment of $1.5 million, as well as $4 million in potential milestone payments, and tiered royalties starting in the low double-digits. See "– Acquisition and License Agreements – License Agreement for YELIVA™".

Competition and Market

YELIVA™, an orally-administered, first-in-class sphingosine kinase-2 (SK2) inhibitor is being developed for various indications, including for the treatment of refractory/relapsed diffused large B-cell lymphoma (DLBCL), for refractory or relapsed multiple myeloma and for radioprotection in cancer patients undergoing therapeutic radiotherapy. Additional oncology and inflammatory disease indications are currently being explored.

DLBCL can affect any age group but occurs mostly in older people (average age is mid-60s). The most widely used treatment for DLBCL is chemotherapy, usually with a regimen of 4 drugs known as CHOP (cyclophosphamide, doxorubicin, vincristine, and prednisone), plus the monoclonal antibody rituximab (Rituxan®). This regimen, known as R-CHOP, is most often given in cycles 3 weeks apart.

According to the American Cancer Society, DLBCL is the most common subtype of non-Hodgkin's lymphoma in the U.S., accounting for an estimated 30% of the approximately 72,000 projected non-Hodgkin's lymphoma cases to be diagnosed in the U.S. in 2016. The total worldwide sales of DLBCL therapies are estimated to reach approximately $1.5 billion in 2016 according to GlobalData. There are several drugs in late-stage clinical development for DLBCL.

According to the American Cancer Society, approximately 30,000 new cases of multiple myeloma will be diagnosed in the U.S. in 2016. The risk of multiple myeloma increases as people age. Most people diagnosed with this cancer are at least 65 years old and less than 1% of cases are diagnosed in people younger than 35. Standard treatment options for multiple myeloma include biological therapy, chemotherapy, corticosteroids, stem cell transplantation and radiation therapy. The total worldwide sales of multiple myeloma therapies are estimated to exceed $12 billion in 2016 according to GlobalData. There are several drugs in late-stage clinical development for multiple myeloma.

Radiation therapy can cause both acute and chronic side effects. The side effects that develop depend, among other things, on the area of the body being treated, the dose given per day, the total dose given, the patient's general medical condition, and other treatments given at the same time. Acute side effects may include skin irritation or damage at regions exposed to the radiation beams. The oral cavity is highly susceptible to direct and indirect toxic effects of cancer chemotherapy and ionizing radiation. According to a 2011 publication by Peterson DE et al., the incidence of World Health Organization (WHO) grade 3 or 4 oral mucositis in patients receiving high-dose head and neck radiation (e.g. 6000–7000 Gy) to the oral cavity approaches 85%, but all treated patients have some degree of oral mucositis. There are currently limited therapeutic options to prevent oral mucositis in cancer patients undergoing radiotherapy. To the best of our knowledge, several drugs are currently in development for prevention of oral mucositis in cancer patients undergoing radiation therapy. The most advanced programs undergoing Phase II clinical studies include IZN-6N4, an oral rinse developed by Izun Pharamaceuticals Corp., GC-4419, a small molecule enzyme replacement developed by Galera Therapeutics, Inc., Brilacidin, a defensin-mimetic antibiotic developed by Cellceutix Corporation and Cobiprostone, a locally acting chloride channel activator, developed by Sucampo Pharmaceuticals, Inc.

To the best of our knowledge, there is only one other SK2 inhibitor being developed by SphynKx Therapeutics LLC. According to the SphynKx Therapeutics website, the company's sphingosine kinase-2 inhibitor program is targeting fibrosis and is currently in pre-clinical development stage of lead optimization.

Clinical Development

ABC-101: Oncology, advanced solid tumors

The last patient completed the final scheduled follow-up visit in the Phase I study evaluating YELIVA™ in advanced solid tumors in the summer of 2015. The Phase I study was conducted at the Medical University of South Carolina Hollings Cancer Center. The open-label, dose-escalation, pharmacokinetic (PK) and pharmacodynamic (PD) first-in-human Phase I study of YELIVA™ enrolled 22 patients with advanced solid tumors. The study met both its primary and secondary objectives. The primary objectives were to identify the maximum tolerated dose (MTD) and the dose limiting toxicities (DLTs) and to evaluate the safety of YELIVA™. The secondary objectives were to determine the pharmacokinetic (PK) and pharmacodynamic (PD) properties of YELIVA™ and to assess its antitumor activity.

Top-line results reported on October 26, 2015 showed that YELIVA™ can be safely administered to cancer patients in doses that provide circulating drug levels that are predicted to have therapeutic activity, based on levels required in preclinical models. A full analysis and the final clinical study report are expected in the first quarter of 2016.

The study was supported by grants from the National Cancer Institute (NCI) and the FDA's Office of Orphan Products Development (OOPD) awarded to Apogee.

ABC-102: Refractory/relapsed diffused large B-cell lymphoma (DLBCL)

In June 2015, we initiated a Phase I/II study in the U.S. evaluating YELIVA™ in patients with refractory/relapsed diffuse large B-cell lymphoma (DLBCL) was initiated at the Louisiana State University Health Sciences Center (LSUHSC) in New Orleans.

The study will evaluate the safety and tolerability of YELIVA™, as well as provide a preliminary evaluation of efficacy of the study drug in patients with refractory/relapsed DLBCL, primarily patients with HIV-related DLBCL. Up to 33 patients are expected to be enrolled in the study. The study is funded primarily by a grant awarded to Apogee by the National Cancer Institute Small Business Technology Transfer program. Dr. Chris Parsons, MD, an associate professor in the Departments of Medicine and Microbiology, Immunology & Parasitology at LSUHSC, is the lead investigator for the study.

ABC-103: Refractory or relapsed multiple myeloma

We plan to initiate a Phase I/II study of YELIVA™ for the treatment of refractory or relapsed multiple myeloma in 2016. The study will be conducted at Duke University Medical Center and is planned to enroll up to 77 patients. Dr. Yubin Kang, MD, associate professor in the Division of Hematologic Malignancies and Cellular Therapy in the Department of Medicine at Duke University School of Medicine, will be the lead investigator for the study, which received Institutional Review Board approval from Duke University. The study is funded primarily by a grant awarded by the National Cancer Institute Small Business Innovation Research program, awarded to Apogee in conjunction with Duke University.

The primary objectives of the first portion of the study (Phase I) are to assess safety and determine the maximum tolerated dose in this group of patients. Secondary objectives include assessment of antitumor activity and determination of the pharmacokinetic (PK) and pharmacodynamic (PD) properties of YELIVA™ in refractory or relapsed multiple myeloma patients.

The primary objectives of the second portion of the study (Phase II) are to assess the overall treatment response rate and overall survival. Secondary objectives include evaluating the treatment response of YELIVA™ in patients with refractory or relapsed multiple myeloma after three cycles of treatment and evaluation of pharmacodynamic markers.

ABC-104: Oncology support, radioprotectant. Prevention of radiation-associated mucositis in the treatment of head and neck cancer.

A Phase II study is planned to evaluate YELIVA™ as a radioprotectant in head and neck cancer patients undergoing therapeutic radiotherapy. We expect to submit this safety and efficacy study with YELIVA™ to the FDA in the second quarter of 2016.

The following chart summarizes the clinical trial history status of YELIVA™:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
ABC-101	Phase I	Safety, pharmacokinetic and pharmacodynamic study in patients with advanced solid tumors.	Medical University of South Carolina, Charleston, U.S.A.	22 (fully enrolled)	Successfully completed. Top-line results indicate the study drug is well tolerated and can be safely administered to cancer patients	Clinical study report expected in Q1 2016
ABC-102	Phase I/IIa	Safety and preliminary efficacy study in refractory or relapsed DLBCL, including patients with virus-induced (e.g., KSHV- or EBV-associated) lymphoma.	Louisiana State University, New Orleans, U.S.A.	Up to 33	Study was initiated. Patient enrollment is anticipated	Initiated June 2015
ABC-103	Phase Ib/II	Safety and efficacy study in patients with refractory or relapsed multiple myeloma that have previously been treated with proteasome inhibitors and immunomodulatory drugs.	Duke University, North Carolina, U.S.A.	Up to 77	The study received IRB approval. No patients enrolled yet	Study initiation anticipated
ABC-104	Phase II	Safety and efficacy study of YELIVA™ in the prevention of mucositis in combination with radiotherapy for treatment of squamous head and neck carcinoma.	Multicenter study primarily across U.S.	TBD	Planned	TBD

We cannot predict with certainty our development costs and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements."

MESUPRON®

MESUPRON® (INN: upamostat) is a proprietary small molecule, first-in-class, urokinase-type plasminogen activator (uPA) inhibitor administered by oral capsule.

MESUPRON® inhibits the uPA system, which has been shown to play a key role in tumor cell growth, invasion and the metastasis process. High uPA levels are associated with poor prognosis in various solid tumor cancers, such as pancreatic, gastric, breast and prostate cancers. MESUPRON® presents a promising new non-cytotoxic approach to cancer therapy with several potential mechanisms of action to inhibit both tumor metastasis and growth.

As mentioned under "– Acquisition and License Agreements – License Agreement for MESUPRON ®", on June 30, 2014, we signed an exclusive license agreement for this oncology therapeutic candidate. Under this agreement, we are responsible for all development, regulatory and commercialization of MESUPRON® in the entire world, excluding China, Taiwan, Macao and Hong Kong.

Competition and Market

MESUPRON® an orally-administered first-in-class urokinase-type plasminogen activator (uPA) inhibitor has been developed for the treatment of solid tumor cancers, including gastrointestinal cancers with the focus on locally advanced non-metastatic pancreatic cancer.

Pancreatic cancer is the fourth leading cause of mortality in western countries. It is characterized as a disease with some of the highest unmet need in oncology. According to the World Cancer Research Fund, with 338,000 new cases diagnosed in 2012 pancreatic cancer is the 12 th most common cancer in the world. According to a report by GlobalData from March 2014, the overall five-year survival rate for the disease is only approximately 5%, representing one of the poorest prognoses across the gastrointestinal cancers. The total worldwide sales of pancreatic cancer therapies are estimated to reach approximately $1.6 billion by 2017 according to GlobalData.

According to the same GlobalData report, the majority of pancreatic cancer cases are diagnosed late, at which point the disease is already locally advanced or metastatic, and these patients are often frail with co-morbidities. Furthermore, pancreatic cancer is predominately a cancer of the elderly, with the median age of diagnosis being 71 years in the U.S. These factors result in a significant minority, approximately 20%, of advanced patients being ineligible for chemotherapy treatment, who are managed with best supportive care (BSC).

Pancreatic adenocarcinoma has some of the highest levels of unmet needs in the oncology space, which present many challenges for physicians treating pancreatic cancer patients. Surgical resection remains the only curative method. Patients who are classified as resectable (no regional or distant organ metastasis) are often treated by surgical intervention, depending on the location of the tumor within the pancreas. Patients with greater than Stage IIb disease are usually deemed unresectable. Of the unresectable group, the majority of locally-advanced patients are treated in the same manner as metastatic patients - with treatment choices that are mainly dependent on their performance status.

There are a number of drugs in late-stage clinical development for pancreatic cancer. To the best of our knowledge, there is currently no uPA inhibitor in late clinical-stage development for this indication. There are several drugs in late-stage clinical development for pancreatic cancer.

Clinical Development

MESUPRON® has completed several Phase I trials and two Phase II proof of concept trials. The first Phase II trial in locally advanced non-metastatic pancreatic cancer and the second trial in metastatic breast cancer established the therapeutic candidate's safety and tolerability profile. The Phase II trials with MESUPRON® in both indications failed to demonstrate significant improvement in either progression-free survival or overall survival. While response rates were arithmetically higher in patients receiving MESUPRON® than in control patients, in no case did these differences approach clinical or statistical significance. A post hoc subgroup analysis of the breast cancer study suggested that a certain clinically defined subgroup may benefit from MESUPRON® added to a standard single agent cytotoxic therapy, capecitabine. In the pancreatic cancer study, patients treated with the higher dose of MESUPRON® along with gemcitabine had a three month longer median overall survival than those treated with gemcitabine alone, although the difference was not statistically significant. The phase II trials with MESUPRON® randomized 227 subjects, of which 95 subjects were in the pancreatic cancer study and 132 subjects were in the metastatic breast cancer study.

None of the prior studies used any molecular markers to target certain patient populations. Using technologies developed since the original clinical trials were performed, we are currently performing several preclinical studies, including biomarker analysis and mechanism of action studies. We expect to have initial data from these preclinical studies in the first half of 2016, which should help us determine the patient populations to be studied in clinical trials.

We cannot predict with certainty our development costs, and they may be subject to changes. See “Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements.”

RP101

RP101 is a proprietary small molecule, first-in-class, heat shock protein 27 (Hsp27) inhibitor, administered orally, which may prevent the induction of resistance to chemotherapy (chemoresistance), thus maintaining sensitivity of the tumor to chemotherapy and potentially enhancing patient survival.

RP101 binds to Hsp27, a chaperone protein which is found in abnormally high levels in cancer cells, and inhibits its activity. The overexpression of Hsp27, which results in the amplification of a multidrug-resistance (MDR) gene, has been linked to tumor resistance to cytotoxic drugs and the development of metastasis. Chemoresistance limits the effectiveness of chemotherapy and can ultimately lead to treatment failure. By inhibiting Hsp27, RP101 may prevent chemoresistance and enhance the sensitivity of tumors to chemotherapy. RP101 activity is based on a new mechanism of action of the anti-viral drug brivudine, a nucleoside analogue approved and marketed in several European countries for the treatment of herpes zoster.

As mentioned under "– Acquisition and License Agreements – License Agreement for RP101", on August 13, 2014, we entered into a binding exclusive option agreement for the acquisition of the oncology therapeutic candidate RP101 and next generation compounds. Under the terms of the agreement, we have a one year option to acquire the exclusive worldwide rights to RP101 for all indications, other than for the pancreatic cancer indication in South Korea. The one year option was extended for an additional year in July 2015. During the option period, we have conducted development activities with RP101.

Competition and Market

RP101 orally-administered nucleoside analogue has been shown to bind to heat shock protein 27 (Hsp27) and inhibit its anti-apoptotic effects. RP101 has been studied as an adjunct treatment of pancreatic cancer with potential applicability to other gastrointestinal cancers.

Please see MESUPRON® Competition and Market section for information on the pancreatic cancer market.

To the best of our knowledge, the only other Hsp27 inhibitor in development for oncology indications is Apatorsen (OGX-427), developed by OncoGeneX Pharmaceuticals Inc. According to OncoGenX's presentation from November 2015, it is conducting a total of seven randomized Phase II studies with Apatorsen in oncology indications, including an investigator-sponsored Phase II study in metastatic pancreatic cancer which has been completed. The results from this study demonstrated that the addition of Apatorsen to ABRAXANE and gemcitabine did not demonstrate a survival benefit compared to ABRAXANE and gemcitabine alone.

Clinical Development

RP101 has completed several Phase I and Phase II clinical trials with a total of 249 subjects treated, including Phase II trials in pancreatic cancer.

RP101 has been granted Orphan Drug designation for the adjunct treatment of pancreatic cancer by the FDA and the European Medicines Agency EMA.

As part of the RP101 global development program and regulatory strategy, we are currently performing several preclinical studies, including studies in immunodeficient mice engrafted with pancreatic cancer tumor cell lines. We expect to have initial data from these preclinical studies in the first half of 2016, which will allow us to make a decision regarding clinical trials.

We cannot predict with certainty our development costs, and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements."

RIZAPORT™

RIZAPORT™ is an oral thin film formulation of rizatriptan intended for the treatment of acute migraine headaches. Migraines are generally treated through the usage of triptans, a class of molecules that narrow (constrict) blood vessels in the brain in order to relieve swelling and other migraine symptoms. Examples of triptans include sumatriptan, zolmitriptan and rizatriptan, the active pharmaceutical ingredient in RIZAPORT™.

RIZAPORT™ is based on a patented technology called "VersaFilm™." This technology allows the production of thin film strips that dissolve rapidly in the mouth, allowing the drug to be absorbed through the oral mucosa and into the bloodstream. The proprietary VersaFilm™ technology is a novel, non-mucoadhesive, fast dissolving oral dosage form.

The VersaFilm™ platform offers potential advantages that include fast absorption of the drug and the convenience of use compared to conventional tablets.

We acquired the rights to RIZAPORT™ under an August 26, 2010 joint development and commercialization agreement with IntelGenx Corp., pursuant to which we received a worldwide, exclusive and perpetual license to various patent rights and know-how related to RIZAPORT™. See "– Acquisition and License Agreements – License Agreement for RIZAPORT™".

Competition and Market

To the best of our knowledge, the main marketing competitors of RIZAPORT™ are oral drugs from the triptan family (5-HT 1B/1D serotonin agonists), such as rizatriptan from Merck and Co., Inc., which is marketed in the U.S. under the name of Maxalt® and in generic form since 2012, and sumatriptan, produced by GlaxoSmithKline and marketed in the U.S. as Imitrex® and in generic form since 2006. According to a report from GlobalData, the prevalence of migraines in the U.S. is estimated to reach over 30 million cases in 2016. The target market for RIZAPORT™ was estimated at approximately $697 million worldwide in 2015 according to an annual sales report from EvaluatePharma, a leading market intelligence and information resource.

In December 2012, the patent on rizatriptan expired and as of the date of this filing, there are various generic versions of Maxalt® and of Maxalt MLT® available for prescription.

We believe that RIZAPORT™ could compare favorably to the other triptan drugs due to the fact that it is delivered through oral dissolution, rather than through conventional tablets. This feature may be especially advantageous to patients suffering dysphagia, and to patients who suffer from migraine-related nausea, which according to an article published by Lipton RB *et al.* is estimated to affect 80% of all of total migraine population. We believe that RIZAPORT™ will also be advantageous to patient populations such as geriatrics who often struggle with swallowing capsules with water.

Clinical Development

In April 2012, we completed, together with our development partner IntelGenx Corp. a bioequivalence clinical study to examine the pharmacokinetic equivalence between the soluble film of RIZAPORT™ and rizatriptan of Merck & Co. Inc. (Maxalt MLT®), using 26 volunteers. The final results of the clinical trial, demonstrated that RIZAPORT™ met its specified endpoints and the FDA criteria in all parameters for bioequivalence with rizatriptan of Merck & Co. Inc. (Maxalt MLT®).

In March 2013, together with IntelGenx Corp., we filed a New Drug Application (NDA) with the FDA for U.S. marketing approval under the 505(b)(2) regulatory path for RIZAPORT™.

On February 4, 2014, together with IntelGenx Corp., we announced the receipt of a complete response letter from the FDA indicating that certain matters would need to be addressed prior to obtaining approval for marketing. These matters related primarily to third party chemistry, manufacturing and controls (CMC) issues, as well as to packaging and labeling of the film. The FDA's letter did not raise any safety issues or questions regarding the results of the clinical trials. On March 3, 2014, together with IntelGenx Corp., we responded to the FDA's complete response letter and in response, the FDA requested additional CMC data. In relation to the FDA response, we were also informed that a supplier of raw material for RIZAPORT™ was having compliance discussions with the FDA that are not specific to RIZAPORT™.

In April 2014, together with IntelGenx Corp., we initiated a comparative bioavailability study with RIZAPORT™ and the European reference drug Maxalt® lingua marketed in Germany by MSD Sharp & Dohme GMBH, based on a positive European Scientific Advice meeting with the German Federal Institute for Drugs and Medical Devices (BfArM) regarding RIZAPORT™ that took place in 2013. In May 2014, together with IntelGenx Corp., we announced the successful completion of the clinical trial that demonstrated bioequivalence based on the criteria discussed with BfArM.

Based on the data from that trial, we submitted a Marketing Authorization Application (MAA) to BfArM, as the reference member state under the European Mutual Recognition Procedure. In October 2015, BfArM informed us that the MAA had been approved. Approval from Luxembourg is anticipated during the first half of 2016.

The following chart summarizes the clinical trial history status of RIZAPORT™:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Number of subjects of the trial	Nature and status of the trial	Schedule
PLT--008-09	Phase I	PK comparison with a parallel product	RA Chem Pharma, India	10	The trial was performed and indicated similarity between the PK profile of the therapeutic candidate and the profile of the reference product	Completed in 2009
RZA-P9-688	Comparative Bioequivalence	PK comparison with Maxalt MLT®	Algorithme Pharma, Canada	26	Successfully completed the study demonstrating bioequivalence as defined by the FDA	Completed in Q2 2012
RZA-P3-697	Comparative Bioequivalence	PK comparison with Maxalt® Lingua	Algorithme Pharma, Canada	26	Successfully completed the study demonstrating bioequivalence as defined by the European Medicines Agency	Completed in Q3 2014

Together with IntelGenx Corp., we are working diligently on a variety of options to ensure continued supply of the raw material.

We cannot predict with certainty our development costs and they may be subject to changes. See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements."

Acquisition and License Agreements

Acquisition of RHB-104, RHB-105 and RHB-106

On August 11, 2010 we entered into an asset purchase agreement with Giaconda Limited, a publicly traded Australian company, pursuant to which Giaconda Limited transferred all of its patents, tangible assets, production files, regulatory approvals and other data related to the "Myoconda", "Heliconda" and "Picoconda" products to us. We renamed these products RHB-104, RHB-105 and RHB-106, respectively. Giaconda Limited further transferred to us products in process, product samples and raw materials, as well as certain rights of first refusal with respect to intellectual property in relation to digestive condition treatments. The agreement excluded the transfer of the rights to two other products of Giaconda Limited that are not related to RHB-104, RHB-105 and RHB-106. However, to the extent that the intellectual property associated with these two other products shall be required for the research, development, manufacture, registration, import/export, use, commercialization, distribution, sale and/or offer for sale of any of RHB-104, RHB-105 and RHB-106, Giaconda Limited granted us an exclusive worldwide assignable right to such intellectual property for such purposes. The closing of this agreement occurred on August 26, 2010.

In consideration for the assets purchased by us, we paid Giaconda Limited $500,000. We and Giaconda Limited also agreed that until the expiration of the last patent transferred to us, we will pay to Giaconda Limited 7% of net sales from the sale of the products by us and 20% of the royalties received from sublicensees, in each case, only after we recoup the amounts and expenses exceeding an approved budget.

Under the agreement, it was agreed that none of Giaconda Limited or, the developer of the products, nor their respective affiliates may compete with us or assist others to compete with us with respect to the products and acquired technology. Such non-compete undertaking shall be in force for a period of time of up to 10 years from the date of the agreement.

The agreement provides that, should we elect not to proceed with the registration proceedings or the maintenance of any patent transferred to us, we will notify Giaconda Limited and Giaconda Limited will have the right to proceed with the registration, maintenance, development and commercialization of such patent at its expense. Should Giaconda Limited exercise such right, it will be entitled to all amounts received in connection with sales relating to such patent.

The agreement also requires us to make a good faith, continuous and commercially reasonable effort to allocate appropriate financial resources to prepare, initiate and complete the clinical development of the products (with the exception of Picoconda) and file an application for regulatory marketing approval in accordance with industry standards. Development failures, negative regulatory decisions, and/or other reasons beyond our control will not constitute a breach of this obligation. Should we breach this obligation with respect to the development of any of the products, and fail to cure the breach within 90 days from the date that Giaconda Limited sends us a default notice, Giaconda Limited may buy back all of the intellectual property rights with respect to such product for the original purchase price, plus the related development costs incurred by us through the date of the buy-back.

In connection with the license agreement with Salix (later acquired by Valeant), dated February 27, 2014, described below, we amended the asset purchase agreement and related agreements by excluding from the non-compete undertakings of Giaconda and certain of its affiliate products, technology and related activities in the purgative field and excluded from such non-compete undertakings certain of Giaconda's affiliates.

License Agreement for BEKINDA™

In March 2014, we entered into a License Agreement with Temple University to directly secure rights to patents related to BEKINDA™. Previously, these rights were licensed to us from SCOLR, which announced that they had ceased business operations in 2013. The agreement with Temple University replaced our previous license agreement with SCOLR Pharma Inc. (SCOLR). SCOLR had itself licensed those patents from Temple University, the original owner of the patents. Under the agreement with Temple University, we will continue to develop its BEKINDA™ formulation and pursue commercialization options once relevant.

License Agreement for YELIVA™

On March 31, 2015 we entered into an exclusive license agreement with Apogee, a privately-held biotech company located in Hummelstown, Pennsylvania, U.S., under which Apogee granted us the exclusive, world-wide development and commercialization rights to ABC294640 (which we then renamed to YELIVA™) and additional intellectual property rights. YELIVA™ is a proprietary, first-in-class, orally-administered sphingosine kinase-2 (SK2) inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple inflammatory, gastrointestinal (GI) and oncology indications. Under the terms of the agreement, we agreed to pay Apogee an upfront payment of $1.5 million, as well as an additional amount of $2 million which will be paid on the earlier of (i) a specific date or (ii) reaching a specific development milestone. In addition, we undertook to pay up to an additional $2 million in potential development milestone payments, and potential tiered royalties starting in the low double-digits. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2015, we paid Apogee the initial amount of $1.5 million and recognized an amount of $2 million as a current liability. The license agreement will stay in effect as of its effective date unless terminated earlier as described in the agreement. We are entitled to terminate the agreement at any time upon 30 day prior written notice to Apogee. The agreement also provides for the right of termination for each party in the event of a material breach committed by the other party.

License Agreement for MESUPRON®

On June 30, 2014 we entered into an exclusive license agreement with Wilex AG, a German biopharmaceutical company focused on oncology (Wilex) under which Wilex granted us the exclusive development and commercialization rights, throughout the world for all indications excluding China, Hong Kong, Taiwan and Macao, to MESUPRON®, a small molecule, proprietary, urokinase-type plasminogen activator (uPA) inhibitor administered by oral capsule.

In consideration for the license we paid Wilex an upfront payment of $1 million. We have agreed to pay Wilex tiered royalties on net revenues, ranging from mid-teens up to 30%.

The license agreement will stay in effect as long as we are required to make royalty payments. We are entitled to terminate the agreement at any time on 30 days written notice to Wilex. The agreement also provides right of termination for each party in the event of a breach.

License Agreement for RP101

On August 13, 2014, we entered into a binding exclusive option agreement for the acquisition of the oncology therapeutic candidate RP101 and next generation compounds, with RESprotect GmbH, a German privately-held biopharmaceitucal company (RESprotect). In July 2015, we extended the term of the exclusive option agreement for an additional year. RP101 is a proprietary, first-in-class, heat shock protein 27 (Hsp27) inhibitor, administered orally. Under the terms of the agreement, we have the option to acquire the worldwide exclusive rights to RP101 for all indications, other than for the pancreatic cancer indication in South Korea.

In consideration for the option, we paid RESprotect for a one year option, and we paid RESprotect for the one year extension. During the option period, which includes the extended option period, we are entitled, at our discretion, to conduct development activities with RP101. If we elect to exercise the option, we will acquire the exclusive rights to RP101 for a total payment of $100,000, covering both the option and the acquisition of the rights. We also undertook to pay future potential milestone payments and tiered royalties on net revenues, ranging from single-digits to mid-teens.

The option agreement will terminate upon the earlier of (i) exercise of the option and subsequent execution of the respective Asset Purchase Agreement, (ii) expiry of the extended option period, and (iii) by written notice of termination by us, at our full discretion for any reason at any time during the option period.

License Agreement for RIZAPORT™

On August 26, 2010, we entered into a joint development and commercialization agreement with IntelGenx Corp. under which IntelGenx Corp. granted us a worldwide, exclusive and perpetual license to use its rights in patents and know-how relating to a triptan formula based on the VersaFilm™ technology and which we call RIZAPORT™.

The license includes the right to grant sublicenses. The license covers the co-developing, selling, offering for sale and importing the product for all indications, including, but not limited to, acute treatment of migraine attacks with or without an aura and all other therapeutic, diagnostic, and other human or animal uses.

The license provides that IntelGenx Corp. reserves the right to grant licenses to manufacture the product, subject to the approval of a steering committee. The agreement further limits our right to grant sublicenses by requiring that we give prior notice to IntelGenx Corp. of the identity of any proposed sub-licensee and provide IntelGenx Corp. with information regarding the main elements of the proposed sublicense agreement. If IntelGenx Corp. objects to a sublicense, the proposed sublicense will be presented for the approval of a steering committee.

Pursuant to the agreement, as amended, the parties agreed on joint product development activities. Accordingly, IntelGenx Corp. agreed to devote sufficient resources (subject to the approved budget in the agreement) in order to conduct clinical trials and file an application with the FDA for marketing of the product, and we agreed to finance the balance of the development in the amount of approximately $1.2 million.

The joint development of the product is to be conducted through a steering committee, comprised of an equal number of members appointed by us and IntelGenx Corp. The committee is charged with supervising progress of our research and development efforts, reporting on possible delays and deciding on required revisions in the plan. IntelGenx Corp. has the deciding vote in any vote relating to issues of development, regulation and manufacture, while we have the deciding vote in any vote relating to issues of licensing, commercialization and collaborations. In consideration for the license, we made up-front and milestone payments in the aggregate amount of $800,000 and we are required to make additional milestone payments of up to $500,000 upon receipt of FDA marketing approval for the product.

In addition, we are required to make royalty payments to IntelGenx Corp. of 20% of net sales if the product is marketed by us and 60% of the first $2 million of net sublicense fees, and 40% of net sublicensing fees thereafter, if the product is marketed by sublicensees. However, if we bear the regulatory costs in a sublicense arrangement, royalties will be 20% of net sublicense fees until we recover these costs, plus 10% interest, and if IntelGenx Corp. bears such costs, royalties will be 70% of net sublicense fees.

The agreement provides that all intellectual property developed or to be developed exclusively by IntelGenx Corp. will belong exclusively to IntelGenx Corp. and will be licensed to us, and the intellectual property to be developed or financed jointly by IntelGenx Corp. and us will be jointly owned by us and IntelGenx Corp., and each party may make use of such joint intellectual property for uses not competing with either the product or the other party.

The agreement is of unlimited duration and will remain in force until terminated in accordance with its terms. Either party may terminate the agreement if (i) the other party is in material breach and does not cure within ninety (90) days; or (ii) a bankruptcy or liquidation event occurs with respect to the other party. This agreement also provides that we may terminate the agreement for convenience upon providing thirty (30) days written notice to IntelGenx Corp.

License Agreement for MAP diagnostic test related to RHB-104

On September 18, 2011, we entered into a license agreement with the University of Central Florida Research Foundation, Inc. pursuant to which we were granted an exclusive license for all indications and medical uses to a patent-protected diagnostic test that identifies the presence of MAP bacterial DNA in peripheral blood through DNA testing. The license covers future commercial use of the test, including its manufacture, marketing, sale and commercialization.

Under the agreement, we may grant sublicenses for the test with the consent of the University of Central Florida Research Foundation, Inc., from whom consent may not be unreasonably withheld.

To date, in consideration for the license, we have made payments in the aggregate amount of $90,000, and are required to make additional annual minimum royalty payments of $35,000 in each subsequent year until the last patent covered by the agreement expires. These annual minimum payment amounts will be deducted from future royalty payments.

In addition, we are required to make royalty payments equal to payments 7% of future sales, or an annual minimum amount noted above, as well as 20% of payments we receive from granting sublicenses.

The agreement will remain in force on a country by country basis until the last patent covered by the agreement expires. The University of Central Florida Research Foundation may terminate the agreement if (i) we are in material breach; (ii) if we fail to pay royalties when due and payable following provision of sixty (60) days notice; or (iii) a bankruptcy or liquidation event occurs with respect to us. We may terminate the agreement at any time by providing ninety (90) days written notice to the University of Central Florida Research Foundation.

License Agreement with University of Minnesota related to MAP diagnostic test for RHB-104

On December 18, 2014, we announced that we licensed certain diagnostic technology from the University of Minnesota. This transaction is part of our efforts to develop a validated and precise method of detecting Mycobacterium avium subspecies paratuberculosis (MAP), which we believe plays an important role in Crohn's disease and potentially other diseases. Under the terms of the agreement, we paid the University of Minnesota a one-time upfront payment and are required to make an additional milestone payment. We are developing a diagnostic test for MAP in conjunction with Q Squared.

Exclusive License Agreement with Valeant Pharmaceuticals International, Inc.

On February 27, 2014 we entered into a worldwide exclusive license agreement with Salix Pharmaceuticals, Ltd. (later acquired by Valeant Pharmaceuticals International, Inc.) by which Salix licensed the worldwide exclusive rights to our RHB-106 encapsulated formulation for bowel preparation, and rights to other purgative developments. Pursuant to the agreement, we granted Salix the right to develop and commercialize RHB-106 and/or the related rights.

Additionally, we waived any applicable rights of first refusal granted to us by Giaconda Limited and its affiliates in our August 2010 asset purchase agreement transaction with respect to intellectual property in relation to digestive condition treatments.

Pursuant to the agreement, we received an up-front payment of $7 million and are entitled to an additional amount of up to $5 million in subsequent milestone payments. In addition, as part of the terms of the agreement, Salix agreed to pay us tiered royalties on net sales, ranging from low single-digit up to low double-digits.

Other than with respect to the rights granted to us, as described below, we agreed, during the term of the agreement, not to compete in the purgative field.

Salix granted us an option to commercialize certain of the products of Salix, in pre-determined territories. This right is subject to such products being available for distribution in the applicable territories and Salix's agreement to a potential exclusive distribution arrangement with us. We were granted exclusivity as to the commercialization right under the option, for a limited period, which has since expired.

The agreement expires on the date the royalties are no longer payable in connection with RHB-106 and/or related rights. Following expiration of the agreement, the rights granted under the agreement shall become fully-paid, perpetual, royalty-free and irrevocable. We have the right, following notice to Valeant, to terminate the agreement in the event that Valeant does not pursue the development of RHB-106 or related rights. This termination right is effective until the date on which all subsequent milestone payments referred to above have been paid to us.

Master Service Agreement with 7810962 Canada Inc.

On April 28, 2011, we entered into a master service agreement, which was later amended, with 7810962 Canada Inc., our Canadian service provider for various project management services. The agreement allowed our Canadian service provider to enter into service agreements with third parties for the relevant services. The agreement may be terminated by either party upon 30 days' advance notice.

The agreement with our Canadian service provider provides that certain research and development services related to our projects will be carried out pursuant to our specific requests and upon the signing of specific agreements for each project. Such agreements shall include a description of the required services, service terms and fees. To date, we, through our Canadian service provider, have entered into manufacturing, clinical services and regulatory agreements mainly related to RHB-104.

Furthermore, pursuant to the agreement, the Canadian service provider may provide us with a discount to the research and development services with respect to incentives programs from various authorities that may be granted to the Canadian service provider in the future. As of December 31, 2015, the estimated discount we will receive from our Canadian service provider is approximately $0.2 million.

Clinical Services Agreements

Clinical Services Agreement related to RHB-104

On June 15, 2011, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with inVentiv Health (f/k/a PharmaNet Canada Inc.), a subsidiary of an international CRO company, and other related entities, for the purpose of performing the clinical trial for RHB-104. InVentiv Health is a leading provider of global drug development services to pharmaceutical and biotechnology companies, offering therapeutically-specialized capabilities for Phase I-IV clinical development, and pursuant to the agreement, is responsible for the performance of the clinical trial, including entering into agreements with medical centers to perform the trial, supervision of the performance and progress of the trial and the analysis of the results, all pursuant and subject to applicable regulatory requirements.

Pursuant to this agreement and subsequent amendments, inVentiv Health is entitled to receive $7.4 million in connection with the MAP US Phase III clinical trial as well as reimbursement of investigator grant costs and pass-through costs to be paid during the trial for an estimated amount of about $5.8 million. The payments will be spread over the period of the clinical trial based upon quarterly administration fees and milestone payments based on patient recruitment, completion of subject dosing and report preparation, investigators grants paid to research centers that participate in the trial, as well as reimbursements of certain expenses. These fees, however, may vary widely from time to time in accordance with the final clinical trial protocol, length of the study and payments to be made to third parties, such as investigator grants costs.

The agreement includes a timetable for the recruitment of patients, performance of the trial and analysis of results, including a timetable for the performance of ongoing patient follow-up. Such timetables may vary as a result of possible delays in recruitment of patients for the clinical trial.

The agreement will remain in force until all relevant services have been provided and we have made all payments thereunder, or until terminated. Either party may terminate the agreement (i) if the other party is in material breach and does not cure within thirty (30) days; or (ii) upon a bankruptcy or liquidation event with respect to the other party. This agreement also provides that we may terminate the agreement at any time without cause upon providing forty five (45) days written notice to our Canadian service provider.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our technology and therapeutic candidates, its therapeutic applications, and related technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on our trade secrets, know-how and continuing technological innovation to develop and maintain our proprietary position. We vigorously defend our intellectual property to preserve our rights and gain the benefit of our technological investments. We have rights either through assignment, asset purchase or in-licensing to a total of approximately 360 issued patents and 115 patent applications. The patents and patent applications are registered in the U.S. and other key jurisdictions, the details of each family of patents being provided below. In addition, we have licensed rights to various platform technologies on a non-exclusive basis.

The patent positions of companies such as ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted.

RHB-105

RHB-105 is protected by two patent families. The first patent family, titled “Improved Method of Eradication of *H.pylori*”, was acquired as part of our asset purchase agreement with Giaconda Limited, and provides patent protection until 2019.

The second patent family, titled “Pharmaceutical Compositions for the Treatment of Helicobacter Pylori”, was filed by us and will provide patent protection until 2034.

RHB-104 – Inflammatory Bowel Disease

RHB-104 for Inflammatory Bowel Disease is protected by two patent families. The first patent family, titled “Methods and Compositions for Treating Inflammatory Bowel Disease”, was acquired as part of our asset purchase agreement with from Giaconda Limited, and provides patent protection until 2018.

The second patent family, titled “Method and Composition for Treating Inflammatory Bowel Disease”, was filed by us and will provide patent protection until 2029.

We have also in-licensed from the University of Central Florida Research Foundation Inc. (UCF) U.S. Patent No. 7,488,580 entitled "Protocol for Detection of the Intracellular Infection *Myobacterium Avium Paratuberculosis* in Blood", which will expire in H1 2026. This patent relates to a method and kit for detection of intracellular MAP infection in blood and blood derivative samples from humans by culture and PCR. The technology can screen for MAP in blood samples from patients having inflammatory and non-inflammatory bowel disease and the results used to identify those patients for appropriate treatment with antibiotics. The method and kit allows monitoring and evaluation of the outcome of antibiotic therapy.

Further, we have in-licensed U.S. Patent Nos. 7,074,559 and 7,867,704 from The University of Minnesota entitled "Mycobacterial Diagnostics". One U.S. patent will expire in 2022, and the other U.S. patent will expire in 2026. The acquired diagnostic technology is intended for the detection of *Mycobacterium avium subspecies paratuberculosis* (MAP) bacterium.

RHB-104 – Autoimmune Diseases

Another patent family that we filed relates to "A Composition and Method for Treating an Autoimmune Disease" and covers compositions comprising effective amounts of rifabutin, clarithromycin and clofazimine to enable treatment of an autoimmune disease by targeting cytokines or cytokine receptors. This patent family, if issued, would provide patent protection for methods of treating autoimmune diseases, such as MS, with RHB 104, up until 2034.

BEKINDA™ - Gastritis, Gastroenteritis and IBS-D

BEKINDA™ for gastroenteritis and other conditions is protected by one patent family that was filed by us, entitled "Ondansetron Extended Release Solid Dosage Forms for Treating Either Nausea, Vomiting or Diarrhea Symptoms", and if issued would provide patent protection through 2035.

BEKINDA™ - Oncology Support

BEKINDA™ for oncology support is protected by two patent families.

The first patent family was, in-licensed by us from Temple University and is entitled "Monolithic tablet for controlled drug release", with a US patent expiry date in 2018. This patent relates to formulations based on a swellable hydrodynamically balanced monolithic matrix.

The second patent family, filed by us, is entitled "Antiemetic Extended Release Solid Dosage Forms", and if issued would provide patent protection through 2034.

RHB-106 - Colonic Evacuation

RHB-106 includes three patent families .The first and second patent families, titled "Picodulfate-containing preparation for colonic evaluation" and "Administering osmotic colonic evacuant containing a picosulfate", were acquired from Giaconda Limited as part of our asset purchase agreement. These patents provide patent protection until 2016 and 2018, respectively.

The third patent family was filed by us and is titled "Formulations and Methods of Manufacturing Formulations for use in Colonic Evacuation". If issued, this patent will provide protection until 2033.

We are party to an exclusive agreement by which Salix (later acquired by Valeant). licensed the worldwide exclusive rights to the RHB-106 patent portfolio. As part of the agreement, Salix is responsible for the patent families related to RHB 106.

YELIVA™ - Inflammatory, Oncology, and Gastrointestinal Indications

This patent portfolio was in-licensed by us from Apogee Biotechnology Corp. YELIVA™ (ABC294640) is a first-in-class, proprietary sphingosine kinase-2 (SK2) inhibitor, administered orally, with anti-cancer and anti-inflammatory activities, targeting a number of potential inflammatory, oncology and gastrointestinal indications.

YELIVA™ includes three patent families. The first, titled "Sphingosine Kinase Inhibitors", provides patent protection through 2028. The second patent family, titled "Methods for the Treatment and Prevention of Inflammatory Diseases", provides patent protection through 2030. The third patent family, titled "Sphingosine Kinase Inhibitor Prodrugs", provides patent protection through 2031.

These patents relate to sphingosine kinase inhibitors, pharmaceutical compositions, methods of preparing the inhibitors, methods of treating inflammatory diseases using the inhibitors, methods of treating cancer using the inhibitors, and methods of inhibiting sphingosine kinase.

MESUPRON® – Oncology

This patent portfolio was in-licensed by us from Wilex AG. MESUPRON® is a first-in-class urokinase-type plasminogen activator (uPA) inhibitor administered by oral capsule.

The first patent family relates to crystalline modifications of N-α -(2,4,6-triisopropylphenylsulfonyl)-3-hydroxyamidino-(L)-phenylalanine 4-ethoxycarbonylpiperazide and/or salts thereof, which can be used as pharmaceutical agents, and to pharmaceutical compositions and pharmaceutical uses comprising these novel crystalline modifications. The patents in this family will expire in 2025.

The second patent family relates to Urokinase inhibitor compounds. The patents in this family will expire in 2024.

The third patent family relates to methods for the production of phenylalanine derivatives. The patents in this family will expire in 2023.

The fourth patent family relates to methods for producing phenylalanine derivatives. The patents in this family will expire in 2025.

The fifth patent family relates to a method for producing phenylalanine derivatives. The U.S. patent will expire October 24, 2025.

The sixth patent family relates to Urokinase Inhibitors. The patents in this family will expire in 2019.

The seventh patent family relates to a method of preparing methylhydroxyalkylcellulose. The U.S. patent will expire September 15, 2026.

The eight patent family relates to formulations for phenylalanine derivatives. The patents in this family will expire in 2025.

The ninth patent family relates to Urokinase inhibitors. The patents in this family will expire in 2018.

RP101 – Oncology

In August 2014, we entered into a binding exclusive option agreement for the acquisition of RP101 and next generation compounds which was extended for an additional twelve months in July 2015. RP101 is an orally administered small molecule which binds to Hsp27, a chaperone protein which is found in abnormally high levels in cancer cells and inhibits its activity.

The first patent family relates to 5' substituted nucleosides and the patents in this family will expire in January 2016.

The second patent family relates to nucleosides and patents issuing from this family will expire in 2027.

The third patent family relates to uracil derivatives. The patents issuing from in this family will expire in 2029.

RIZAPORT™ - Acute Migraines

We have in-licensed from IntelGenx Corp., three issued U.S. patents, three pending U.S. non-provisional patent applications, and 15 pending international patent applications covering various aspects of the VersaFilmTM technology.

Government Regulations and Funding

Pharmaceutical companies are subject to extensive regulation by national, state and local agencies such as the FDA in the U.S., the Ministry of Health in Israel, or the European Medicines Agency (EMA). The manufacture, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the U.S. and various foreign countries. Additionally, in the U.S., we must follow rules and regulations established by the FDA requiring the presentation of data indicating that our products are safe and efficacious and are manufactured in accordance with current good manufacturing practices (cGMP) regulations. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or not allow us to manufacture or market our products, and we may be criminally prosecuted. We and our manufacturers and clinical research organizations may also be subject to regulations under other federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. The U.S. government has increased its enforcement activity regarding illegal marketing practices domestically and internationally. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

These regulatory requirements impact our operations and differ in one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval in another country. However, securing the approval of a more stringent body, *i.e.* the FDA, may facilitate receiving the approval by a regulatory authority in a different country where the regulatory requirements are similar or less stringent. The approval procedures involve high costs and are manpower intensive, usually extend over many years and require highly skilled and professional resources.

U.S. Food and Drug Administration Approval Process

The steps required to be taken before a new drug product candidate may be marketed in the U.S. generally include:

- completion of pre-clinical laboratory and animal testing;
- the submission to the FDA of an investigational new drug, or IND, application which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product candidate for its intended use; and
- submission and approval of an NDA.

Clinical studies are conducted under protocols detailing, among other things, the objectives of the study, what types of patients may enter the study, schedules of tests and procedures, drugs, dosages, and length of study, as well as the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical study and any subsequent protocol amendments must be submitted to the FDA as part of the IND.

In all the countries that are signatories of the Helsinki Declaration (including Israel), the prerequisite for conducting clinical trials (on human subjects) is securing the preliminary approval of the competent authorities of that country to conduct medical experiments on human subjects in compliance with the other principles established by the Helsinki Declaration.

The clinical testing of a drug product candidate generally is conducted in three sequential phases prior to approval, but the phases may overlap or be combined. A fourth, or post approval, phase may include additional clinical studies. The phases are generally as follows:

Phase I. In Phase I clinical studies, the drug product candidate is tested in a small number of patients with the target condition or disease or in healthy volunteers. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the drug product candidate in humans, side effects associated with increasing doses, and, in some cases, to gain early evidence on efficacy. The number of participants included in Phase I studies is generally in the range of 20 to 80.

Phase II . In Phase II studies, in addition to safety, the sponsor evaluates the efficacy of the product candidate on targeted indications to determine dosage tolerance and optimal dosage and to identify possible adverse effects and safety risks. Phase II studies typically are larger than Phase I but smaller than Phase III studies and may involve several hundred participants

Phase III . Phase III studies typically involve an expanded patient population at geographically-dispersed test sites. They are performed after preliminary evidence suggesting effectiveness of the product candidate has been obtained and are designed to further evaluate clinical efficacy and safety, to establish the overall benefit-risk relationship of the product candidate and to provide an adequate basis for a potential product approval. Phase III studies usually involve several hundred to several thousand participants.

Phase IV. Phase IV clinical trials are post marketing studies designed to collect additional safety data as well as potentially expand a product indication. Post marketing commitments are required of, or agreed to by, a sponsor after the FDA has approved a product for marketing. These studies are used to gain additional information from the treatment of patients in the intended therapeutic indication and to verify a clinical benefit in the case of drugs approved under accelerated approval regulations. If the FDA approves a product while a company has ongoing clinical trials that were not necessary for approval, a company may be able to use the data from these clinical trials to meet all or part of any Phase IV clinical trial requirement. These clinical trials are often referred to as Phase IV post-approval or post marketing commitments. Failure to promptly conduct Phase IV clinical trials could result in the inability to deliver the product into interstate commerce, misbranding charges, and civil monetary penalties.

Clinical trials must be conducted in accordance with the FDA's good clinical practices, or GCP, requirements. The U.S. Food and Drug Administration may order the temporary or permanent discontinuation of a clinical study at any time or impose other sanctions if it believes that the clinical study is not being conducted in accordance with FDA requirements or that the participants are being exposed to an unacceptable health risk. An institutional review board, or IRB, generally must approve the clinical trial design and patient informed consent at study sites that the IRB oversees and also may halt a study, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions. Additionally, some clinical studies are overseen by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or committee. This group recommends whether or not a trial may move forward at designated check points based on access to certain data from the study. The clinical study sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

As a product candidate moves through the clinical testing phases, manufacturing processes are further defined, refined, controlled and validated. The level of control and validation required by the FDA would generally increases as clinical studies progress. We and the third-party manufacturers on which we rely for the manufacture of our product candidates and their respective components (including the active pharmaceutical ingredient, or API) are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. To comply with cGMP requirements, manufacturers must continue to spend time, money and effort to meet requirements relating to personnel, facilities, equipment, production and process, labeling and packaging, quality control, recordkeeping and other requirements.

Assuming completion of all required testing in accordance with all applicable regulatory requirements, detailed information on the product candidate is submitted to the FDA in the form of an NDA, requesting approval to market the product for one or more indications, together with payment of a user fee, unless waived. An NDA includes all relevant data available from pertinent nonclinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information on the chemistry, manufacture, control and proposed labeling, among other things. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate for its intended use to the satisfaction of the FDA

If an NDA submission is accepted for filing, the FDA begin an in-depth review of the NDA. Under the Prescription Drug User Fee Act, or PDUFA, the FDA's goal is to complete its initial review and respond to the applicant within twelve months of submission, unless the application relates to an unmet medical need in a serious or life-threatening indication, in which case the goal may be within eight months of NDA submission. However, PDUFA goal dates are not legal mandates and FDA response often occurs several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the U.S. Food and Drug Administration requests or the NDA sponsor otherwise provides additional information or clarification regarding information already provided in the NDA. The NDA review process can, accordingly, be very lengthy. During its review of an NDA, the FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it typically follows such recommendations. Data from clinical studies are not always conclusive and the FDA and/or any advisory committee it appoints may interpret data differently than the applicant.

After the FDA evaluates the NDA and inspects manufacturing facilities where the drug product candidate and/or its API will be produced, it will either approve commercial marketing of the drug product candidate with prescribing information for specific indications or issue a complete response letter indicating that the application is not ready for approval and stating the conditions that must be met in order to secure approval of the NDA. If the complete response letter requires additional data and the applicant subsequently submits that data, the FDA nevertheless may ultimately decide that the NDA does not satisfy its criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategies, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing. Such post-marketing testing may include phase 4 clinical studies and surveillance to further assess and monitor the product's safety and efficacy after approval. Regulatory approval of products for serious or life-threatening indications may require that participants in clinical studies be followed for long periods to determine the overall survival benefit of the drug product candidate.

If the FDA approves one of our therapeutic candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report, among other things, certain adverse reactions and production problems to the FDA, provide updated safety and efficacy information and comply with requirements concerning advertising and promotional labeling for any of our products. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval, and the FDA periodically inspects manufacturing facilities to assess compliance with cGMP, which imposes extensive procedural, substantive and record keeping requirements. If we seek to make certain changes to an approved product, such as certain manufacturing changes, we will need FDA review and approval before the change can be implemented. For example, if we change the manufacturer of a product or its API, the FDA may require stability or other data from the new manufacturer, which will take time and is costly to generate, and the delay associated with generating this data may cause interruptions in our ability to meet commercial demand, if any. While physicians may use products for indications that have not been approved by the FDA, we may not label or promote the product for an indication that has not been approved. Securing FDA approval for new indications is similar to the process for approval of the original indication and requires, among other things, submitting data from adequate and well-controlled studies that demonstrate the product's safety and efficacy in the new indication. Even if such studies are conducted, the FDA may not approve any change in a timely fashion, or at all.

We rely, and expect to continue to rely, on third parties for the manufacture of clinical and future commercial, quantities of our therapeutic candidates. Future FDA and state inspections may identify compliance issues at these third-party facilities that may disrupt production or distribution or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved NDA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. Newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Many of the foregoing could limit the commercial value of an approved product or require us to commit substantial additional resources in connection with the approval of a product. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

Section 505(b)(2) New Drug Applications

As an alternate path for FDA approval of new indications or new formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the Food, Drug, and Cosmetic Act, or FDC, was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Some examples of products that may be allowed to follow a 505(b)(2) path to approval are drug product candidates that have a new dosage form, strength, route of administration, formulation or indication.

The Hatch-Waxman Amendments permit the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's conclusions from prior review of such studies. The FDA may require companies to perform additional studies or measurements to support any changes from the approved product. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the NDA. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification and validation data related to the manufacturing and quality of the new product must be included in an NDA submitted under Section 505(b)(2).

To the extent that the Section 505(b)(2) applicant is relying on the FDA's conclusions regarding studies conducted for an already approved product, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The Section 505(b)(2) application also will not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the reference product has expired. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized.

Orphan Drug Designation

The Orphan Drug Act of 1983, or Orphan Drug Act, encourages manufacturers to seek approval of products intended to treat "rare diseases and conditions" with a prevalence of fewer than 200,000 patients in the U.S. or for which there is no reasonable expectation of recovering the development costs for the product. For products that receive Orphan Drug designation by the FDA, the Orphan Drug Act provides tax credits for clinical research, FDA assistance with protocol design, eligibility for FDA grants to fund clinical studies, waiver of the FDA application fee, and a period of seven years of marketing exclusivity for the product following FDA marketing approval.

GAIN Act

The FDA's Generating Antibiotic Incentives Now (GAIN) Act is intended to encourage development of new antibiotic drug product candidates for the treatment of serious or life-threatening infections. For products that receive Qualified Infectious Disease Product (QIDP) designation under the Act, the Act provides Fast-Track development status with an expedited development pathway and Priority Review status which potentially provides shorter review time by the FDA of a future potential marketing application. Following FDA approval, an additional five years of U.S. market exclusivity applies, received on top of the standard exclusivity period.

C. Organizational Structure

Not applicable.

D. Property, Plant and Equipment

We lease approximately 826 square meters of office space, a 27 square meter warehouse and eleven parking spaces in the "Platinum" building at 21 Ha'arba'a Street, Tel Aviv, Israel, of which we sublease 216 square meters of office space to a third party. The projected yearly rental expenses are approximately $357,000 per year. The term under our lease agreement will expire on January 31, 2020. These offices have served as our corporate headquarters since April 2011.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion of our financial condition and results of operations in conjunction with the financial statements and the notes thereto included elsewhere in this Annual Report. The following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly those in "Item 3. Key Information – Risk Factors."

Company Overview

We are a biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases and cancer.

Depending on the specific development program, our therapeutic candidates are designed to provide improvements over existing drugs by improving their safety profile, reducing side effects, lowering the number of daily administrations, using a more convenient administration form, providing a cost advantage and/or exhibiting greater efficacy. Where applicable, we intend to seek FDA approval for the commercialization of certain of our therapeutic candidates through the alternative Section 505(b)(2) regulatory path under the Federal Food, Drug, and Cosmetic Act of 1938, as amended, and in corresponding regulatory paths in other foreign jurisdictions. Our current pipeline consists of eight late clinical development therapeutic candidates, including one therapeutic candidate RP101 of which we have an option to acquire.

We have funded our operations primarily through public and private offerings of our securities. Because our therapeutic candidates are currently in development, we cannot estimate when and if we will generate significant revenues in the future.

The following is a description of our eight therapeutic candidates:

RHB-105 is a patented combination of three drugs – omeprazole, which is a proton pump inhibitor, amoxicillin and rifabutin, both of which are antibiotics. RHB-105 is intended for the treatment of *H. pylori* bacterial infection. We acquired ownership rights in patents, tangible assets, production files and regulatory approvals and other data and certain third party agreements related to RHB-105 pursuant to the Asset Purchase Agreement with Giaconda Limited described above. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106."

RHB-104 is a patented combination of three antibiotics (i.e. , clarithromycin, clofazamine and rifabutin) in a single capsule that is intended for the treatment Crohn's disease and potentially other autoimmune diseases. Unlike other drugs on the market for the treatment of Crohn's disease that are immunosuppressive agents, RHB-104 is intended to directly address the suspected cause of the disease. On August 11, 2010, we entered into an asset purchase agreement with Giaconda Limited, pursuant to which we acquired ownership rights in patents, tangible assets, production files and regulatory approvals and other data and certain third party agreements related to RHB-104, RHB-105 and RHB-106 in exchange for $500,000 and royalty payments of 7% of net sales and 20% of sublicense fees, in each case, only after we recoup the amounts and expenses exceeding the approved budget. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106."

BEKINDA™ (RHB-102) is a patented formulation once-daily controlled release oral formulation of ondansetron, in combination with salts, intended for the prevention of chemotherapy and radiotherapy induced nausea and vomiting, by means of an oral formulation of ondansetron. BEKINDA™ is anticipated to prevent chemotherapy and radiotherapy induced nausea and vomiting over a time frame of approximately 24 hours. On May 2, 2010, we received a worldwide, exclusive and perpetual license to use patents and know how relating to BEKINDA™ from SCOLR Pharma, Inc. in exchange for an up-front payment of $100,000, future potential milestone payments of up to $500,000 and future royalties, for a fixed period of time as determined under the agreement, of 8% of our net sales or sublicense fees. SCOLR Pharma announced during 2013 that it had ceased business operations, and we entered into a License Agreement with Temple University to secure direct rights to patents related to BEKINDA™. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements - License Agreement for BEKINDA™." See "Item 3. Key Information – D. Risk Factors – Risk Related to Our Business and Regulatory Matters – If we are not able to secure and/or defend patents related to BEKINDA™, our ability to commercialize BEKINDA™ or enter into commercialization agreements with potential partners with respect to this product may be adversely affected."

RHB-106 is a patented formulation in tablet form intended for the preparation and cleansing of the gastrointestinal tract prior to the performance of abdominal procedures. We acquired ownership rights in patents, tangible assets, production files and regulatory approvals and other data and rights in certain third party agreements related to RHB-106 pursuant to the Asset Purchase Agreement with Giaconda Limited described above. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106." On February 27, 2014, we entered into a licensing agreement with Salix (later acquired by Valeant) by which Salix licensed the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation, and rights to other purgative developments.

YELIVA™ (ABC294640) is a patent-protected, first-in-class, orally-administered sphingosine kinase-2 (SK2) inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple inflammatory, gastrointestinal (GI) and oncology indications. On March 31, 2015, we entered into an exclusive worldwide license agreement with Apogee, under which agreement Apogee granted us the exclusive worldwide development and commercialization rights to ABC294640 (which we then renamed to YELIVA™) and additional intellectual property for all indications. Under the terms of the agreement, we agreed to pay Apogee an upfront payment of $1.5 million in addition to another $4 million in potential development milestones and tiered royalties starting in the low double digits. For more information regarding this agreement, see "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for YELIVA™."

MESUPRON® is a patent-protected uPA inhibitor, administered by oral capsule, targeting gastrointestinal and other solid tumor cancers. On June 30, 2014 we acquired from WILEX AG the exclusive development and commercialization rights to MESUPRON®, excluding China, Hong Kong, Taiwan and Macao, for all indications. We made an upfront payment to WILEX of $1.0 million with potential tiered royalties on net revenues, ranging from mid-teens up to 30%. We are responsible for all development, regulatory and commercialization of MESUPRON®. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for MESUPRON®."

RP101 is a patent-protected, orally administered small molecule which may prevent the induction of resistance to chemotherapy (chemoresistance), thus maintaining sensitivity of the tumor to chemotherapy and potentially enhancing patient survival. RP101 has been granted Orphan Drug designation for the adjunct treatment of pancreatic cancer by the FDA and EMA. On August 13, 2014, we entered into a binding exclusive option agreement for the potential acquisition of RP101 and next generation compounds. Under the terms of the agreement, we have the option to acquire the worldwide exclusive rights to RP101 for all indications, other than to the pancreatic cancer indication in South Korea. We agreed to pay RESprotect for a one year option, which was extended by us under certain agreed terms. During the option period, we may, at our discretion, conduct development activities with RP101. If we elect to exercise the option, we will acquire the exclusive rights to RP101 for a total payment, for both the option and the acquisition of the rights, of $100,000, as well as potential milestone payments and tiered royalties on net revenues, ranging from single-digit to mid-teens. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for RP101."

RIZAPORT™ (RHB-103) is a patented oral thin film formulation of rizatriptan intended for the treatment of acute migraine headaches. On August 26, 2010, we entered into a joint development and commercialization agreement with IntelGenx Corp. pursuant to which IntelGenx Corp. granted us a worldwide, exclusive and perpetual license to use RIZAPORT™ and to grant sublicenses. In consideration for the license, we made up-front and milestone payments in the aggregate amount of $800,000 and are required to make additional milestone payments of up to $500.000. In addition, we are required to make royalty payments to IntelGenx Corp. of 20% of net sales if the product is marketed by us and 40% of net sublicense fees if the product is marketed by sublicensees. However, in certain events the royalty payments could range between 20% to 70% of net sublicense fees. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for RIZAPORT™."

JOBS Act

We are an emerging growth company. As an "emerging growth company", we also elected to rely on various exemptions, including without limitation, not (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404 and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis). These exemptions will apply until the earliest of (a) the last day of our fiscal year during which we have total annual gross revenues of at least $1.0 billion; (b) the last day of our fiscal year following the fifth anniversary of the date of the first sale of our ordinary shares pursuant to an effective registration statement (in our case, December 31, 2018); (c) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (d) the date on which we are deemed to be a "large accelerated filer" under the Exchange Act of 1934, which would occur if the market value of our ordinary shares held by non-affiliates is $700 million or more as of the last business day of our most recently completed fiscal quarter.

Components of Statement of Comprehensive Loss

Revenues

In 2015 and 2013 we recorded non-significant revenues in connection with royalty payments received from a third party licensee of limited rights to a patent that we acquired from Giaconda Limited. In 2014, for the first time we had meaningful revenues as a result of the Salix transaction. Our therapeutic candidates are currently in development therefore we cannot estimate when and if we will generate significant revenues in the future.

Cost of Revenues

Direct costs related to the revenues such royalties to third parties and other related costs.

Research and Development Expenses

See "– C. Research and Development, Patents and Licenses" below.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees, directors and consultants in executive and operational functions and professional services. Other significant general and administration costs include office related expenses and travel, conferences, investor relations and other costs.

Financial Income and Expense

Financial income and expense consist of non-cash financing expenses in connection with changes in Derivative financial instruments fair value, interest earned on our cash, cash equivalents and short-term bank deposits, bank fees and other transactional costs and expense or income resulting from fluctuations of the U.S. dollar and other currencies, in which a portion of our assets and liabilities are denominated in NIS.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with International Financial Reporting Standards, or IFRS, requires companies to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and judgments are subject to an inherent degree of uncertainty, and actual results may differ. Our significant accounting policies are more fully described in Note 2 to our financial statements included elsewhere in this Annual Report. Critical accounting estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances, and are particularly important to the portrayal of our financial position and results of operations. Our estimates are primarily guided by observing the following critical accounting policies:

Impairment of Intangible Assets - Since the development of our therapeutic candidates has not yet been completed and they are defined as research and development assets acquired by us, we review, on an annual basis or when indications of impairment are present, whether those assets are impaired. We make judgments to determine whether indications are present that require reviewing the impairment of these intangible assets. An impairment loss is recognized for the amount by which the assets' carrying amount exceeds its recoverable amount. The recoverable amounts of cash generating units are based on our estimates as to the development of the therapeutic candidates, changes in market scope, market competition and timetables for regulatory approvals. Since the above require certain judgments and the use of estimates, actual results may differ from our estimations and as a result would increase or decrease our related actual results.

Recent Accounting Pronouncements

The recent accounting pronouncements are set forth in Note 2 to our audited financial statements beginning on page F-1 of this Annual Report. We are assessing the expected effect of the accounting pronouncements on our financial statements.

A. Operating Results

History of Losses

Since inception in 2009, we have generated significant losses mainly in connection with the research and development of our therapeutic candidates. Such research and development activities are expected to expand over time and will require further resources if we are to be successful. As a result, we expect to continue incurring operating losses, which may be substantial over the next several years, and we will need to obtain additional funds to further develop our research and development programs. As of December 31, 2015, we had an accumulated deficit of approximately $61.9 million.

We expect to continue to fund our operations over the next several years through public or private equity offerings, debt financings or through commercialization of our therapeutic candidates.

As of December 31, 2015, we had approximately $58 million of cash, cash equivalents and short term investments, and as of February 22, 2016, we had cash and short term investments of approximately $55 million.

Quarterly Results of Operations

The following tables show our unaudited quarterly statements of operations for the periods indicated. We have prepared this quarterly information on a basis consistent with our audited financial statements and we believe it includes all adjustments, consisting of normal recurring adjustments necessary for a fair statement of the information shown. Operating results for any quarter are not necessarily indicative of results for a full fiscal year.

Three Months Ended

Statements of operations	March 31	June 30	Sep. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31
	2013				2014				2015			
Revenues	4	4	3	1	7,005	4	4	1	1	1	1	-
Cost of revenue	-	-	-	-	1,050	-	-	-	-	-	-	-
Research and development expenses, net	1,346	1,982	2,207	2,565	1,736	3,157	4,103	3,704	3,829	5,090	3,901	4,951
General and administrative expenses	675	548	545	916	1,027	961	912	1,111	927	801	692	1,714
Other (income) expenses	-	-	-	-	(100)	-	-	-	-	-	-	100
Operating loss (income)	2,017	2,526	2,749	3,480	(3,292)	4,114	5,011	4,814	4,755	5,890	4,592	6,765
Financial income	43	17	53	45	89	133	415	-	286	167	1,420	235
Financial expenses	3	3	3	5	4	543	(360)	514	173	873	120	30
Net loss (income)	1,977	2,512	2,699	3,440	(3,377)	4,524	4,236	5,328	4,642	6,596	3,292	6,560

Our quarterly revenues and operating results of operations have varied in the past and are expected to vary in the future due to numerous factors. We believe that period-to-period comparisons of our operating results are not necessarily meaningful and should not be relied upon as indications of future performance.

Comparison of the Year Ended December 31, 2015 to the Year Ended December 31, 2014

Research and Development Expenses

Research and development expenses for the year ended December 31, 2015 were approximately $17.8 million, an increase of $5.1 million, or approximately 40%, compared to $12.7 million for the year ended December 31, 2014. The increase resulted primarily from clinical trial costs of approximately $13.6 million, net, related mainly to the Phase III clinical studies with RHB-104 (Crohn's disease), RHB-105 (H. pylori) and BEKINDA™ (gastroenteritis and gastritis).

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2015 were approximately $4.1 million, an increase of $0.1 million, or approximately 2%, compared to $4.0 million for the year ended December 31, 2014. The increase was mainly due to an increase in professional services.

Operating Loss

Operating loss for the year ended December 31, 2015 was approximately $22.0 million compared to $10.6 million for the year ended December 31, 2014. The increase was mainly due to revenues from the Salix licensing transaction in 2014 and to an increase in research and development Expenses in 2015.

Financing Income and Expenses

We recognized financial income, net of $0.9 million for the year ended December 31, 2015, compared to financial expenses, net of $0.1 million for the year ended December 31, 2014. The financing income, net in 2015 was mainly derived from a fair value gain on derivative financial instruments while the financing expenses, net in 2014 mainly derived from changes in exchange rates.

Comparison of the Year Ended December 31, 2014 to the Year Ended December 31, 2013

Revenues and Cost of revenues

In 2014, we had for the first time meaningful revenues of $7 million from the Salix transaction, while in 2013 and 2012, we recorded non-significant revenues in connection with royalty payments received from a third party licensee of limited rights to a patent that we acquired from Giaconda Limited.

Cost of Revenues

Cost of Revenues for the year ended December 31, 2014 were $1 million, primarily due to a payment of $1 million to Giaconda Limited under the agreement with Giaconda, which was triggered by the first payment received by us from the Salix transaction in 2014.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2014 were $12.7 million, an increase of $4.6 million, or 57%, compared to $8.1 million for the year ended December 31, 2013. The increase resulted primarily from approximately $3.5 million in clinical trial costs related mainly to RHB-104, RHB-105 and BEKINDA™.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2014 were $4.0 million, an increase of $1.3 million, or 48%, compared to $2.7 million for the year ended December 31, 2013. The increase resulted primarily from an increase in payroll and related expenses as result of recruitments of new employees and an increase in share-based payments and professional services.

Operating Loss

During the year ended December 31, 2014, our operating loss was approximately $10.6 million, a decrease of $0.2 million, or 2%, compared to $10.8 million for the year ended December 31, 2013. The decrease in operating loss was mainly due to our revenues from Salix transaction mentioned above that were partially offset by an increase in research and development expenses.

Financial Income and Expenses

We recognized financial expenses, net of $0.1 million for the year ended December 31, 2014, compared to financial income, net of $0.1 million for the year ended December 31, 2013. The financial income and expenses, net for the years of 2014 and 2013 were derived mainly from changes in exchange rates.

B. Liquidity and Capital Resources

Liquidity and Capital Resources

Our therapeutic candidates are in the research and development stage and therefore do not generate significant revenues. Since inception, we have funded our operations primarily through public and private offerings of our equity securities, investor loans, and a payment received under our Exclusive License Agreement with Valeant. As of December 31, 2015, we had approximately $58.1 million of cash, cash equivalents and short term investments.

On February 3, 2011, we raised gross proceeds of approximately $14 million in connection with our initial public offering on the Tel Aviv Stock Exchange of 14,302,300 ordinary shares and 7,151,150 tradable Series 1 Warrants. Each tradable Series 1 Warrant was exercisable through February 2, 2014 into one ordinary share. By February 2, 2014, the warrant expiration date, 3,246,082 Series 1 Warrants had been exercised for an aggregate amount of $4 million (based on the representative U.S. dollar–NIS rate of exchange of 3.498 on February 2, 2014).

On January 10, 2013, we issued in a private placement 6,481,280 ordinary shares at a price per share of NIS 4.00 (approximately $1.06 based on the representative U.S. dollar – NIS rate of exchange of 3.78 on January 10, 2013) and non-tradable warrants to purchase up to 3,240,640 ordinary shares at exercise prices ranging from $1.18 to $1.54, depending on the date of exercise.

On January 10, 2015, the remaining 2,558,440 unexercised warrants expired along with any right or claim whatsoever of the holders. By the warrant expiration date, 682,200 warrants had been exercised for an aggregate amount of approximately $1.0 million.

On January 8, 2014, we issued in a private placement a total of 894,740 units, each consisting of one ADS and a three-year warrant to purchase 0.4 of an ADS, at a purchase price of $9.50 per Unit, for an aggregate gross amount of $8.5 million. We also issued warrants to purchase 357,896 ADSs in the aggregate at an exercise price of $11 per ADS. Investors in the private placement were OrbiMed Israel Partners Limited Partnership and Broadfin Healthcare Master Fund, LTD.

On January 21, 2014, we issued in a private placement a total of 10,458,740 ordinary shares at a purchase price of NIS 3.9 per share and three-year warrants to purchase 4,183,496 ordinary shares in the aggregate at an exercise price of NIS 4.9 per ordinary share, linked to changes in the NIS-US dollar exchange rate, for an aggregate gross amount of $11.7 million (based on the representative U.S. dollar–NIS rate of exchange of 3.49 on January 22, 2014). Investors in the private placement were Israeli institutional investors Migdal Insurance Company, Yelin Lapidot, and Excellence Nessuah, as well as Sphera Global Healthcare Master Fund and two private Israeli investment firms.

On February 27, 2014, we entered into a Worldwide Exclusive License Agreement with Salix Pharmaceuticals, Ltd. (later acquired by Valeant) by which Salix licensed the worldwide exclusive rights to our RHB-106 encapsulated formulation for bowel preparation, and rights to other purgative developments. Under the license agreement, Salix paid an upfront payment of $7.0 million. We are also entitled to milestone payments and royalties based on net sales of RHB-106. See "*Exclusive License Agreement with Valeant Pharmaceuticals International, Inc.*"

On February 13, 2015, we sold 1,000,000 ADSs in an underwritten public offering of our ADSs in the U.S. at a public offering price of $12.50 per ADS, for gross proceeds to us of $12.5 million, before underwriting discounts and commissions and other offering expenses. On February 18, 2015, the underwriters exercised in full their over-allotment option to purchase from us an additional 150,000 ADSs (15% of the original offering amount) at the public offering price of $12.50 per ADS, for gross proceeds of $1.9 million. Following exercise of the over-allotment option, our offering totaled 1,150,000 ADSs representing gross proceeds of approximately $14.4 million, before underwriting discounts and commissions and other offering expenses.

On July 22, 2015, we sold 2,462,000 ADSs in an underwritten public offering of our ADS in the U.S. at a public offering price of $16.25 per ADS, for gross proceeds to us of approximately $40 million, before underwriting discounts and commissions and other offering expenses. On July 28, 2015, the underwriters partially exercised their over-allotment option to purchase from us an additional 277,143 ADSs (approximately 11% of the original offering amount) at the public offering price of $16.25 per ADS, for gross proceeds of approximately $4.5 million. Following the exercise of the over-allotment option, our offering totaled 2,739,143 ADSs representing gross proceeds of approximately $44.5 million, before underwriting discounts and commissions and other offering expenses.

We estimate that so long as no significant revenues are generated from our therapeutic candidates, we will need to raise substantial additional funds to acquire, develop and commercialize therapeutic candidates, as our current cash and short-term investments are not sufficient to complete the research and development of all of our therapeutic candidates and fund our operations. However, additional financing may not be available on acceptable terms, if at all. Our future capital requirements will depend on many factors including but not limited to:

- the regulatory path of each of our therapeutic candidates;
- our ability to successfully commercialize our therapeutic candidates, including securing commercialization agreements with third parties and favorable pricing and market share;
- the progress, success and cost of our clinical trials and research and development programs;
- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing sales, marketing and distribution channels;
- consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated; and
- we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

If we are unable to commercialize or out-license our therapeutic candidates or obtain future financing, we may be forced to delay, reduce the scope of, or eliminate one or more of our research and development programs related to the therapeutic candidates, which may have material adverse effect on our business, financial condition and results of operations. “Item 3. Key Information – D. Risk Factors – Risk Related to Our Financial Condition and Capital Requirements – Our current working capital is not sufficient to complete our research and development with respect to all of our therapeutic candidates. We will need to raise additional capital to achieve our strategic objectives of acquiring, developing and commercializing therapeutic candidates, and our failure to raise sufficient capital would significantly impair our ability to fund our operations, develop our therapeutic candidates, attract development and/or commercial partners and retain key personnel.”

Cash Flow

Operating activities

For the year ended December 31, 2015, net cash flow used in operating activities was approximately $17.8 million, compared to approximately $12.2 million for the year ended December 31, 2014 and $8.4 million for the year ended December 31, 2013. The increase in net cash flow used in operating activities was a direct result of the increase in our operations, reflected by increased research and development activities which were partially offset by the revenues from the Salix transaction in 2014.

Investment activities

Net cash flow used in investing activities for the year ended December 31, 2015 was approximately $21.2 million, compared to approximately net cash flow used in investing activities of $17.9 million in the year ended December 31, 2014 and net cash flow provided by investing activities of $1.1 million in the year ended December 31, 2013. For the year ended December 31, 2015, we invested a total of $19.5 million in bank deposits and $1.6 million in purchasing of intangible assets. For the year ended December 31, 2014, we invested a total of $17 million in bank deposits and $1.0 million in purchasing of intangible assets. For the year ended December 31, 2013, we invested a total of $0.2 million in intangible assets and we received proceeds of $0.9 million from the sale of financial assets at a fair value and $0.5 million from withdrawal of bank deposits to cash and cash equivalents.

Financing activities

Net cash flow provided by financing activities for the year ended December 31, 2015 amounted to approximately $54.8 million, compared with approximately $24.4 million for the year ended December 31, 2014 and $2.3 million for the year ended December 31, 2013. In 2015, most of the cash flows from financing activities resulted from the two underwritten public offerings for a total net amount of $54.7 million. In 2014, most of the cash flows from financing activities resulted from the January 2014 private placements for a total net amount of $19.4 million and from the exercise of warrants for a net amount of $5.0 million, while in 2013 most of the cash flow from financing activities resulted from the exercise of warrants in a total amount of $2.2 million.

We did not have any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment or interests in other companies, as of December 31, 2015.

C. Research and Development, Patents and Licenses

Our research and development expenses consist primarily of costs of clinical trials, professional services, share-based payments and payroll and related expenses. The clinical trials costs are mainly related to payments to third parties to manufacture our therapeutic candidates, to perform clinical trials with our therapeutic candidates and to provide us with regulatory services. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our therapeutic candidates.

	2015	2014	2013
Payroll and related expenses	0.6	0.6	0.5
Professional services	2.0	1.7	1.3
Share-based payments	0.9	0.9	0.8
Clinical trials, net	13.4	8.5	5.0
Intellectual property development	0.2	0.6	0.2
Other	0.7	0.4	0.3
Total	17.8	12.7	8.1

Due to the inherently unpredictable nature of clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of the therapeutic candidates in our pipeline for potential commercialization.

While we are currently focused on advancing each of our therapeutic candidates, our future research and development expenses will depend on the clinical success of each therapeutic candidate, as well as available resources and the ongoing assessments of each therapeutic candidate's commercial potential. In addition, we cannot forecast with any degree of certainty which therapeutic candidates may be subject to future commercialization arrangements, when such commercialization arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. See "Item 3. Key Information – D. Risk Factors – If we and/or our commercialization partners are unable to obtain FDA and/or other foreign regulatory authority approval for our therapeutic candidates, we and/or our commercialization partners will be unable to commercialize our therapeutic candidates."

As we obtain results from clinical trials, we may elect to discontinue or delay development and clinical trials for certain therapeutic candidates in order to focus our resources on more promising therapeutic candidates or projects. Completion of clinical trials by us or our licensees may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a therapeutic candidate. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Business and Regulatory Matters."

We expect our research and development expenses to increase from current levels as we continue the advancement of our clinical trials and therapeutic candidates' development. The lengthy process of completing clinical trials and seeking regulatory approvals for our therapeutic candidates requires substantial expenditures. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Due to the factors set forth above, we are not able to estimate with any certainty if and when we would recognize any net revenues from our projects.

D. Trend Information

We are an emerging biopharmaceutical company focused primarily on the development and acquisition of our therapeutic candidates. It is not possible for us to predict with any degree of accuracy the outcome of our research and development or our commercialization success with regard to any of our therapeutic candidates. Our research and development expenditure is our primary expenditure. Increases or decreases in research and development expenditures are primarily attributable to the level and results of our clinical trial activities and the amount of expenditure on those trials.

E. Off-Balance Sheet Arrangements

Since inception, we have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our significant contractual obligations on December 31, 2015:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
		(U.S. dollars in thousands) (Unaudited)			
Office lease obligations	1,481	357	1,094	30	-
Accounts payable and accrued expenses	3,514	3,514	-	-	-
Payable in respect of intangible asset purchase	2,000	2,000	-	-	-
Total	6,995	5,871	1,094	30	-

The foregoing table does not include our in-license agreements with Temple University, IntelGenx Corp., Wilex AG, Apogee, the option agreement with RESprotect GmbH, our asset sale agreement with Giaconda Limited and our agreement with the University of Central Florida Research Foundation, Inc., pursuant to which we are obligated to make various payments upon the achievement of agreed upon milestones and/or make certain royalty payments since we are unable to currently estimate the actual amount or timing of these payments. If all of the milestones are achieved over the life of each in-licensing agreement, we will be required to pay, in addition to the amounts in the above table and royalties on our net income, an aggregate amount of approximately $4.7 million. All of our in-licensing agreements are terminable at-will by us upon prior written notice. See "Item 4. Information on the Company — Business Overview — Acquisition and License Agreements."

The foregoing table does not include our manufacturing agreements pursuant to which we are obligated to make various payments upon the achievement of agreed upon milestones. We are unable to currently estimate the actual amount or timing of these payments. If all of the milestones are achieved over the life of the manufacturing agreements, we will be required to pay, in addition to the above table and royalties on our net income, an aggregate amount of approximately $2.3 million. All of our manufacturing agreements are terminable at-will by us upon prior written notice.

The foregoing table also does not include payments payable under our clinical services agreements, all of which are contingent upon the completion of milestones. See "Item 4. Information on the Company – Business Overview – Clinical Services Agreements."

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth the name, age and position of each of our executive officers and directors as of the date of this Annual Report.

Name	Age	Position(s)
Executive Officers		
Dror Ben-Asher	50	Chief Executive Officer and Chairman of the board of directors
Ori Shilo (1)	49	Deputy Chief Executive Officer Finance and Operations
Reza Fathi, Ph.D.	61	Senior Vice President Research and Development
Gilead Raday	41	Senior Vice President Corporate and Product Development
Adi Frish	46	Senior Vice President Business Development and Licensing
Guy Goldberg	40	Chief Business Officer
Uri Hananel Aharon	35	Chief Accounting Officer

Directors		
Dr. Shmuel Cabilly (3)	66	Director
Eric Swenden	72	Director
Dr. Kenneth Reed	62	Director
Dan Suesskind (2)	72	Director
Rick D. Scruggs	56	Director
Ofer Tsimchi (2), (3)	56	External Director
Nurit Benjamini (2), (3)	49	External Director

(1) Mr. Micha Ben-Chorin (age 46) will replace Mr. Ori Shilo as Chief Financial Officer effective March 1, 2016.
(2) Member of our audit committee that also serves as our financial statements committee.
(3) Member of our compensation committee.

Executive officers

Dror Ben-Asher has served as our Chief Executive Officer and as a director since August 3, 2009. Since May 4, 2011, Mr. Ben- Asher has also served as Chairman of our board of directors. From January 2002 to November 2010, Mr. Ben- Asher served as a manager at P.C.M.I. Ltd., an affiliate of ProSeed Capital Holdings CVA, which provides us with certain advisory services. Mr. Ben-Asher is currently a director at Agrea Ltd. Mr. Ben-Asher holds an LLB from the University of Leicester, UK, an MJur. from Oxford University, UK and completed LLM studies at Harvard University in the U.S.

Ori Shilo has served as our Deputy Chief Executive Officer Finance and Operations since November 1, 2010 and as a director from August 3, 2009 until November 1, 2015. From 2009 to 2010, Mr. Shilo served as our Vice President Finance and Operations. From 2000 to 2010, Mr. Shilo served as Chief Executive Officer of P.C.M.I. Ltd. Mr. Shilo holds a B.A in Business Administration from the Academic College for Management in Rishon Lezion, Israel and an MBA in Business Administration from the Ben Gurion University in Beer Sheva, Israel.

Reza Fathi, Ph.D ., has served as our Senior Vice President Research and Development since May 1, 2010. From 2005 to 2009, Dr. Fathi served as a Director of Research in XTL Biopharmaceuticals Inc., a biotechnology company engaged in developing small molecule clinical candidates for infectious diseases. Prior to that, between 2000-2005, Dr. Fathi served as Director of Research at Vivoquest, Inc., responsible for developing a number of novel natural product based combinatorial technologies for infectious diseases such as HCV and HIV. Between 1998-2000, he served as a Manager of Chemical Biology Research at the Institute of Chemistry and Chemical Biology (ICCB) at Harvard Medical School, pioneering chemical genetics to identify small molecules in cancer biology, and from 1991-1998 headed the Discovery Group at PharmaGenics, Inc. Dr. Fathi holds a Postdoctoral and Ph.D. in Chemistry from Rutgers University, NJ, U.S.

Gilead Raday has served as our Senior Vice President Corporate and Product Development since December 5, 2012. From November 2010 to December 2012, Mr. Raday served as our Vice President Corporate and Product Development. From January 2010 until October 2010, Mr. Raday served as Interim Chief Executive Officer of Sepal Pharma Plc., an oncology drug development company, and from January 2009 to December 2009, he was an independent consultant, specializing in business development and project management in the field of life sciences. From 2004 to 2008, Mr. Raday was a partner in Charles Street Securities Europe, LLP, an investment banking firm, where he was responsible for the field of life sciences. Mr. Raday serves on the boards of Sepal Pharma Plc., and ViDAC Limited. Mr. Raday previously served on the boards of Morria Biopharmaceuticals Plc., Vaccine Research International Plc., TKsignal Plc., and Miras Medical Imaging Plc. He received his MSc in Neurobiology from the Hebrew University of Jerusalem and an MPhil in Biotechnology Management from Cambridge University, UK.

Adi Frish has served as our Senior Vice President Business Development and Licensing since December 5, 2012. From October 2010 to December 2012, Mr. Frish served as our Vice President Business Development and Licensing. From 2006 to 2010, Mr. Frish served as the Chief Business Development at Medigus Ltd., a medical device company in the endoscopic field, and from 1998 to 2006, Mr. Frish was an associate and a partner at the law firm of Y. Ben Dror & Co. Mr. Frish holds an LLB from Essex University, UK and an LLM in Business Law from the Bar-Ilan University, Israel.

Guy Goldberg has served as our Chief Business Officer since July 16, 2012. From July 2007 to July 2012, Mr. Goldberg served as Vice President and then as Senior Vice President of Business Operations at Eagle Pharmaceuticals, a specialty injectable drug development company, based in New Jersey. From 2004 to 2007, Mr. Goldberg was an associate at ProQuest Investments, a healthcare focused venture capital firm, and from 2002 to 2004, Mr. Goldberg was a consultant at McKinsey & Company. Mr. Goldberg holds a B.A. in Economics and Philosophy from Yale University and a J.D. from Harvard Law School in the U.S.

Uri Hananel Aharon has served as our Chief Accounting Officer since April 12, 2011. From 2007 to 2011, Mr. Aharon served as a team manager at Ernst & Young Israel, specializing in auditing and financial consulting for companies traded on The Nasdaq Stock Market and the Tel Aviv Stock Exchange, both in the biotech and high-tech sectors. From 2004 to 2007, Mr. Aharon served as an accounting intern at Ziv Haft, BDO. Mr. Aharon holds a BA in Accounting and Economics from the Hebrew University of Jerusalem, Israel and an MBA in Business Taxation from the Academic College for Management in Rishon Lezion, Israel.

Micha Ben Chorin will serve as our new Chief Financial Officer effective March 1, 2016. Prior to joining RedHill he was a member of the team that built GVT (currently Telefonica Brazil). During his seven years as Chief Financial Officer at GVT, he led its financial department through pivotal financial transactions and preparations for its successful IPO. From 2014 until 2016, Mr. Ben Chorin served as Chief Financial Officer of Pyramid Analytics. From 2009 until 2013 he served as CFO of Starhome B.V., a leading international roaming vendor, where he oversaw a turnaround from operational losses to significant EBITDA margins and positive cash flow. Mr. Ben Chorin holds an M.A. and a B.A. from Tel-Aviv University and is a Certified Public Accountant.

Directors

Dr. Shmuel Cabilly has served as a member of our board of directors since August 26, 2010, and has served on our compensation committee since May 5, 2011. Dr. Cabilly is a scientist and inventor in the field of immunology. In the Backman Research Institute of the City of Hope he initiated the development of a new breakthrough technology for recombinant antibody production, which was patented and known as the "Cabilly Patent". Dr. Cabilly was also a co-founder and a Chief Scientist of Ethrog Biotechnology, where he invented dry buffer technologies enabling the production of a liquid free disposable apparatus for gel electrophoresis and a technology that enables the condensation of molecular separation zones to a small gel area. This technology was sold to Invitrogen in 2001. Dr. Cabilly is now an investor and serves as a board member of several companies, including BioKine Therapeutics Ltd., Neuroderm Ltd., Biologic Design Ltd., Ornim Inc. and Efranat Ltd.. Dr. Cabilly holds a BSC Biology from the Ben Gurion University of Beer Sheva, Israel, an MSC in Immunology and Microbiology from the Hebrew University of Jerusalem, Israel and a PhD in Immunology and Microbiology from the Hebrew University of Jerusalem, Israel.

Eric Swenden has served as a member of our board of directors since May 3, 2010, and has served on our investment committee since May 5, 2011. From 1966 until 2001 Mr. Swenden served in various positions including Chief Executive Officer (since 1985) and Executive Chairman (since 1990) of Vandemoortele Food Group, a privately held Belgium-based European food group with revenue of approximately EUR 2 billion, and he currently serves on the board of directors of Lifeline Scientific, Inc., TBC S.A., Alterpharma N.V. and Gudrun N.V. Mr. Swenden holds an M.A. in Commercial Science from the University of Antwerp, Belgium. The board of directors has determined that Mr. Swenden is a financial and accounting expert under Israeli law.

Dr. Kenneth Reed has served as a member of our board of directors since December 15, 2009. Dr. Reed is a dermatologist, practicing in a private practice under the name of Kenneth Reed MD PC. Dr. Reed currently serves on the board of directors of Minerva Biotechnologies Corporation. Dr. Reed received his B.A from Brown University in the U.S. and a M.D. from the University of Medicine and Dentistry of New Jersey in the U.S. Dr. Reed is a board certified dermatologist with over 25 years of clinical experience since completing the Harvard Medical School Residency Program in Dermatology.

Dan Suesskind has served as a member of our board of directors since February 21, 2011, and has served on our audit committee and investment committee since May 5, 2011. From 1977 to 2008, Mr. Suesskind served as the Chief Financial Officer of Teva Pharmaceutical Industries Ltd. Mr. Suesskind served as a director of Teva Pharmaceutical Industries Ltd. between 1981 to 2001 and again between 2010 - 2014. In addition, Mr. Suesskind currently serves on the board of directors of Syneron Medical Ltd., Israel Corporation Ltd. as well as a member of the board of trustees of the Hebrew University. Mr. Suesskind is one of the founders and a member of the steering committee of the Israeli Forum of Chief Financial Officers. Mr. Suesskind holds a BA in Economics and Political Science from the Hebrew University of Jerusalem, Israel and an MBA in Business Administration from University of Massachusetts in the U.S. The board of directors has determined that Mr. Suesskind is a financial and accounting expert under Israeli law.

Rick D. Scruggs has served as a member of our board of directors since January 1, 2016. Mr. Scruggs most recently served as Executive Vice President of Business Development at Salix Pharmaceuticals, Ltd., up to its acquisition by Valeant Pharmaceuticals International in March 2015. Mr. Scruggs joined Salix in 2000, after working at Oclassen Pharmaceuticals Inc. and Watson Pharmaceuticals, and helped build Salix's commercial organization, serving in various sales and commercial trade related positions. He was appointed as Executive Vice President in 2011 and was responsible for all business development activities as well as the worldwide distribution of Salix innovative products and intellectual property. Mr. Scruggs also served as the Head of the Board of Directors of Oceana Therapeutics, Salix's European subsidiary. Mr. Scruggs holds a BS in Criminal Justice from the Appalachian State University in North Carolina, U.S.A.

Ofer Tsimchi has served as an external director on our board of directors since May 4, 2011, a member of our audit committee and as the Chairman of our compensation committee since May 5, 2011. From 2008 - 2012, Mr. Tsimchi served as the Chairman of the board of directors of Polysack Plastic Industries Ltd. and Polysack-Agriculture Products, and since 2006 he has served as a Partner in the Danbar Group Ltd., a holding company. Mr. Tsimchi currently serves on the board of directors of Kidron Industrial Materials Ltd., Amutat Zionut 2000, Danbar Group Ltd, and Polysack Agriculture Hi-Technologies, CaesarStone Sdot-Yam Ltd. and Maabarot Products Ltd. Mr. Tsimchi received his BA in Economics and Agriculture from the Hebrew University of Jerusalem, Israel. The board of directors has determined that Mr. Tsimchi is a financial and accounting expert under Israeli law.

Nurit Benjamini, MBA, has served as an external director on our board of directors and a member of our audit committee and our compensation committee since February 16, 2016. Since December 2013, Ms. Benjamini has served as the Chief Financial Officer of TabTale Ltd. a company that develops, designs and manufactures interactive digital content to be displayed on electronic devices and websites. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wixpress Ltd. (Nasdaq: WIX); from 2007 through 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd. now Sigma Designs Israel, a subsidiary of Sigma Designs Inc. (Nasdaq: SIGM); and from 2000 through 2007, she served as the Chief Financial Officer of Compugen Ltd. (Nasdaq: CGEN). Prior to that, from 1993 through 1998, Ms. Benjamini served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd. (formerly Nasdaq: ALDN). Ms. Benjamini serves as an external director of BiolineRx Ltd. (Nasdaq/TASE: BLRX), and as the chairperson of its audit committee, and on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (Nasdaq/TASE: ALLT). Ms. Benjamini holds a B.A. in economics and business and an M.B.A. in finance, both from Bar Ilan University, Israel.

B. Compensation

The aggregate compensation paid, and benefits in-kind granted to or accrued on behalf of all of our executive officers and directors for their services, in all capacities, to us during the year ended December 31, 2015 was approximately $2.3 million. Out of that amount $1.4 million was paid as salary and consultants fees, $0.6 million was attributed to the value of the options granted to directors and senior management during 2015, approximately $0.1 million was attributed to retirement plans and $0.1 million attributed to other long-term benefits. No additional amounts have been set aside or accrued by us to provide pension, retirement or similar benefits.

The compensation terms for our directors and officers is derived from their employment agreements and comply with our Compensation Policy for Executive Officers and Directors as approved by the Company's shareholders on July 31, 2013 (Compensation Policy).

The table and summary below outline the compensation granted to our five highest compensated directors and officers during the year ended December 31, 2015. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2015.

Name and Position of director or officer	Base Salary or Other Payment (1)	Value of Social Benefits (2)	Bonuses	Value of Equity Based Compensation Granted (3)	All Other Compensation (4)	Total
Amounts in $ U.S. dollars are based on 2015 monthly average representative U.S. dollar – NIS rate of exchange						
Dror Ben-Asher, Chief Executive Officer (5)	232,395	52,824	-	-	18,513	303,732
Gilead Raday, Senior Vice President Corporate and Products Developments	235,200	-	-	158,491	17,323	411,014
Reza Fathi, Senior Vice President Research and Development	240,000	-	-	146,751	17,504	404,255
Guy Goldberg, Chief Business officer	160,426	40,883	-	146,751	12,342	360,402
Adi Frish, Senior Vice President Business Development and Licensing	152,781	41,840	-	146,751	12,343	353,715

(1) "Base Salary or Other Payment" means the aggregate yearly gross monthly salaries or other payments with respect to the Company's Executive Officers and members of the Board of Directors for the year 2015.

(2) "Social Benefits" include payments to the National Insurance Institute, advanced education funds, managers' insurance and pension funds; vacation pay; and recuperation pay as mandated by Israeli law.

(3) Consists of the fair value of the equity-based compensation granted during 2015 in exchange for the directors and officers services recognized as an expense in profit or loss and is carried to accumulated deficit under equity. The total amount recognized as an expense over the vesting period of the options.

(4) "All Other Compensation" includes, among other things, car-related expenses (including tax gross-up), communication expenses, basic health insurance, and holiday presents.

(5) Mr. Ben-Asher's employment terms as the Company's Chief Executive Officer provide that Mr. Ben-Asher is entitled to a monthly base gross salary of NIS 75,000 (approximately $19,200). Mr. Ben-Asher is further entitled to vacation days, sick days and convalescence pay in accordance with market practice and applicable law, monthly remuneration for a study fund, contribution by the Company to an insurance policy and pension fund, and additional benefits, including communication expenses. In addition, Mr. Ben-Asher is entitled to reimbursement of car-related expenses from the Company. Mr. Ben-Asher's employment terms include an advance notice period of 180 days by the Company and 90 days by Mr. Ben-Asher. During such advance notice period, Mr. Ben-Asher will be entitled to all of the compensation elements, and to the continuation of vesting of any options or restricted shares granted to him. Additionally, in the event Mr. Ben-Asher's employment is terminated in connection with a "hostile takeover," he will be entitled to a special one-time bonus equal to his then current monthly salary and retirement benefits, including payments to an advanced study fund and pension arrangement and car expense reimbursement, multiplied by 12. A "hostile takeover" is defined as an occurrence where a person, entity or group that was not an interested party under the Israeli Securities Law 1968 on the date of the initial public offering of our ordinary shares, becomes a "controlling shareholder," asdefined in the Israeli Securities Law 1968, or a "holder," as defined in the Israel Securities Law 1968, of 25% or more of the voting rights in the Company. In addition, in case of an "hostile takeover", all options granted to Mr. Ben-Asher will immediately vest in full.

In addition, all of our directors and executive officers are covered under our directors' and executive officers' liability insurance policies and were granted letters of indemnification by us.

Employment Agreements

We have entered into employment or consultant agreements with each of our executive officers. All of these agreements contain customary provisions regarding noncompetition, confidentiality of information and assignment of inventions. However, the enforceability of the noncompetition provisions may be limited under applicable laws.

For information on exemption and indemnification letters granted to our officers and directors, please see " – 6.C. Board Practices – Exemption, Insurance and Indemnification of Directors and Officers."

Director Compensation

Under the Israeli Companies Law, and related regulations, external directors are entitled to a fixed annual compensation and an additional payment for each meeting attended. We currently pay our external directors an annual cash fee of NIS 83,480 (approximately $21,400) and a cash fee of NIS 4,390 (approximately $1,120) per meeting (or a smaller amount in case they do not physically attend the meeting).

Dr. Reed, Mr. Swenden, Dr. Cabilly, Mr. Suesskind, and Mr. Scruggs receive the same cash remuneration as was approved for the external directors as described above.

Compensation Policy

On July 31, 2013, our shareholders approved a compensation policy for our officers and directors in accordance with Amendment No. 20 to the Israeli Companies Law, pursuant to which we are required to determine the compensation of our officers and directors in accordance with a D&O compensation policy. The policy was previous approved by our Board of Directors, upon recommendation of our Compensation Committee.

The compensation policy is in effect for three years from the 2013 annual general meeting. The compensation policy principles were designed to grant proper, fair and well-considered remuneration to our officers, in alignment with our long-term best interests and overall organizational strategy. Part of the rationale is that the Compensation Policy should encourage our officers to identify with our objectives, and an increase in officer satisfaction and motivation should retain the employment of high-quality officers in our service over the long term.

C. Board Practices

Appointment of Directors and Terms of Officers

Pursuant to our articles of association, the size of our board of directors shall be no less than 5 persons but no more than 7, excluding at least two external directors. The directors, except for our external directors, are divided into three classes, as nearly equal in number as possible. At each annual general meeting, which is required to be held annually, but not more than fifteen months after the prior annual general meeting, the term of one class of directors expires, and the directors of such class are re-nominated to serve an additional three year term that expires at the annual general meeting held in the third year following such election. This process continues indefinitely. The director of the first class, currently consisting of Dror Ben-Asher, will hold office until our annual general meeting to be held in the year 2017. The directors of the second class, currently consisting of Dr. Kenneth Reed, and Eric Swenden, will hold office until our annual general meeting to be held in the year 2018 and the directors of the third class, currently consisting of Dr. Shmuel Cabilly and Dan Suesskind, will hold office until our annual general meeting to be held in the year 2016. Rick Scruggs, appointed by our board of directors in accordance with our articles of association, will hold office until our annual general meeting to be held in 2016. Until the next annual general meeting, the board of directors may elect new directors to fill vacancies, or increase the number of members of the board of directors up to the maximum number provided in our articles of association. Any director so appointed may hold office until the first general shareholders' meeting convened after the appointment.

Pursuant to the Israeli Companies Law, one may not be elected and may not serve as a director in a public company if he or she does not have the required qualifications and the ability to dedicate an appropriate amount of time for the performance of his duties as a director in the company, taking into consideration, among other things, the special needs and size of the company. In addition, a public company may convene an annual general meeting of shareholders to elect a director, and may elect such director, only if prior to such shareholders meeting, the nominee declares, among other things, that he or she possesses all of the required qualifications to serve as a director (and lists such qualifications in such declaration) and has the ability to dedicate an appropriate amount of time for the performance of his duties as a director of the company.

Under the Israeli Companies Law, the entering by a public company into a contract with a non-controlling director as to the terms of his office, including exculpation, indemnification or insurance, requires the approval of the compensation committee, the board of directors and the shareholders of the company.

A recent amendment to the Israeli Companies Law requires that the terms of service and engagement of the CEO, directors or controlling shareholders (or a relative thereof) receive the approval of the compensation committee, board of directors, and shareholders, subject to limited exceptions. Similarly, the terms of service and engagement of any officer other than the CEO must receive the approval of the compensation committee and board of directors. However, shareholder approval (with approval by a Special Majority, as defined below) is required if the compensation of such officer other than the CEO is not in accordance with a new compensation policy the Company is required to adopt. The recent amendment to the Israeli Companies Law requires that by August 11, 2013 the board and shareholders (with approval by a Special Majority) adopt a compensation policy applicable to Company officers and directors which must take into account, among other things, providing proper incentives to directors and officers, the risk management of the company, the officer's contribution to achieving corporate objectives and increasing profits, and the function of the officer or director. Under the Israeli Companies Law, a Special Majority requires (i) the vote of at least a majority of the shares held by shareholders who are not controlling shareholders or have a personal interest in the proposal (shares held by abstaining shareholders shall not be taken into account); or (ii) that the aggregate number of shares voting against the proposal held by such shareholders does not exceed 2% of the Company's voting shareholders.

We have a service contract with one of our directors, Dror Ben-Asher that provides for benefits upon termination of his employment as director. For more information, see " – B. Compensation – Executives and Director Compensation."

Independent and External Directors - Israeli Companies Law Requirements

We are subject to the provisions of the Israeli Companies Law. The Israeli Minister of Justice has adopted regulations exempting companies like us whose shares are traded outside of Israel from some provisions of the Israeli Companies Law.

Under the Israeli Companies Law, companies incorporated under the laws of Israel whose shares are either (i) listed for trading on a stock exchange or (ii) have been offered to the public in or outside of Israel, and are held by the public (Public Company) are required to appoint at least two external directors. The Israeli Companies Law provides that a person may not be appointed as an external director if the person is a relative of the controlling shareholder or if the person or the person's relative, partner, employer, someone to whom he is subordinated directly or indirectly or any entity under the person's control, has, as of the date of the person's appointment to serve as external director, or had, during the two years preceding that date, any affiliation with us, our controlling shareholder, any relative of our controlling shareholder, as of the date of the person's appointment to serve as external director, or any entity in which, currently or within the two years preceding the appointment date, the controlling shareholder was the company or the company's controlling shareholder; and in a company without a controlling shareholder or without a shareholder holding 25% or more of the voting rights in the company, any affiliation to the chairman of the board of directors, to the general manager (Chief Executive Officer), to a shareholder holding 5% or more of the company's shares or voting rights, or to the chief officer in the financial or economic field as of the date of the person's appointment. The term "affiliation" includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- control; and
- service as an office holder, other than service as a director who was appointed in order to serve as an external director of a company when such company was about to make an initial public offering.

Under the Israeli Companies Law, an "office holder" is defined as a general manager, chief business manager, deputy general manager, vice-general manager, any person filing any of these positions in a company even if he holds a different title, director or any manager directly subordinate to the general manager.

However, a person may not serve as an external director if the person or the person's relative, partner, employer, someone to whom he is subordinated directly or indirectly or any entity under the person's control has business or professional relationship with an entity which an affiliation with is prohibited as detailed above, even if such relationship is not on a regular basis (excluding negligible relationship). In addition, an external director may not receive any compensation other than the compensation permitted by the Israeli Companies Law.

Regulations under the Israeli Companies Law, provide for various instances and kinds of relationships in which an external director will not be deemed to have "affiliation" with the public company for which he serves, or is a candidate for serving as an external director.

No person can serve as an external director if the person's positions or other businesses create, or may create a conflict of interests with the person's responsibilities as a director or may impair his ability to serve as a director. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company. Until the lapse of two years from termination of office, a company, its controlling shareholder, or a company controlled by him may not engage an external director, his spouse, or child to serve as an office holder in the company or in any entity controlled by the controlling shareholder and cannot employ or receive professional services for consideration from that person, and may not grant such person any benefit either directly or indirectly, including through a corporation controlled by that person. The same restrictions apply to relatives other than a spouse or a child, but such limitations shall only apply for one year from the date such external director ceased to be engaged in such capacity. In addition, if at the time an external director is appointed, all current members of the board of directors, who are neither controlling shareholders nor relatives of controlling shareholders, are of the same gender, then the external director to be appointed must be of the other gender.

Under the Israeli Companies Law, a public company is required to appoint as an external director, a person who has "professional expertise" or a person who has "financial and accounting expertise," provided that at least one of the external directors must have "financial and accounting expertise." However, if at least one of our other directors (1) meets the independence requirements of the Securities Exchange Act of 1934, as amended, (2) meets the standards of the Nasdaq Stock Market for membership on the audit committee and (3) has financial and accounting expertise as defined in the Israeli Companies Law and applicable regulations, then neither of our external directors is required to possess financial and accounting expertise as long as both possess other requisite professional qualifications. The determination whether a director possesses financial and accounting expertise is made by the board of directors.

Under the Israeli Companies Law regulations, a director having financial and accounting expertise is a person who, due to his education, experience and qualifications is highly skilled in respect of, and understands, business-accounting matters and financial reports in a manner that enables him to understand in depth the company's financial statements and to stimulate discussion regarding the manner in which the financial data is presented. Under the Israeli Companies Law regulations, a director having professional expertise is a person who has an academic degree in either economics, business administration, accounting, law or public administration or another academic degree or has completed other higher education studies, all in an area relevant to the main business sector of the company or in a relevant area for the board of directors position, or has at least five years of experience in one of the following or at least five years of aggregate experience in two or more of the following: a senior management position in the business of a corporation with a substantial scope of business, in a senior position in the public service or a senior position in the main field of the company's business.

Under the Israeli Companies Law, each Israeli public company is required to determine the minimum number of directors with "accounting and financial expertise" that such company believes is appropriate in light of the company's type, size, the scope and complexity of its activities and other factors. Once a company has made this determination, it must ensure that the necessary appointments to the board of directors are made in accordance with this determination. Our board of directors determined that two directors with "accounting and financial expertise" is appropriate for us. Our board of directors currently has five directors with such "accounting and financial expertise."

External directors are to be elected by a majority vote at a shareholders' meeting, provided that either (1) the majority of shares voted at the meeting, including at least a majority of the votes of the shareholders who are not controlling shareholders (as defined in the Israeli Companies Law), do not have a personal interest in the appointment (excluding a personal interest which did not result from the shareholder's relationship with the controlling shareholder), vote in favor of the election of the director without taking abstentions into account; or (2) the total number of shares of the above mentioned shareholders who voted against the election of the external director does not exceed two percent of the aggregate voting rights in the company.

The initial term of an external director is three years and may be extended for two additional three-year terms under certain circumstances and conditions. Nevertheless, regulations under the Israeli Companies Law provide that companies, whose shares are listed for trading both on the Tel Aviv Stock Exchange and on the Nasdaq Stock Market, may appoint an external director for additional three-year terms, under certain circumstances and conditions. External directors may be removed only in a general meeting, by the same percentage of shareholders as is required for their election, or by a court, and in both cases only if the external directors cease to meet the statutory qualifications for their appointment or if they violate their duty of loyalty to us. Each committee authorized to exercise any of the powers of the board of directors, is required to include at least one external director and the audit committee is required to include all of the external directors.

An external director is entitled to compensation and reimbursement of expenses in accordance with regulations promulgated under the Israeli Companies Law and is otherwise prohibited from receiving any other compensation, directly or indirectly, in connection with serving as a director except for certain exculpation, indemnification and insurance provided by the company.

Mr. Ofer Tsimchi and Ms. Nurit Benjamini currently serve as our external directors.

Committees

Israeli Companies Law Requirements

Our board of directors has established three standing committees, the audit committee, the compensation committee and the investment committee.

Audit Committee

Under the Israeli Companies Law, the board of directors of a public company must appoint an audit committee, comprised of at least three directors including all of the external directors.

The majority of the members of the audit committee, as well as the majority of members present at audit committee meetings, must be "independent" (as such term is defined below) and the chairman of the audit committee must be an external director. In addition, the following are disqualified from serving as members of the audit committee: the chairman of the board of directors, the controlling shareholder and her or his relatives, any director employed by the company or by its controlling shareholder or by an entity controlled by the controlling shareholder, a director who regularly provides services to the company or to its controlling shareholder or to an entity controlled by the controlling shareholder, and any director who derives most of its income from the controlling shareholder. Any persons not qualified from serving as a member of the audit committee may not be present at the audit committee meetings during the discussion and at the time decisions are made, unless the chairman of the audit committee determines that the presence of such person is required to present a matter to the meeting or if such person qualifies under an available exemption in the Companies Law.

An "independent director" is defined as an external director or a director who meets the following conditions: (i) satisfies certain conditions for appointment as an external director (as described above) and the audit committee has determined that such conditions have been met and (ii) has not served as a director of the company for more than nine consecutive years, with any interruption of up to two years in service not being deemed a disruption in the continuity of such service.

The role of the audit committee under the Israel Companies Law is to examine suspected flaws in our business management, in consultation with the internal auditor or our independent accountants and suggest appropriate course of action in order to correct such flaws. In addition, the approval of the audit committee is required to effect specified actions and related party transactions.

Additional functions to be performed by the audit committee include, among others, the following:

- determination whether certain related party actions and transactions are "material" or "extraordinary" for purposes of the requisite approval procedures;
- to determine whether to approve actions and transactions that require audit committee approval under the Israel Companies Law;
- to assess the scope of work and compensation of the company's independent accountant;
- to assess the company's internal audit system and the performance of its internal auditor and if the necessary resources have been made available to the internal auditor considering the company's needs and size; and
- to determine arrangements for handling complaints of employees in relation to suspected flaws in the business management of the company and the protection of the rights of such employees.

Our audit committee also serves as our financial statements committee. The members of our audit committee are Ms. Nurit Benjamini, Mr. Ofer Tsimchi and Mr. Dan Suesskind.

Compensation Committee

According to the Companies Law, the board of directors of a public company must establish a compensation committee consisting of at least three directors and including all of the external directors who must constitute a majority of its members. The remaining members must be qualified to serve on the audit committee pursuant to Companies Law requirements described above. The compensation committee chairman must be an external director. Any persons not qualified from serving as a member of the compensation committee may not be present at the compensation committee meetings during the discussion and at the time decisions are made, unless the chairman of the compensation committee determines that the presence of such person is required to present a matter to the meeting or if such person qualifies under an available exemption in the Companies Law.

The provisions of the Companies Law that govern the compensation and reimbursement terms of external directors also apply to members of the compensation committee who are not external directors. Our compensation committee, which consists of Mr. Ofer Tsimchi (chairman), Dr. Shmuel Cabilly and Ms. Nurit Benjamini, administers issues relating to our global compensation plan with respect to our employees, directors and consultants. Our compensation committee is responsible for making recommendations to the board of directors regarding the issuance of share options and compensation terms for our officers and directors and for determining salaries and incentive compensation for our executive officers and incentive compensation for our other employees and consultants. Each of the members of the compensation committee is "independent" as such term is defined in the Nasdaq Listing Rules.

Investment Committee

Our investment committee, which consists of Mr. Eric Swenden (chairman) and Mr. Dan Suesskind, assists the board in fulfilling its responsibilities with respect to the Company's financial and investment strategies and policies, including determining policies and guidelines on these matters and monitoring implementation. It is also authorized to approve certain financial transactions and review risk factors associated with management of the Company finances and the mitigation of such risks, as well as financial controls and reporting and various other finance-related matters.

Nasdaq Stock Market Requirements

Under the Nasdaq Marketplace Rules, we are required to maintain an audit committee consisting of at least three members, all of whom are independent and are financially literate and one of whom has accounting or related financial management expertise.

The independence requirements of Rule 10A-3 of the Securities Exchange Act of 1934, as amended, implement two basic criteria for determining independence:

- audit committee members are barred from accepting directly or indirectly any consulting, advisory or other compensatory fee from the issuer or an affiliate of the issuer, other than in the member's capacity as a member of the board of directors and any board committee, and
- audit committee members may not be an "affiliated person" of the issuer or any subsidiary of the issuer apart from her or his capacity as a member of the board of directors and any board committee.

The Securities and Exchange Commission has defined "affiliate" for non-investment companies as "a person that directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, the person specified." The term "control" is intended to be consistent with the other definitions of this term under the Securities Exchange Act of 1934, as amended, as "the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise." A safe harbor has been adopted by the Securities and Exchange Commission, under which a person who is not an executive officer or 10% shareholder of the issuer would be deemed not to have control of the issuer.

In accordance with the Sarbanes-Oxley Act of 2002 and the Nasdaq Marketplace Rules, the audit committee is directly responsible for the appointment, compensation and performance of our independent auditors. In addition, the audit committee is responsible for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal controls and our compliance with legal and regulatory requirements. The audit committee also oversees our major financial risk exposures and policies for managing such potential risks, discusses with management and our independent auditor significant risks or exposure and assesses the steps management has taken to minimize such risk.

As noted above, the members of our audit committee include Ms. Nurit Benjamini, Mr. Ofer Tsimchi and Mr. Dan Suesskind, with Ms. Benjamini serving as chairman. All members of our audit committee meet the requirements for financial literacy under the Nasdaq Marketplace Rules. Our board of directors has determined that each of Mr. Ofer Tsimchi and Ms. Nurit Benjamini is an audit committee financial expert as defined by the Securities and Exchange Commission rules and all members of the audit committee have the requisite financial experience as defined by the Nasdaq Marketplace Rules. Each of the members of the audit committee is "independent" as such term is defined in Rule 10A-3(b)(1) under the Securities Exchange Act of 1934, as amended.

Corporate Governance Practices

Internal Auditor

Under the Israeli Companies Law, the board of directors must appoint an internal auditor proposed by the audit committee. The role of the internal auditor is, among others, to examine whether our actions comply with the law and orderly business procedure. Under the Israeli Companies Law, the internal auditor may not be an interested party, an office holder, a relative of an interested party, or a relative of an office holder, nor may the internal auditor be our independent accountant or its representative. Ms. Dana Gottesman-Erlich, Partner at Risk Advisory and Internal Auditing Group at BDO Israel, serves as our internal auditor.

Duties of Office Holders and Approval of Specified Related Party Transactions Under Israeli Law

Fiduciary Duties of Office Holders

The Israeli Companies Law imposes a duty of care and a duty of loyalty on all office holders of a company, including directors and executive officers. The duty of care requires an office holder to act with the level of care, according to which a reasonable office holder in the same position would have acted under the same circumstances.

The duty of care includes a duty to use reasonable means to obtain:

- information on the appropriateness of a given action brought for the office holder's approval or performed by him by virtue of his position; and
- all other important information pertaining to the previous actions.

The duty of loyalty requires an office holder to act in good faith and for the benefit of the company, and includes a duty to:

- refrain from any action involving a conflict of interest between the performance of the office holder's duties in the company and his personal affairs;
- refrain from any activity that is competitive with the company's business;
- refrain from usurping any business opportunity of the company to receive a personal gain for the office holder or others; and
- disclose to the company any information or documents relating to a company's affairs which the office holder has received due to his position as an office holder.

Under the Israeli Companies Law, directors' compensation arrangements require compensation committee approval, board of directors' approval and shareholder approval.

The Israeli Companies Law requires that an office holder of a company promptly and, in any event, not later than the first board meeting at which the transaction is discussed, disclose any personal interest that he may have and all related material facts or document known to her or him, in connection with any existing or proposed transaction by the company. A personal interest of an office holders includes a personal interest of the office holder's relative, of a company in which the office holder or the office holder's relative is, a shareholder which holds 5% or more of a company's share capital or its voting rights, a director or a general manager, or in which the office holder has the right to appoint at least one director or the general manager. A personal interest also includes a personal interest of a person who votes according to a proxy of another person, even if the other person has no personal interest, and a personal interest of a person who gave a proxy to another person to vote on his behalf – all whether the discretion how to vote lies with the person voting or not. In the case of an extraordinary transaction, the office holder's duty to disclose applies also to a personal interest of the office holder's relative.

Under Israeli law, an extraordinary transaction is a transaction:

- other than in the ordinary course of business;
- other than on market terms; or
- that is likely to have a material impact on the company's profitability, assets or liabilities.

Under the Israeli Companies Law, once an office holder complies with the above disclosure requirement, the board of directors may approve an ordinary transaction between the company and an office holder, or a third party in which an office holder has a personal interest, unless the articles of association provide otherwise. A transaction does not benefit to the company's interest cannot be approved. Subject to certain exceptions, the compensation committee and the board of directors must approve the conditions and term of office of an office holder (which is not a director).

If the transaction is an extraordinary transaction, both the audit committee and the board of directors, in that order, must approve the transaction. Under specific circumstances, shareholder approval may also be required. Whoever has a personal interest in a matter, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of such person is required to present a matter to the meeting, such officer holder may be present at the meeting. Notwithstanding the foregoing, if the majority of the directors have a personal interest in a matter, a director who has the personal interest in this matter may be present at this meeting or vote on this matter, but the board of directors decision requires the shareholder approval.

Controlling Shareholder Transactions and Actions

Under the Israeli Companies Law, the disclosure requirements which apply to an office holder also apply to a controlling shareholder of a public company and to a person who would become a controlling shareholder as a result of a private placement. A controlling shareholder includes a person who has the ability to direct the activities of a company, other than if this power derives solely from his/her position on the board of directors or any other position with the company. In addition, for such purposes a controlling shareholder includes a shareholder that holds 25% or more of the voting rights in a public company if no other shareholder owns more than 50% of the voting rights in the company. Extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, including a private placement in which a controlling shareholder has a personal interest; and the terms of engagement of the company, directly or indirectly, with a controlling shareholder or his or her relative (including through a corporation controlled by a controlling shareholder), regarding the company's receipt of services from the controlling shareholder, and if such controlling shareholder is also an office holder of the company or an employee, regarding his or her terms of office and employment, require the approval of the audit committee, the board of directors and the shareholders of the company, in that order. The shareholders approval must include either:

- a majority of the shareholders who have no personal interest in the transaction and who are participating in the voting, in person, by proxy or by written ballot, at the meeting (votes abstaining shall not be taken into account); or
- the total number of shares voted against the proposal by shareholders without a personal interest does not exceed 2% of the aggregate voting rights in the Company.

In addition, any such transaction whose term is more than three years requires the above mentioned approval every three years, unless, with respect to transactions not involving the receipt of services or compensation, the audit committee approves a longer term as reasonable under the circumstances.

However, under regulations, promulgated pursuant to the Israeli Companies Law, certain transactions between a company and its controlling shareholders, or the controlling shareholder's relative, do not require shareholder approval.

For information concerning the direct and indirect personal interests of certain of our office holders and principal shareholders in certain transactions with us, see "Item 7. Major Shareholders – B. Related Party Transactions."

The Israeli Companies Law requires that every shareholder that participates, either by proxy or in person, in a vote regarding a transaction with a controlling shareholder indicate whether or not that shareholder has a personal interest in the vote in question, the failure of which results in the invalidation of that shareholder's vote.

The Israeli Companies Law further provides that an acquisition of shares or voting rights in a public company must be made by means of a tender offer if as a result of the acquisition the purchaser would become a holder of 45% of the voting rights of the company, unless there is a holder of more than 45% of the voting rights of the company or would become a holder of 25% of the voting rights unless there is another person holding 25% of the voting rights. This restriction does not apply to:

- an acquisition of shares in a private placement, if the acquisition had been approved in a shareholders meeting under certain circumstances;
- an acquisition of shares from a holder of at least 25% of the voting rights, as a result of which a person would become a holder of at least 25% of the voting rights; and
- an acquisition of shares from a holder of more than 45% of the voting rights, as a result of which the acquirer would become a holder of more than 45% of the voting rights in the company.

The Israeli Companies Law further provides that a shareholder has a duty to act in good faith towards the company and other shareholders when exercising his rights and duties and shall refrain from oppressing other shareholders, including in connection with the voting at a shareholders' meeting on:

- any amendment to the articles of association;
- an increase in the company's authorized share capital;
- a merger; or
- approval of certain transactions with control persons and other related parties, which require shareholder approval.

In addition, any controlling shareholder, any shareholder who knows that it possesses power to determine the outcome of a shareholder vote and any shareholder who, pursuant to the provisions of a company's articles of association, has the power to appoint or prevent the appointment of an office holder in the company, or has any other power over the company, is under a duty to act with fairness towards the company. Under the Israeli Companies Law, the laws that apply to a breach of a contract will generally also apply to a breach of duty of fairness.

Exemption, Insurance and Indemnification of Directors and Officers

Office Holder Exemption

Under the Israeli Companies Law, a company may not exempt an officer or director from liability with respect to a breach of his duty of loyalty, but may exempt in advance an officer or director from liability to the company, in whole or in part, with respect to a breach of his duty of care, except in connection with a prohibited distribution made by the company, if so provided in its articles of association. Our articles of association provide for this exemption from liability for officers and directors.

Office Holder Insurance

The Israeli Companies Law and our articles of association provide that, subject to the provisions of the Israeli Companies Law, we may obtain insurance for our officers and directors for any liability stemming from any act performed by an officer or director in his capacity as an officer or director, as the case may be with respect to any of the following:

- a breach of such officer's or director's duty of care to us or to another person;
- a breach of such officer's or director's duty of loyalty to us, provided that such officer or director acted in good faith and had reasonable cause to assume that his act would not prejudice our interests;
- a financial liability imposed upon such officer or director in favor of another person;

- financial liability imposed on the officer or director for payment to persons or entities harmed as a result of violations in administrative proceedings as described in Section 52(54)(a)(1)(a) of the Israeli Securities Law (Party Harmed by the Breach);
- expenses incurred by such officer or director in connection with an administrative proceeding conducted in his matter, including reasonable litigation expenses, including legal fees; or
- a breach of any duty or any other obligation, to the extent insurance may be permitted by law.

In July 2013, our shareholders approved our Compensation Policy, which includes, among others, provisions relating to directors and officers liability insurance. Pursuant to the Compensation Policy, we may obtain a liability insurance policy, which would apply to our and/or our subsidiaries directors and officers, as they may be, from time to time, subject to the following terms and conditions: (a) the total insurance coverage under the insurance policy may not exceed $50 million; and (b) the annual premium payable by us for the insurance premium may not exceed $400,000 annually. In addition, pursuant to the Compensation Policy, should we sell our operations (in whole or in part) and/or in case of merger, spin-off or any other significant business combination involving us and/or part or all of our assets, we may obtain a director's and officers' liability insurance policy (run-off) for our directors and officers in office with regard to the relevant operations, subject to the following terms and conditions: (a) the insurance term shall not exceed seven years; (b) the coverage amount may not exceed $50 million; (c) the premium payable by us may not exceed $400,000 annually. The Compensation Policy is in effect for three years from the 2013 annual general meeting.

Subsequent to the approval of the terms of the Compensation Policy, our compensation committee and board of directors resolved to purchase directors and officers liability insurance policy, pursuant to which the total amount of insurance covered under the policy would be $40 million This insurance was renewed in December 2015, for the period commencing on December 16, 2015 and ending on December 15, 2016. Pursuant to the foregoing approvals, we carry directors and officers liability insurance.

Indemnification of Office Holders

The Israeli Companies Law provides that a company may indemnify an officer or director for payments or expenses associated with acts performed in his capacity as an officer or director of the company, provided the company's articles of association include the following provisions with respect to indemnification:

- a provision authorizing the company to indemnify an officer or director for future events with respect to a monetary liability imposed on him in favor of another person pursuant to a judgment (including a judgment given in a settlement or an arbitrator's award approved by the court), so long as such indemnification is limited to types of events which, in the board of directors' opinion, are foreseeable at the time of granting the indemnity undertaking given the company's actual business, and in such amount or standard as the board of directors deems reasonable under the circumstances. Such undertaking must specify the events that, in the board of directors' opinion, are foreseeable in view of the company's actual business at the time of the undertaking and the amount or the standards that the board of directors deemed reasonable at the time;
- a provision authorizing the company to indemnify an officer or director for future events with respect to reasonable litigation expenses, including counsel fees, incurred by an officer or director in which he is ordered to pay by a court, in proceedings that the company institutes against him or instituted on behalf of the company or by another person, or in a criminal charge from which he was acquitted, or a criminal charge in which he was convicted for a criminal offense that does not require proof of criminal intent;
- a provision authorizing the company to indemnify an officer or director for future events with respect to reasonable litigation fees, including attorney's fees, incurred by an officer or director due to an investigation or proceeding filed against him by an authority that is authorized to conduct such investigation or proceeding, and that resulted without filing an indictment against him and without imposing on him financial obligation in lieu of a criminal proceeding, or that resulted without filing an indictment against him but with imposing on him a financial obligation as an alternative to a criminal proceeding in respect of an offense that does not require the proof of criminal intent or in connection with a monetary sanction;
- a provision authorizing the company to indemnify an officer or director for future events with respect to a Party Harmed by the Breach;
- a provision authorizing the company to indemnify an officer or director for future events with respect to expenses incurred by such officer or director in connection with an administrative proceeding, including reasonable litigation expenses, including legal fees; and

- a provision authorizing the company to retroactively indemnify an officer or director.

Limitations on Insurance, Exemption and Indemnification

The Israeli Companies Law and our articles of association provide that a company may not exempt or indemnify an office holder nor enter into an insurance contract, which would provide coverage for any monetary liability incurred as a result of any of the following:

- a breach by the officer or director of his duty of loyalty, except for insurance and indemnification where the officer or director acted in good faith and had a reasonable basis to believe that the act would not prejudice the company;
- a breach by the officer or director of his duty of care if the breach was done intentionally or recklessly, except if the breach was solely as a result of negligence;
- any act or omission done with the intent to derive an illegal personal benefit; or
- any fine, civil fine, monetary sanctions, or forfeit imposed on the officer or director.

In addition, under the Israeli Companies Law, exemption of, indemnification of, and procurement of insurance coverage for, our officers and directors must be approved by our audit committee and board of directors and, in specified circumstances, by our shareholders.

Letters of Indemnification

We have issued our officers and directors letters of indemnification, pursuant to which we have agreed to indemnify each officer and director in advance for any liability or expense imposed on or incurred by him in connection with acts performed by him in the capacity of an officer or director, subject to the provisions of the letters of indemnification agreement. As approved by our shareholders on July 18, 2013, the amount of the advance indemnity is limited up to $5 million.

As part of the indemnification letters, we exempted our directors and officers, in advance, to the extent permitted under law, from any liability for any damage incurred by them, either directly or indirectly, due to the breach of an officer's or director's duty of care *vis- à-vis* us, within his acts in his capacity as an officer or director. The letter provides that so long as not permitted under law, we do not exempt an officer or director in advance from his liability to us for a breach of the duty of care upon distribution, to the extent applicable to the officer or director, if any. The letter also exempts an officer or director from any liability for any damage incurred by him, either directly or indirectly, due to the breach of the officer or director's duty of care *vis- à-vis* us, by his acts in his capacity as an officer or director prior to the letter of exemption and indemnification becoming effective.

D. Employees

As of February 22, 2016, we had 12 employees and we also received services from 13 consultants who provide services to us in the U.S., Canada and Belgium.

	As of December 31,					
	2013		2014		2015	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management and administration	8	2	9	2	11	2
Research and development	0	8	1	8	1	11

While none of our employees is party to a collective bargaining agreement, certain provisions of the collective bargaining agreements between the Histadrut (General Federation of Labor in Israel) and the Coordination Bureau of Economic Organizations (including the Industrialists' Associations) are applicable to our employees by order of the Israel Ministry of Labor. These provisions primarily concern the length of the workday, minimum daily wages for professional workers, pension fund benefits for all employees, insurance for work-related accidents, procedures for dismissing employees, determination of severance pay and other conditions of employment. We generally provide our employees with benefits and working conditions beyond the required minimums.

We have never experienced any employment-related work stoppages and believe our relationship with our employees is good.

E. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding ordinary shares as of February 22, 2016 of each of our directors and executive officers individually and as a group based on information provided to us by our directors and executive officers. The information in this table is based on 127,114,294 ordinary shares outstanding as of such date. The number of ordinary shares beneficially owned by a person includes ordinary shares subject to options or warrants held by that person that were currently exercisable at, or exercisable within 60 days of, February 22, 2016. The ordinary shares issuable under these options and warrants are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options and warrants but not the percentage ownership of any other person. None of the holders of the ordinary shares listed in this table have voting rights different from other holders of the ordinary shares.

	Number of Shares Beneficially Held	Percent of Class
Directors		
Dr. Kenneth Reed (1)	4,636,672	4.64%
Dr. Shmuel Cabilly (2)	4,254,178	3.34%
Dan Suesskind (3)	1,119,100	*
Eric Swenden (4)	983,746	*
Ofer Tsimchi (5)	270,000	*
Rick D. Scruggs	-	-
Nurit Benjamini	-	-
Executive officers		
Dror Ben-Asher (6)	5,980,030	4.58%
Ori Shilo (7)	5,327,715	4.10%
Reza Fathi, Ph.D. (8)	1,276,250	*
Gilead Raday (9)	911,250	*
Adi Frish (10)	823,750	*
Guy Goldberg (11)	443,750	*
Uri Hananel Aharon (12)	297,750	*
All directors and executive officers as a group (12 persons)	26,323,941	18.90%

* Less than 1.0%

(1) Includes options to purchase 355,000 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.165 and $1.48 per share, and the options expiry date range between 2017 and 2021. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(2) Includes options to purchase 360,000 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.5 and $1.48 per share, and the options expiry date range between 2017 and 2021. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(3) Includes options to purchase 975,000 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.5 and $1.48 per share, and the options expiry date range between 2018 and 2021. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(4) Includes options to purchase 355,000 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.165 and $1.48 per share, and the options expiry date range between 2017 and 2021. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(5) Includes options to purchase 270,000 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $1.05 and $1.48 per share, and the options expiry date range between 2018and 2021.

(6) Includes options to purchase 3,340,000 ordinary shares exercisable within 60 days of February 22, 2015 and. The exercise price of these options range between $0.165 and $1.48 per share, and the options expiry date range between 2017 and 2021. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(7) Includes options to purchase 2,732,500 Ordinary exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.165 and $1.48 per share, and the options expiry date range between 2017 and 2021. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(8) Includes options to purchase 1,276,250 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.165 and $1.56 per share, and the options expiry date range between 2017 and 2022.

(9) Includes options to purchase 911,250 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.165 and $1.65 per share, and the options expiry date range between 2017 and 2022.

(10) Includes options to purchase 823,750 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.165 and $1.56 per share, and the options expiry date range between 2017 and 2022.

(11) Includes options to purchase 443,750 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.7 and $1.56 per share, and the options expiry date range between 2019 and 2022.

(12) Includes options to purchase 297,750 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.69 and $1.56 per share, and the options expiry date range between 2018 and 2022.

Option Plans

2010 Option Plan

In 2010, we adopted the RedHill Biopharma Ltd. 2010 Option Plan. The 2010 Option Plan provides for the granting of options to our directors, officers, employees, consultants and service providers and individuals who are their employees, and to the directors, officers, employees, consultants and service providers of our subsidiaries and affiliates. The 2010 Option Plan provides for options to be issued at the determination of our board of directors in accordance with applicable laws. As of February 22, 2016, there were 20,511,338 ordinary shares issuable upon the exercise of outstanding options under the 2010 Option Plan.

Administration of Our Option Plan

Our option plan is administered by our compensation committee regarding the granting of options and the terms of option grants, including exercise price, method of payment, vesting schedule, acceleration of vesting and the other matters necessary in the administration of these plans. Options granted under the 2010 Option Plan to eligible Israeli employees, officers and directors are granted under Section 102 of the Israel Income Tax Ordinance pursuant to which the options or the ordinary shares issued upon their exercise must be allocated or issued to a trustee and be held in trust for two years from the date upon which such options were granted in order to benefit from the provisions of Section 102. Under Section 102, any tax payable by an employee from the grant or exercise of the options is deferred until the transfer of the options or ordinary shares by the trustee to the employee or upon the sale of the options or ordinary shares, and gains may qualify to be taxed as capital gains at a rate equal to 25%, subject to compliance with specified conditions. See "Item 10. Additional Information – E. Taxation – Israeli Tax Considerations."

Options granted under 2010 Option Plan as amended generally vest over a period of 4 years and expire seven (7) years after the grant date. The 2010 Option Plan, however, permits options to have a term of up to 10 years. If we terminate a grantee for cause (as such term is defined in the 2010 Option Plan) the right to exercise all the options granted to the grantee, the grantee's vested and unvested options will expire immediately, on the earlier of:

- termination of the engagement; or
- the date of the notice of the termination of the engagement.

Upon termination of employment for any other reason, other than in the event of death, disability, retirement after the age of 60 or for cause, all unvested options will expire and all vested options will generally be exercisable for 90 days following termination, or such other period as determined by the plan administrator, subject to the terms of the 2010 Option Plan and the governing option agreement.

Under our 2010 Option Plan, as amended, in the event any person, entity or group that was not an interested party at the time of our initial public offering on the Tel Aviv Stock Exchange becoming a controlling shareholder, all options granted by us under the plan will be accelerated, so that the grantee will be entitled to exercise all of those options. A "controlling shareholder" in this paragraph is a controlling shareholder, as defined in the Israel Securities Law, 1968. An "interested party" is defined in the Securities Law and includes, among others:

- a holder of 5% or more of the outstanding shares or voting rights of an entity;
- a person entitled to appoint one or more of the directors or chief executive officer of an entity;
- a director of an entity or its chief executive officer;
- an entity, in which an individual referred to above holds 25% or more of its outstanding shares or voting rights, or is entitled to appoint 25% or more of its directors; or
- a person who initiated the establishment of the entity.

Upon termination of employment due to death or disability, or retirement after the age of 60, subject to the board of directors' approval, all the vested options at the time of termination will be exercisable for 24 months, or such other period as determined by the plan administrator, subject to the terms of the 2010 Option Plan and the governing option agreement.

In the event of the sale of all or a substantial part of our assets, or a merger transaction in which we are not the surviving corporation and the surviving corporation does not assume the options granted under the 2010 Option Plan or otherwise grants options to purchase the surviving corporation's shares in exchange for such option, all of the options that were scheduled to vest within 12 months of the date of such transaction shall vest immediately prior the closing of such transaction.

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth certain information regarding the beneficial ownership of our outstanding ordinary shares as of February 25, 2015, by each person or entity known to beneficially own 5.0% or more of our outstanding ordinary shares. The information with respect to beneficial ownership of the ordinary shares is given based on information reported in such shareholder's Schedule 13G, and if no Schedule 13G was filed, based on the information provided to us by the shareholders.

The information in this table is based on 127,114,294 ordinary shares outstanding as of such date. In determining the number of ordinary shares beneficially owned by a person, we include any shares as to which the person has sole or shared voting power or investment power, as well as any ordinary shares subject to options or warrants held by that person that were currently exercisable at, or exercisable within 60 days of February 22, 2016. The ordinary shares issuable under these options and warrants are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options and warrants but not the percentage ownership of any other person. None of the holders of the ordinary shares listed in this table have voting rights different from other holders of ordinary shares.

	Number of Shares Beneficially Held	Percent of Outstanding Equity
Broadfin Capital (1) (2)	9,351,700 (2)	9.16%
OrbiMed Israel Partners Limited Partnership (3) (4)	8,175,320 (4)	5.94%

(1) Broadfin Capital LLC (Broadfin") is the investment advisor of Broadfin Healthcare Master Fund, LTD (Broadfin Fund), which holds the ADSs and warrants. Broadfin, as the investment advisor may be deemed to share voting and investment power with respect to the ordinary shares underlying the ADSs and warrants held by Broadfin Fund. The address of Broadfin Fund is 300 Park Avenue, 26th Floor, New York, NY 10022.

(2) Includes warrants to purchase 105,264 ADSs with exercise price of $11 and an expiration date of January 7, 2017 purchased by Broadfin in the private placement that closed on January 8, 2014. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

(3) OrbiMed Israel GP Ltd. (OrbiMed Israel) is the general partner of OrbiMed Israel BioFund GP Limited Partnership (OrbiMed BioFund), which is the general partner of OrbiMed Israel Partners Limited Partnership, an Israel limited partnership (OrbiMed Partners), which holds the ADSs and warrants. OrbiMed Israel, as the general partner of OrbiMed BioFund, and OrbiMed BioFund, as the general partner of OrbiMed Partners, may be deemed to share voting and investment power with respect to the ordinary shares underlying the ADSs and warrants held by OrbiMed Partners. The address of OrbiMed Israel Partners Limited Partners is 89 Medinat HaYehudim St., Herzliya 46766, Israel.

(4) Includes warrants to purchase 252,632 ADSs with exercise price of $11 and an expiration date of January 7, 2017 purchased by OrbiMed Israel Partners Limited Partnership in the private placement that closed on January 8, 2014. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants. The Warrants to purchase ADSs contain an issuance limitation that prohibits the holder from exercising the Warrants to the extent that after giving effect to such issuance after exercise the holder (together with the holder's affiliates, and any other persons acting as a group together with the holder or any of the holder's affiliates), would beneficially own in excess of 9.9% of the ordinary shares outstanding immediately after giving effect to the issuance of the ADSs issuable upon exercise of the warrants.

On February 12, 2016, 6,190,236 ADSs (equivalent to 61,902,360 ordinary shares, or approximately 49% of our total issued and outstanding ordinary shares), were held of record by four record holders in the U.S., of which two holders had a U.S. address. As of February 22, 2016, there was one shareholder of record of our ordinary shares, which was located in Israel. The number of record holders is not representative of the number of beneficial holders of our ADSs or ordinary shares because many of the ADSs and ordinary shares are held by brokers or other nominees.

B. Related Party Transactions

November 2012 Private Placement

On January 10, 2013, we issued in a private placement 6,481,280 ordinary shares at a price per share of NIS 4.00 and non-tradable warrants to purchase up to 3,240,640 ordinary shares. As part of this private placement, Dr. Cabilly invested $1 million and Mr. Suesskind invested $75,000 out of a total of $6.56 million. For more information on the private placement, please see "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources".

Acquisition of Royalties Rights

From June 2010 to August 2010, we entered into loan agreements with a number of investors, pursuant to which we received gross proceeds of approximately $3.5 million. The loans we received under these loan agreements accrued interest at an annual rate of 8%, which was payable upon the conversion of the loans.

Under the terms of the loan agreements, we agreed to pay the investors 5% of the proceeds of (i) net sales by us or our sublicensees or distributors; and (ii) down payments and milestone payments from sublicenses or distributor transactions paid to us in connection with the first two new products purchased by us subsequent to the closing of this loan financing. Such royalties were payable (i) with regard to net sales over a period of five years from the date of the first commercial sale of either of these products; and (ii) with regard to down payments and milestone payments over a period of five years commencing from August 11, 2010. Following approvals from our board of directors and shareholders, it was determined that the investors would be entitled to royalties with respect to RIZAPORT™ for the treatment of acute migraine headaches and RHB-104 for the treatment of Crohn's disease.

On August 31, 2010, each of these loan agreements was replaced in their entirety by a new mandatory convertible loan agreement. However, the obligation to pay the investors the royalty payments described above remained in full force and effect.

On January 10, 2013, following approval of our shareholders, we issued an aggregate of 2,317,186 ordinary shares in exchange for the acquisition and termination of the royalty rights granted to investors pursuant to the August 2010 mandatory convertible loan agreement. In connection with such transaction, each investor received a number of shares on a pro-rata basis in accordance with their respective royalty rights. As part of the transaction, the following three directors who were investors in the August 2010 mandatory convertible loan agreement were issued ordinary shares: Dr. Kenneth Reed - 233,688 ordinary shares; Mr. Eric Swenden - 433,993 ordinary shares; and Dr. Shmuel Cabilly - 333,841 ordinary shares, and Mr. Amram Hayut, a brother-in-law of Mr. Shilo, received 56,753 ordinary shares, out of a total amount of approximately $3.5 million.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Financial Statements and Other Financial Information

The financial statements required by this item are found at the end of this Annual Report, beginning on page F-1.

Legal Proceedings

From time to time, we may become party to legal proceedings and claims in the ordinary course of business. We are not currently a party to any significant legal proceedings.

Dividend Policy

We have never declared or paid cash dividends to our shareholders. Currently we do not intend to pay cash dividends. We currently intend to reinvest any future earnings in developing and expanding our business. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including future earnings, our financial condition, operating results, contractual restrictions, capital requirements, business prospects, applicable Israeli law and other factors our board of directors may deem relevant.

B. Significant Changes

Except as otherwise disclosed in this Annual Report, no significant change has occurred since December 31, 2015.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our ordinary shares have been trading on the Tel Aviv Stock Exchange under the symbol "RDHL" since February 2011.

Ordinary Shares

The following table sets forth, for the periods indicated, the reported high and low closing sales prices of our ordinary shares on the Tel Aviv Stock Exchange in NIS and U.S. dollars. U.S. dollar per ordinary share amounts are calculated using the U.S. dollar representative rate of exchange on the date to which the high or low market price is applicable, as reported by the Bank of Israel.

	NIS		U.S.$	
	Price per Ordinary Share		Price per Ordinary Share	
Annual	High	Low	High	Low
2015	7.80	4.34	2.03	1.12
2014	6.80	3.00	1.96	0.78
2013	4.29	3.23	1.15	0.92
2012	4.19	1.71	1.08	0.45
2011 (beginning on February 3, 2011)	3.80	1.82	1.05	0.49
Quarter				
2015				
Fourth quarter	5.42	4.34	1.39	1.12
Third quarter	7.10	4.62	1.88	1.19
Second quarter	7.80	5.52	2.03	1.41
First quarter	6.16	4.89	1.57	1.26
2014				
Fourth quarter	5.38	3.00	1.38	0.78
Third quarter	5.89	4.18	1.72	1.20
Second quarter	6.80	4.80	1.96	1.39
First quarter	5.04	3.96	1.44	1.14
Most Recent Six Months				
February 2016 (through February 22, 2016)	3.88	3.32	0.98	0.86
January 2016	5.14	3.86	1.32	0.97
December 2015	5.01	4.56	1.29	1.17
November 2015	5.42	4.34	1.39	1.12
October 2015	5.19	4.57	1.34	1.18
September 2015	5.91	5.00	1.53	1.27
August 2015	5.65	4.62	1.50	1.19

On February 22, 2016, the last reported sales price of our ordinary shares on the TASE was NIS 3.73 per share, or $0.95 per share (based on the exchange rate reported by the Bank of Israel for such date). On February 22, 2016 the exchange rate of the NIS to the U.S. dollar was $1.00 = NIS 3.907, as reported by the Bank of Israel.

ADSs

Our ADSs have been trading on the Nasdaq Capital Market under the symbol "RDHL" since December 27, 2012.

The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on the Nasdaq Capital Market in U.S. dollars.

	U.S. $ Price per ADS	
	High	**Low**
Annual		
2015	19.79	11.05
2014	19.20	8.03
2013	13.60	8.31
Quarter		
2015		
Fourth quarter	13.72	11.05
Third quarter	18.46	12.16
Second quarter	19.79	14.03
First quarter	15.92	12.52
2014		
Fourth quarter	13.40	8.03
Third quarter	17.35	12.14
Second quarter	19.20	14.01
First quarter	14.50	12.38
Most Recent Six Months		
February 2016 (through February 22, 2016)	9.43	8.21
January 2016	12.61	9.75
December 2015	12.90	11.64
November 2015	13.70	11.05
October 2015	13.72	11.31
September 2015	15.28	12.78
August 2015	14.63	12.16

On February 22, 2016, the last reported price of our ADSs on the Nasdaq Capital Market was $9.37 per ADS.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are listed and traded on the Tel Aviv Stock Exchange, and our ADSs, each representing ten ordinary share and evidenced by an American depositary receipt, or ADR, are traded on the Nasdaq Capital Market under the symbol "RDHL." The ADRs were issued pursuant to a Depositary Agreement entered into with The Bank of New York.

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable

ITEM 10. ADDITIONAL INFORMATION

A. Share Capital

Not applicable

B. Memorandum and Articles of Association

Securities Registers

Our transfer agent and register is Bank of New York Mellon and its address is 101 Barclay Street, New York, NY.

Objects and Purposes

According to Section 4 of our articles of association, we shall engage in any legal business. Our number with the Israeli Registrar of Companies is 514304005.

Private Placements

Under the Israeli Companies Law, if (i) as a result of a private placement a person would become a controlling shareholder or (ii) a private placement will entitle investors to receive 20% or more of the voting rights of a company as calculated before the private placement, and all or part of the private placement consideration is not in cash or in public traded securities or is not in market terms and if as a result of the private placement the holdings of a substantial shareholder shall increase or as a result of it a person shall become a substantial shareholder, then in either case, the allotment must be approved by the board of directors and by the shareholders of the company. A "substantial shareholder" is defined as a shareholder who holds five percent or more of the company's outstanding share capital, assuming the exercise of all of the securities convertible into shares held by that person. In order for the private placement to be on "market terms" the board of directors has to determine, on the base of detailed explanation, that the private placement is on market terms, unless proven otherwise.

Board of Directors

Under our articles of association, resolutions by the board of directors shall be decided by a majority of votes of the directors present, or participating, in the case of voting by media, and voting, each director having one vote.

In addition, the Israeli Companies Law requires that certain transactions, actions and arrangements be approved as provided for in a company's articles of association and in certain circumstances by the compensation or audit committee and by the board of directors itself. Those transactions that require such approval pursuant to a company's articles of association must be approved by its board of directors. In certain circumstances, compensation or audit committee and shareholder approval is also required. See "Item 6. Directors, Senior Management and Employees – C. Board Practices."

The Israeli Companies Law requires that a member of the board of directors or senior management of the company promptly and, in any event, not later than the first board meeting at which the transaction is discussed, disclose any personal interest that he or she may have, either directly or by way of any corporation in which he or she is, directly or indirectly, a 5% or greater shareholder, director or general manager or in which he or she has the right to appoint at least one director or the general manager, as well as all related material information known to him or her, in connection with any existing or proposed transaction by the company. In addition, if the transaction is an extraordinary transaction, (that is, a transaction other than in the ordinary course of business, otherwise than on market terms, or is likely to have a material impact on the company's profitability, assets or liabilities), the member of the board of directors or senior management must also disclose any personal interest held by his or her spouse, siblings, parents, grandparents, descendants, spouse's descendants, siblings and parents, and the spouses of any of the foregoing.

Once the member of the board of directors or senior management complies with the above disclosure requirement, a company may approve the transaction in accordance with the provisions of its articles of association. Under the provisions of the Israeli Companies Law, whoever has a personal interest in a matter, which is considered at a meeting of the board of directors or the audit committee, may not be present at this meeting or vote on this matter, unless it is not an extraordinary transaction as defined in the Israeli Companies Law. However, if the chairman of the board of directors or the chairman of the audit committee has determined that the presence of an office holder with a personal interest is required for the presentation of a matter, such officer holder may be present at the meeting. Notwithstanding the foregoing, if the majority of the directors have a personal interest in a matter, they shall be allowed to participate and vote on this matter, but an approval of the transaction by the shareholders in the general meeting shall be required.

Our articles of association provide that, subject to the Israeli Companies Law, all actions executed in good faith by the board of directors or by a committee thereof or by any person acting as a director or a member of a committee of the board of directors, will be deemed to be valid even if, after their execution, it is discovered that there was a flaw in the appointment of these persons or that any one of these persons was disqualified from serving at his or her office.

Our articles of association provide that, subject to the provisions of the Israeli Companies Law, the board of directors may appoint board of directors' committees. The committees of the board of directors shall report to the board of directors their resolutions or recommendations on a regular basis, as shall be prescribed by the board of directors. The board of directors may cancel the resolution of a committee that has been appointed by it; however, such cancellation shall not affect the validity of any resolution of a committee, pursuant to which we acted, vis-à-vis another person, who was not aware of the cancellation thereof. Decisions or recommendations of the committee of the board which require the approval of the board of directors will be brought to the directors' attention a reasonable time prior to the discussion at the board of directors.

According to the Israeli Companies Law, a contract of a company with its directors, regarding their conditions of service, including the grant to them of exemption from liability from certain actions, insurance, and indemnification as well as the company's contract with its directors on conditions of their employment, in other capacities, require the approval of the compensation committee, the board of directors, and the shareholders by a Special Majority.

Description of Securities

Ordinary Shares

The following is a description of our ordinary shares. Our authorized share capital is 300,000,000 ordinary shares, par value NIS 0.01 per share.

The ordinary shares do not have preemptive rights, preferred rights or any other right to purchase our securities. Neither our articles of association nor the laws of the State of Israel restrict the ownership or voting of ordinary shares by non-residents of Israel, except for subjects of countries which are enemies of Israel.

Transfer of Shares. Fully paid ordinary shares are issued in registered form and may be freely transferred pursuant to our articles of association unless that transfer is restricted or prohibited by another instrument.

Notices. Under the Israeli Companies Law and our articles of association, we are required to publish notices in two Hebrew-language daily newspapers at least 14 calendar days' prior notice of a shareholders' meeting. However, under regulations promulgated under the Israeli Companies Law, we are required to publish notice in two daily newspapers at least 35 calendar days prior any shareholders' meeting in which the agenda includes matters which may be voted on by voting instruments. Regulations under the Israeli Companies Law exempt companies whose shares are listed for trading both on a stock exchange in and outside of Israel, from some provisions of the Israeli Companies Law. An amendment to these regulations exempts us from the requirements of the Israeli proxy regulation, under certain circumstances.

According to the Israeli Companies Law and the regulations promulgated thereunder, for purposes of determining the shareholders entitled to notice and to vote at such meeting, the board of directors may fix the record date not more than 40 nor less than four calendar days prior to the date of the meeting, provided that an announcement regarding the general meeting shall be given prior to the record date.

Election of Directors. The number of directors on the board of directors shall be no less than five but no more than seven, not including at least two external directors. The general meeting is entitled, at any time and from time to time, in a resolution approved by a majority of 75% or more of the votes cast by those shareholders present and voting at the meeting in person, by proxy or by a voting instrument, not taking into consideration abstaining votes, to change the minimum and/or maximum number of directors as stated above as well as to amend the board classification under our Articles. For more information, please see "Item 6. Directors, Senior Management and Employees – C. Board Practices – Appointment of Directors and Terms of Office."

Dividend and Liquidation Rights. Our profits, in respect of which a resolution was passed to distribute them as dividend or bonus shares, shall be paid pro rata to the amount paid or credited as paid on account of the nominal value of shares held by the shareholders. In the event of our liquidation, the liquidator may, with the general meeting's approval, distribute parts of our property in specie among the shareholders and he may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above deems fit.

Voting, Shareholders' Meetings and Resolutions. Holders of ordinary shares are entitled to one vote for each ordinary share held on all matters submitted to a vote of shareholders. The quorum required for an ordinary meeting of shareholders consists of at least two shareholders present, in person or by proxy, or who has sent us a voting instrument indicating the way in which he is voting, who hold or represent, in the aggregate, at least 25% of the voting rights of our outstanding share capital. A meeting adjourned for lack of a quorum is adjourned to the following day at the same time and place or any time and place as prescribed by the board of directors in notice to the shareholders. At the reconvened meeting one shareholder at least, present in person or by proxy constitutes a quorum except where such meeting was called at the demand of shareholders. With the agreement of a meeting at which a quorum is present, the chairman may, and on the demand of the meeting he must, adjourn the meeting from time to time and from place to place, as the meeting resolves. Annual general meetings of shareholders are held once every year within a period of not more than 15 months after the last preceding annual general shareholders' meeting. The board of directors may call special general meetings of shareholders. The Israeli Companies Law provides that a special general meeting of shareholders may be called by the board of directors or by a request of two directors or 25% of the directors in office, whichever is the lower, or by shareholders holding at least 5% of our issued share capital and at least 1% of the voting rights, or of shareholders holding at least 5% of our voting rights.

An ordinary resolution requires approval by the holders of a majority of the voting rights present, in person or by proxy, at the meeting and voting on the resolution.

Allotment of Shares. Our board of directors has the power to allot or to issue shares to any person, with restrictions and condition as it deems fit.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's issued and outstanding share capital is required by the Israeli Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company.

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the same class for the purchase of all of the issued and outstanding shares of the same class.

If the shareholders who do not respond to or accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class of the shares, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will be accepted if the shareholders who do not accept it hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of the shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition the Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may determine in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

The description above regarding a full tender offer shall also apply, with necessary changes, when a full tender offer is accepted and the offeror has also offered to acquire all of the company's securities.

Special tender offer

The Israeli Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of at least 25% of the voting rights in the company. This rule does not apply if there is already another holder of at least 25% of the voting rights in the company.

Similarly, the Israeli Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company.

These requirements do not apply if the acquisition (i) occurs in the context of a private offering, on the condition that the shareholders meeting approved the acquisition as a private offering whose purpose is to give the acquirer at least 25% of the voting rights in the company if there is no person who holds at least 25% of the voting rights in the company, or as a private offering whose purpose is to give the acquirer 45% of the voting rights in the company, if there is no person who holds 45% of the voting rights in the company; (ii) was from a shareholder holding at least 25% of the voting rights in the company and resulted in the acquirer becoming a holder of at least 25% of the voting rights in the company; or (iii) was from a holder of more than 45% of the voting rights in the company and resulted in the acquirer becoming a holder of more than 45% of the voting rights in the company.

The special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the special tender offer is accepted by a majority of the votes of those offerees who gave notice of their position in respect of the offer; in counting the votes of offerees, the votes of a holder in control of the offeror, a person who has personal interest in acceptance of the special tender offer, a holder of at least 25% of the voting rights in the company, or any person acting on their or on the offeror's behalf, including their relatives or companies under their control, are not taken into account.

In the event that a special tender offer is made, a company's board of directors is required to express its opinion on the advisability of the offer or shall abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An office holder in a target company who, in his or her capacity as an office holder, performs an action the purpose of which is to cause the failure of an existing or foreseeable special tender offer or is to impair the chances of its acceptance, is liable to the potential purchaser and shareholders for damages resulting from his acts, unless such office holder acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, office holders of the target company may negotiate with the potential purchaser in order to improve the terms of the special tender offer, and may further negotiate with third parties in order to obtain a competing offer.

If a special tender offer was accepted by a majority of the shareholders who announced their stand on such offer, then shareholders who did not respond to the special offer or had objected to the special tender offer may accept the offer within four days of the last day set for the acceptance of the offer. In the event that a special tender offer is accepted, then the purchaser or any person or entity controlling it and any corporation controlled by them shall refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

The Israeli Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Israeli Companies Law are met, a majority of each party's shareholders, by a majority of each party's shares that are voted on the proposed merger at a shareholders' meeting.

The board of directors of a merging company is required pursuant to the Israeli Companies Law to discuss and determine whether in its opinion there exists a reasonable concern that, as a result of a proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, taking into account the financial condition of the merging companies. If the board of directors has determined that such a concern exists, it may not approve a proposed merger. Following the approval of the board of directors of each of the merging companies, the boards of directors must jointly prepare a merger proposal for submission to the Israeli Registrar of Companies.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voting at the shareholders meeting (excluding abstentions) that are held by parties other than the other party to the merger, any person who holds 25% or more of the means of control (See "Management – Audit Committee – Approval of Transactions with Related Parties" for a definition of means of control) of the other party to the merger or any one on their behalf including their relatives (See "Management – External Directors – Qualifications of External Directors" for a definition of relatives) or corporations controlled by any of them, vote against the merger.

In addition, if the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders.

If the transaction would have been approved but for the separate approval of each class of shares or the exclusion of the votes of certain shareholders as provided above, a court may still rule that the company has approved the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the appraisal of the merging companies' value and the consideration offered to the shareholders.

Under the Israeli Companies Law, each merging company must send a copy of the proposed merger plan to its secured creditors. Unsecured creditors are entitled to receive notice of the merger, as provided by the regulations promulgated under the Israeli Companies Law. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the target company. The court may also give instructions in order to secure the rights of creditors.

In addition, a merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger was filed with the Israeli Registrar of Companies and 30 days from the date that shareholder approval of both merging companies was obtained.

Anti-takeover Measures

The Israeli Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred or additional rights to voting, distributions or other matters and shares having preemptive rights. We do not have any authorized or issued shares other than ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of a majority of our shares represented and voting at a general meeting. Shareholders voting at such a meeting will be subject to the restrictions under the Israeli Companies Law described in "— Voting."

C. Material Contracts

For a description of other material agreements, please see "Information on the Company – B. Business Overview.

D. Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our ordinary shares. Dividends, if any, paid to holders of our ordinary shares, and any amounts payable upon our dissolution, liquidation or winding up, as well as the proceeds of any sale in Israel of our ordinary shares to an Israeli resident, may be paid in non-Israeli currency or, if paid in Israeli currency, may be converted into U.S. dollars at the rate of exchange prevailing at the time of conversion.

E. Taxation

Israeli Tax Considerations

General

The following is a summary of the material tax consequences under Israeli law concerning the purchase, ownership and disposition of our ordinary shares or American Depositary Shares (Shares).

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of our Shares. In particular, this discussion does not take into account the specific circumstances of any particular investor (such as tax-exempt entities, financial institutions, certain financial companies, broker-dealers, investors that own, directly or indirectly, 10% or more of our outstanding voting rights, all of whom are subject to special tax regimes not covered under this discussion). To the extent that issues discussed herein are based on legislation which has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will accord with any such interpretation in the future.

Potential investors are urged to consult their own tax advisors as to the Israeli or other tax consequences of the purchase, ownership and disposition of the Shares, including, in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax, currently at the rate of 25% of a company's taxable income.

Taxation of Shareholders

Capital Gains

Capital gains tax is imposed on the disposal of capital assets by an Israeli resident and on the disposal of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless an exemption is available or unless an applicable double tax treaty between Israel and the seller's country of residence provides otherwise. The Israeli Income Tax Ordinance distinguishes between "Real Gain" and the "Inflationary Surplus." Real Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposal. Inflationary Surplus is not subject to tax.

Real Gain accrued by individuals on the sale of the Shares will be taxed at the rate of 25%. However, if the individual shareholder is a "Controlling Shareholder" (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company's means of control) at the time of sale or at any time during the preceding 12 month period, such gain will be taxed at the rate of 30%.

Corporate and individual shareholders dealing in securities in Israel are taxed at the tax rates applicable to business income which is 26.5% in 2015 for corporations, and a marginal tax rate of up to 50% in 2015 for individuals, including a 2% excess tax (as discussed below).

Notwithstanding the foregoing, capital gains generated from the sale of our Shares by a non-Israeli shareholder may be exempt from Israeli tax under the Israeli Income Tax Ordinance provided that the following cumulative conditions are met: (i) the Shares were purchased upon or after the registration of the Shares on the stock exchange and (ii) the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the income or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of the Shares may be exempt from Israeli capital gains tax under the provisions of an applicable double tax treaty. For example, the Convention between the Government of the U.S. and the Government of the State of Israel with respect to Taxes on Income (U.S.- Israel Double Tax Treaty) exempts a U.S. resident (for purposes of the treaty) from Israeli capital gain tax in connection with the sale of the Shares, provided that: (i) the U.S. resident owned, directly or indirectly, less than 10% of the voting power of the company at any time within the 12 month period preceding such sale; (ii) the U.S. resident, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel; however, under the U.S-Israel Double Tax Treaty, the taxpayer would be permitted to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition, subject to the limitations under U.S. law applicable to foreign tax credits. The U.S-Israel Double Tax Treaty does not relate to U.S. state or local taxes.

Payers of consideration for the Shares, including the purchaser, the Israeli stockbroker or the financial institution through which the Shares are held, are obligated, subject to certain exemptions, to withhold tax upon the sale of Shares at a rate of 25% or 26.5% of the consideration for individuals and corporations, respectively.

Upon the sale of traded securities, a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid to the Israeli Tax Authority on January 31 and July 31 of every tax year in respect of sales of traded securities made within the previous six months. However, if all tax due was withheld at source according to applicable provisions of the Israeli Income Tax Ordinance and regulations promulgated thereunder, such return need not be filed and no advance payment must be paid. Capital gains are also reportable on annual income tax returns.

Dividends

Dividends distributed by a company to a shareholder who is an Israeli resident individual will be generally subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a Controlling Shareholder, as defined above, at the time of distribution or at any time during the preceding 12 month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will be generally exempt from Israeli income tax provided that the income from which such dividend is distributed, derived or accrued within Israel.

Dividends distributed by an Israeli resident company to a non-Israeli resident (either an individual or a corporation) are generally subject to Israeli withholding tax on the receipt of such dividends at the rate of 25% (30% if the dividend recipient is a Controlling Shareholder at the time of distribution or at any time during the preceding 12 month period). These rates may be reduced under the provisions of an applicable double tax treaty. For example, under the U.S.-Israel Double Tax Treaty, the following tax rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain types of interest or dividends the tax rate is 12.5%; (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate under The Law for the Encouragement of Capital Investments, 1959, the tax rate is 15%; and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income is attributed to a permanent establishment of the U.S. resident in Israel.

Excess Tax

Individual shareholders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) and who have taxable income that exceeds NIS 800,000 in a tax year (linked to the Israeli Consumer Price Index each year (NIS 810,720 for 2015, which is approximately $203,000)), will be subject to an additional tax at the rate of 2% on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

Foreign Exchange Regulations

Non-residents of Israel who hold our Shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated, and may be restored at any time by administrative action.

U.S Federal Income Tax Considerations

The following is a summary of the material U.S. federal income tax consequences relating to the ownership and disposition of our Ordinary Shares and ADSs by U.S. Holders, as defined below. This summary addresses solely U.S. Holders who acquire ADSs pursuant to this offering and who hold Ordinary Shares or ADSs, as applicable, as capital assets for tax purposes. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended (Code), current and proposed Treasury regulations promulgated thereunder, and administrative and judicial decisions as of the date hereof, all of which are subject to change, possibly on a retroactive basis. In addition, this section is based in part upon representations of the depositary and the assumption that each obligation in the deposit agreement and any related agreement will be performed in accordance with its terms. This summary does not address all U.S. federal income tax matters that may be relevant to a particular holder or all tax considerations that may be relevant with respect to an investment in our Ordinary Shares or ADSs.

This summary does not address tax considerations applicable to a holder of our Ordinary Shares or ADSs that may be subject to special tax rules including, without limitation, the following:

- dealers or traders in securities, currencies or notional principal contracts;
- financial institutions;
- insurance companies;
- real estate investment trusts;
- banks;
- persons subject to the alternative minimum tax;
- tax-exempt organizations;
- traders that have elected mark-to-market accounting;
- investors that hold Ordinary Shares or ADSs as part of a “straddle”, “hedge”, or “conversion transaction” with other investments;
- regulated investment companies;
- persons that actually or constructively own 10 percent or more of our voting shares;
- persons that are treated as partnerships or other pass through entities for U.S. federal income purposes and persons who hold the Shares through partnerships or other pass through entities; and
- persons whose functional currency is not the U.S. dollars.

This summary does not address the effect of any U.S. federal taxation other than U.S. federal income taxation. In addition, this summary does not include any discussion of state, local, or foreign tax consequences to a holder of our Ordinary Shares or ADSs.

You are urged to consult your own tax advisor regarding the foreign and U.S. federal, state, and local and other tax consequences of an investment in Ordinary Shares or ADSs.

For purposes of this summary, a "U.S. Holder" means a beneficial owner of an Ordinary Share or ADS that is for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the U.S..;
- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the United States or under the laws of the U.S. or any political subdivision thereof;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) if (a) a court within the United States is able to exercise primary supervision over the administration of the trust and (b) one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

If an entity that is classified as a partnership for U.S. federal tax purposes holds Ordinary Shares or ADSs, the United States federal tax treatment of its partners will generally depend upon the status of the partners and the activities of the partnership. Entities that are classified as partnerships for U.S. federal tax purposes and persons holding Ordinary Shares or ADSs through such entities should consult their own tax advisors.

In general, if you hold ADSs, you will be treated as the holder of the underlying Ordinary Shares represented by those ADSs for U.S. federal income tax purposes. Accordingly, gain or loss generally will not be recognized if you exchange ADSs for the underlying Ordinary Shares represented by those ADSs.

Distributions

Subject to the discussion under "Passive Foreign Investment Companies" below, the gross amount of any distribution, including the amount of any Israeli taxes withheld from such distribution (see "Israeli Tax Considerations"), actually or constructively received by a U.S. Holder with respect to our Ordinary Shares (or, in the case of ADSs, received by the depositary) will be taxable to the U.S. Holder as foreign source dividend income to the extent of our current and accumulated earnings and profits as determined under U.S. federal income tax principles. The U.S. Holder will not be eligible for any dividends received deduction in respect of the dividends paid by us. Distributions in excess of earnings and profits will be non-taxable to the U.S. Holder to the extent of the U.S. Holder's adjusted tax basis in its Ordinary Shares or ADSs. Distributions in excess of such adjusted tax basis will generally be taxable to the U.S. Holder as capital gain from the sale or exchange of property as described below under "Sale or Other Disposition of Ordinary Shares or ADSs." If we do not report to a U.S. Holder the portion of a distribution that exceeds earnings and profits, the distribution will generally be taxable as a dividend. The amount of any distribution of property other than cash will be the fair market value of that property on the date of distribution.

Under the Code, certain dividends received by non-corporate U.S. Holders will be subject to a maximum federal income tax rate of 20%. This reduced income tax rate is only applicable to dividends paid by a "qualified foreign corporation" that is not a PFIC for the year in which the dividend is paid or for the preceding taxable year, and only with respect to Ordinary Shares or ADSs held by a qualified U.S. Holder (i.e., a non-corporate holder) for a minimum holding period (generally 61 days during the 121-day period beginning 60 days before the ex-dividend date). As discussed below, however, we believe we may be a "passive foreign investment company" (see "Passive Foreign Investment Companies" below) for our current taxable year and future taxable years. Accordingly, dividends paid by us to individual U.S. Holders may not be eligible for the reduced income tax rate applicable to qualified dividends. You should consult your own tax advisor regarding the availability of this preferential tax rate under your particular circumstances.

The amount of any distribution paid in a currency other than U.S. dollars (a "foreign currency"), including the amount of any withholding tax thereon, will be included in the gross income of a U.S. Holder in an amount equal to the U.S. dollar value of the foreign currency calculated by reference to the exchange rate in effect on the date of the U.S. Holder's (or, in the case of ADSs, the depositary's) receipt of the dividend, regardless of whether the foreign currency is converted into U.S. dollars. If the foreign currency is converted into U.S. dollars on the date of receipt, a U.S. Holder generally should not be required to recognize a foreign currency gain or loss in respect of the dividend. If the foreign currency received in the distribution is not converted into U.S. dollars on the date of receipt, a U.S. Holder will have a basis in the foreign currency equal to its U.S. dollar value on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of the foreign currency will be treated as U.S. source ordinary income or loss.

Subject to certain conditions and limitations, any Israeli taxes withheld on dividends may be creditable against a U.S. Holder's U.S. federal income tax liability, subject to generally applicable limitations. The rules relating to foreign tax credits and the timing thereof are complex. U.S. Holders should consult their own tax advisors regarding the availability of a foreign tax credit in their particular situation.

Sale or Other Disposition of Ordinary Shares or ADSs

Subject to the discussion under "Passive Foreign Investment Companies" below, if a U.S. Holder sells or otherwise disposes of its Ordinary Shares or ADSs, gain or loss will be recognized for U.S. federal income tax purposes in an amount equal to the difference between the amount realized on the sale or other disposition and such holder's adjusted basis in the Ordinary Shares or ADSs. Such gain or loss generally will be a capital gain or loss, and will be a long-term capital gain or loss if the holder had held the Ordinary Shares or ADSs for more than one year at the time of the sale or other disposition. Long-term capital gains realized by non-corporate U.S. Holders are generally subject to a preferential U.S. federal income tax rate. In general, gain or loss recognized by a U.S. Holder on the sale or other disposition or our Ordinary Shares or ADSs will be U.S. source gain or loss for purposes of the foreign tax credit limitation. As discussed below in "Passive Foreign Investment Companies," however, we may be a PFIC for our current taxable year and future taxable years. If we are a PFIC, any such gain will be subject to the PFIC rules, as discussed below, rather than being taxed as a capital gain.

If a U.S. Holder receives foreign currency upon a sale or exchange of Ordinary Shares or ADSs, gain or loss will be recognized in the manner described above under "Distributions." However, if such foreign currency is converted into U.S. dollars on the date received by the U.S. Holder, the U.S. Holder generally should not be required to recognize any foreign currency gain or loss on such conversion.

As discussed above under the heading "Israeli Tax Considerations-Taxation of Shareholders," a U.S. Holder who holds Ordinary Shares or ADSs through an Israeli broker or other Israeli intermediary may be subject to Israeli withholding tax on any capital gains recognized on a sale or other disposition of the Ordinary Shares or ADSs if the U.S. Holder does not obtain approval of an exemption from the Israeli Tax Authorities or claim any allowable refunds or reductions. U.S. Holders are advised that any Israeli tax paid under circumstances in which an exemption from (or a refund of or a reduction in) such tax was available will not be creditable for U.S. federal income tax purposes. U.S. Holders are advised to consult their Israeli broker or intermediary regarding the procedures for obtaining an exemption or reduction.

Medicare Tax on Unearned Income

Certain U.S. Holders that are individuals, estates or trusts are required to pay an additional 3.8% tax on their net investment income, which would include dividends paid on the Ordinary Shares or ADSs and capital gains from the sale or other disposition of the Ordinary Shares or ADSs.

Passive Foreign Investment Companies

Based on the value and composition of our assets, we may be a PFIC for U.S. federal income tax purposes for our current taxable year and future taxable years. A non-U.S. corporation is considered a PFIC for any taxable year if either:

- at least 75% of its gross income for such taxable year is passive income, or
- at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income.

For purposes of the above calculations, if a non-U.S. corporation owns, directly or indirectly, 25% or more of the total value of the outstanding shares of another corporation, it will be treated as if it (a) held a proportionate share of the assets of such other corporation and (b) received directly a proportionate share of the income of such other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains, but generally excludes rents and royalties which are derived in the active conduct of a trade or business and which are received from a person other than a related person.

A separate determination must be made each taxable year as to whether we are a PFIC (after the close of each such taxable year). Because the value of our assets for purposes of the asset test will generally be determined by reference to the market price of the ADSs, our PFIC status will depend in large part on the market price of the ADSs, which may fluctuate significantly. Based on our retention of a significant amount of cash and cash equivalents, and depending on the market price of the ADSs, we may be a PFIC for the current taxable year and future taxable years.

If we are a PFIC for any year during which you hold the ADSs, we generally will continue to be treated as a PFIC with respect to you for all succeeding years during which you hold the ADSs, unless we cease to be a PFIC and you make a "deemed sale" election with respect to the ADSs you hold. If such election is made, you will be deemed to have sold the ADSs you hold at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain from such deemed sale would be subject to the consequences described below. After the deemed sale election, the ADSs with respect to which the deemed sale election was made will not be treated as shares in a PFIC unless we subsequently become a PFIC.

For each taxable year we are treated as a PFIC with respect to you, you will be subject to special tax rules with respect to any "excess distribution" you receive and any gain you realize from a sale or other disposition (including a pledge) of the ADSs, unless you make a "mark-to-market" election as discussed below. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the ADSs will be treated as an excess distribution. Under these special tax rules, if you receive any excess distribution or realize any gain from a sale or other disposition of the ADSs:

- the excess distribution or gain will be allocated ratably over your holding period for the ADSs
- the amount of excess distribution or gain allocated to the current taxable year, and any taxable year before the first taxable year in which we were a PFIC, shall be included in gross income (as ordinary income) for the current tax year, and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to

The tax liability for amounts allocated to years before the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ADSs cannot be treated as capital, even if you hold the ADSs as capital assets.

If we are treated as a PFIC with respect to you for any taxable year, to the extent any of our subsidiaries are also PFICs, you will be deemed to own your proportionate share of any such lower-tier PFIC, and you may be subject to the rules described in the preceding two paragraphs with respect to the shares of such lower-tier PFICs you would be deemed to own. As a result, you may incur liability for any "excess distribution" described above if we receive a distribution from such lower-tier PFICs or if any shares in such lower-tier PFICs are disposed of (or deemed disposed of). You should consult your own tax advisor regarding the application of the PFIC rules to any of our subsidiaries.

Alternatively, a U.S. Holder of "marketable stock" (as defined below) in a PFIC may make a mark-to-market election for such stock to elect out of the general tax treatment for PFICs discussed above. If you make a mark-to-market election for the ADSs, you will include in income for each year we are a PFIC an amount equal to the excess, if any, of the fair market value of the ADSs as of the close of your taxable year over your adjusted basis in such Ordinary Shares. You are allowed a deduction for the excess, if any, of the adjusted basis of the ADSs over their fair market value as of the close of the taxable year. However, deductions are allowable only to the extent of any net mark-to-market gains on the ADSs included in your income for prior taxable years. Amounts included in your income under a mark-to-market election, as well as gain on the actual sale or other disposition of the ADSs, are treated as ordinary income. Ordinary loss treatment also applies to the deductible portion of any mark-to-market loss on the ADSs, as well as to any loss realized on the actual sale or disposition of the ADSs to the extent the amount of such loss does not exceed the net mark-to-market gains previously included for the ADSs. Your basis in the ADSs will be adjusted to reflect any such income or loss amounts. If you make a valid mark-to-market election, the tax rules that apply to distributions by corporations which are not PFICs would apply to distributions by us, except the lower applicable tax rate for qualified dividend income would not apply. If we cease to be a PFIC when you have a mark-to-market election in effect, gain or loss realized by you on the sale of the ADSs will be a capital gain or loss and taxed in the manner described above under "Sale or Other Disposition of Ordinary Shares or ADSs."

The mark-to-market election is available only for "marketable stock," which is stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs are listed on The NASDAQ and, accordingly, provided the ADSs are regularly traded, if you are a holder of ADSs, the mark-to-market election would be available to you if we are a PFIC. Once made, the election cannot be revoked without the consent of the IRS unless the ADSs cease to be marketable stock. If we are a PFIC for any year in which the U.S. Holder owns ADSs but before a mark-to-market election is made, the interest charge rules described above will apply to any mark-to-market gain recognized in the year the election is made. If any of our subsidiaries are or become PFICs, the mark-to-market election will not be available with respect to the shares of such subsidiaries that are treated as owned by you. Consequently, you could be subject to the PFIC rules with respect to income of the lower-tier PFICs the value of which already had been taken into account indirectly via mark-to-market adjustments. A U.S. Holder should consult its own tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

In certain circumstances, a U.S. Holder of stock in a PFIC can make a "qualified electing fund election" to mitigate some of the adverse tax consequences of holding stock in a PFIC by including in income its share of the corporation's income on a current basis. However, we do not currently intend to prepare or provide the information that would enable you to make a qualified electing fund election.

Unless otherwise provided by the United States Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the United States Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their own tax advisors regarding the requirements of filing such information returns under these rules, taking into account the uncertainty as to whether we are currently treated as or may become a PFIC.

YOU ARE STRONGLY URGED TO CONSULT YOUR OWN TAX ADVISOR REGARDING THE IMPACT OF OUR POTENTIAL PFIC STATUS ON YOUR INVESTMENT IN THE ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ADSs.

Backup Withholding and Information Reporting

Payments of dividends with respect to Ordinary Shares or ADSs and the proceeds from the sale, retirement, or other disposition of Ordinary Shares or ADSs made by a U.S. paying agent or other U.S. intermediary will be reported to the IRS and to the U.S. Holder as may be required under applicable U.S. Treasury regulations. We, or an agent, a broker, or any paying agent, as the case may be, may be required to withhold tax (backup withholding), currently at the rate of 28%, if a non-corporate U.S. Holder that is not otherwise exempt fails to provide an accurate taxpayer identification number and comply with other IRS requirements concerning information reporting. Certain U.S. Holders (including, among others, corporations and tax-exempt organizations) are not subject to backup withholding. Any amount of backup withholding withheld may be used as a credit against your U.S. federal income tax liability provided that the required information is furnished to the IRS. U.S. Holders should consult their own tax advisors as to their qualification for exemption from backup withholding and the procedure for obtaining an exemption.

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our Ordinary Shares or ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). As described above under "Passive Foreign Investment Companies," each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than $100,000 for our Ordinary Shares or ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF AN INVESTMENT IN OUR ORDINARY SHARES OR ADSs IN LIGHT OF SUCH INVESTOR'S PARTICULAR CIRCUMSTANCES.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Securities Exchange Act of 1934, as amended, applicable to foreign private issuers, and under those requirements we file reports with the Securities and Exchange Commission. Those other reports or other information may be inspected without charge at the Securities and Exchange Commission's public reference room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. Copies of the material may be obtained by mail from the Public Reference Branch of the Securities and Exchange Commission at such address, at prescribed rates. Please call the Securities and Exchange Commission at 1-800-SEC-0330 for further information on the public reference room. Our filings with the Securities and Exchange Commission are also available to the public through the Securities and Exchange Commission's website at *http://www.sec.gov* .

As a foreign private issuer, we are exempt from the rules under the Securities Exchange Act of 1934, as amended, 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 Securities Exchange Act of 1934, as amended. In addition, we are not required under the Securities Exchange Act of 1934, as amended, to file annual, quarterly and current reports and financial statements with the Securities and Exchange Commission as frequently or as promptly as U.S. companies whose securities are registered under the Securities Exchange Act of 1934, as amended. However, we are required to comply with the informational requirements of the Securities Exchange Act of 1934, as amended, and, accordingly, file current reports on Form 6-K, annual reports on Form 20-F and other information with the Securities and Exchange Commission.

In addition, since our ordinary shares are traded on the Tel Aviv Stock Exchange, we have filed Hebrew language periodic and immediate reports with, and furnish information to, the Tel Aviv Stock Exchange and the Israeli Securities Authority, as required under Chapter Six of the Israel Securities Law, 1968. Copies of our filings with the Israeli Securities Authority can be retrieved electronically through the MAGNA distribution site of the Israeli Securities Authority (*www.magna.isa.gov.il*) and the Tel Aviv Stock Exchange website (*www.maya.tase.co.il*). We maintain a corporate website at *www.redhillbio.com* . Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report.

I. Subsidiary Information

Not applicable.

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the risk of loss related to changes in market prices, including interest rates and foreign exchange rates, of financial instruments that may adversely impact our financial position, results of operations or cash flows. Our overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on our financial performance.

Risk of Interest Rate Fluctuation and Credit Exposure Risk

In the near future, we do not anticipate undertaking any significant long-term borrowings. At present, our credit and interest risk arises from cash and cash equivalents, deposits with banks as well as accounts receivable. A substantial portion of our liquid instruments is invested in short-term deposits in highly-rated institutions.

We estimate that because the liquid instruments are invested mainly for the short-term and with highly-rated institutions, the credit and interest risk associated with these balances is immaterial. The primary objective of our investment activities is to preserve principal while maximizing the income we receive from our investments without significantly increasing risk and loss. Our investments are exposed to market risk due to fluctuations in interest rates, which may affect our interest income and the fair market value of our investments. We manage this exposure by performing ongoing evaluations of our investments.

Market Price Risk

We may be exposed to market price risk because of investments in tradable securities held by us and classified in our financial statements on as financial assets at fair value through profit or loss. To manage the price risk arising from investments in tradable securities, we invest in marketable securities with high ratings and diversify our investment portfolio.

Foreign Currency Exchange Risk

Our foreign currency exposures give rise to market risk associated with exchange rate movements of the U.S. dollar, our functional and reporting currency, mainly against the NIS and other currencies. Although the U.S. dollar is our functional currency and reporting currency, a portion of our expenses are denominated in NIS. Our NIS expenses consist principally of payments to employees or service providers and short term investments in currencies other than the U.S. dollar. We anticipate that a sizable portion of our expenses will continue to be denominated in currencies other than the U.S. dollar. If the U.S. dollar fluctuates significantly against the NIS it may have a negative impact on our results of operations. We manage our foreign exchange risk by aligning the currencies for holding short term investments with the currencies of expected expenses, based on our expected cash flows.

Portfolio diversification is performed based on risk level limits that we set. To date, we have not engaged in hedging transactions. In the future, we may enter into currency hedging transactions to decrease the risk of financial exposure from fluctuations in the exchange rates of our principal operating currencies. These measures, however, may not adequately protect us from the material adverse effects of such fluctuations.

(A) Set forth below is a sensitivity test to possible changes in U.S. dollars/ NIS exchange rate as of December 31, 2015:

Sensitive instrument	Income (loss) from change in exchange rate (U.S. dollars in thousands)		Value (U.S. dollars in thousands)	Income (loss) from change in exchange rate (U.S. dollars in thousands)	
	Down 2%	Down 5%		Up 5%	Up 2%
Cash and cash equivalents	2	6	21,516	(6)	(2)
Bank deposits	3	7	36,756	(7)	(3)
Accounts receivable (except prepaid expenses)	-	1	2,260	(1)	-
Accounts payable and accrued expenses	(1)	(2)	(3,514)	2	1
Payable in respect of intangible asset purchase	-	-	(2,000)	-	-
Total loss	4	12		(12)	(4)

(B) As of the date of this Annual Report, our interest rate risk exposure is in respect to bank deposits, which expose us to risk due to change in fair value interest rates. As of December 31, 2015, these deposits carry annual interest of 0.25%-1.10%. Under these low interest rates, reasonable changes in interest rates are expected have negligible impact on the fair value of these assets.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable

C. Other Securities

Not applicable

D. American Depositary Shares

Each of our American Depositary Shares, or ADSs, represents 10 of our ordinary shares. Our ADSs trade on The Nasdaq Capital Market.

The form of the deposit agreement for the ADSs and the form of American Depositary Receipt (ADR) that represents an ADS have been incorporated by reference as exhibits to this Annual Report on Form 20-F. Copies of the deposit agreement are available for inspection at the principal office of The Bank of New York Mellon, located at 101 Barclay Street, New York, New York 10286, and at the principal office of our custodians, Bank Leumi Le-Israel, 34 Yehuda Halevi St., Tel-Aviv 65546, Israel and Bank Hapoalim B.M., 104 Hayarkon Street, Tel Aviv 63432, Israel.

Fees and Expenses

Persons depositing or withdrawing shares or American Depositary Share holders must pay :	***For :***
$5.00 (or less) per 100 American Depositary Shares (or portion of 100 American Depositary Shares)	• Issuance of American Depositary Shares, including issuances resulting from a distribution of shares or rights or other property
	• Cancellation of American Depositary Shares for the purpose of withdrawal, including if the deposit agreement terminates
$0.05 (or less) per American Depositary Share	• Any cash distribution to American Depositary Share holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of American Depositary Shares	• Distribution of securities distributed to holders of deposited securities which are distributed by the depositary to American Depositary Share holders
$0.05 (or less) per American Depositary Shares per calendar year	• Depositary services
Registration or transfer fees	• Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	• Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement)
	• converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian have to pay on any American Depositary Share or share underlying an American Depositary Share, for example, stock transfer taxes, stamp duty or withholding taxes	• As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	• As necessary

The depositary collects its fees for delivery and surrender of American Depositary Shares directly from investors depositing shares or surrendering American Depositary Shares for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse and/or share revenue from the fees collected from American Depositary Share holders, or waive fees and expenses for services provided, generally relating to costs and expenses arising out of establishment and maintenance of the American Depositary Share program. In performing its duties under the deposit agreement, the depositary may use brokers, dealers or other service providers that are affiliates of the depositary and that may earn or share fees or commissions.

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable

ITEM 15. CONTROLS AND PROCEDURES

(a) **Disclosure Controls and Procedures**

We performed an evaluation of the effectiveness of our disclosure controls and procedures that are designed to ensure that information required to be disclosed on Form 20-F and filed with the Securities and Exchange Commission is recorded, processed, summarized and reported timely within the time period specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Securities Exchange Act of 1934, as amended, is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. There can be no assurance that our disclosure controls and procedures will detect or uncover all failures of persons within the company to disclose information otherwise required to be set forth in our reports. Nevertheless, our disclosure controls and procedures are designed to provide reasonable assurance of achieving the desired control objectives. Based on our evaluation, our management, including our Chief Executive Officer and Deputy CEO Finance and Operations, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d) - 15(e) of the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this report are effective at such reasonable assurance level.

(b) **Management's Annual Report on Internal Control over Financial Reporting**

Our management, under the supervision of our Chief Executive Officer and Deputy CEO Finance and Operations, is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act of 1934, as amended. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Internal control over financial reporting includes policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect our transactions and asset dispositions;
- provide reasonable assurance that transactions are recorded as necessary to permit the preparation of our financial statements in accordance with generally accepted accounting principles;
- provide reasonable assurance that receipts and expenditures are made only in accordance with authorizations of our management and board of directors (as appropriate); and
- provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

Due to its inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our chief executive officer and Deputy CEO Finance and Operations, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the framework for Internal Control-Integrated Framework set forth by The Committee of Sponsoring Organizations of the Treadway Commission (COSO)(2013).

Based on our assessment and this framework, our management concluded that the Company's internal control over financial reporting were effective as of December 31, 2015.

(c) **Attestation Report of Registered Public Accounting Firm**

Not applicable.

(d) **Changes in Internal Controls over Financial Reporting**

There were no changes in our internal control over financial reporting that occurred during the year ended December 31, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Ofer Tsimchi, Dan Suesskind and Nurit Benjamini are audit committee financial experts. Mr. Tsimchi, Mr. Suesskind and Ms. Benjamini are independent directors for the purposes of the Nasdaq rules.

ITEM 16B. CODE OF ETHICS

As of the date of this Annual Report, we have adopted a code of ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. This code of ethics is posted on our website, http://ir.redhillbio.com/coporate-governance.cfm

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the aggregate fees billed by our independent registered public accounting firm for professional services.

	Year Ended December 31,	
Services Rendered	2015	2014
	(U.S. dollars in thousands)	
Audit (1)	118	122
Audit related services (2)	110	20
Tax (3)	7	24
Total	235	166

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.
(2) Audit related services relate to work regarding prospectus supplements and ongoing consultation.
(3) Tax fees relate to tax compliance, planning and advice.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company include the approval of audit and non-audit services to be provided by the external auditor. The audit committee approves in advance the particular services or categories of services to be provided to the Company during the following yearly period and also sets forth a specific budget for such audit and non-audit services. Additional non-audit services may be pre-approved by the audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES.

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS.

Not applicable

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT.

Not applicable

ITEM 16G. CORPORATE GOVERNANCE

Nasdaq Stock Market Listing Rules and Home Country Practices

As a foreign private issuer, we are permitted to follow Israeli corporate governance practices instead of Nasdaq Marketplace Rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. We rely on this "foreign private issuer exemption" with respect to the following items:

- *Independent Directors* - Our board of directors includes two external directors in accordance with the Israeli Companies Law, but does not require that a majority of our board members be independent as required by the Nasdaq Listing Rules.

- *Shareholder Approval* - We seek shareholder approval for all corporate actions requiring such approval in accordance with the requirements of the Israeli Companies Law, which are different from the shareholder approval requirements under the Nasdaq Listing Rules. The NASDAQ Listing Rules require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity-based compensation plans and arrangements, issuances that will result in a change of control of a company, certain transactions other than a public offering involving issuances of 20% or more of the shares or voting power in a company, and certain acquisitions of the stock or assets of another company involving issuances of 20% or more of the shares or voting power in a company or if any director, officer or holder of 5% or more of the shares or voting power of the company has a 5% or greater interest in the company or assets to be acquired or consideration to be paid and the transaction could result in an increase in the outstanding common shares or voting power by 5% or more.

  Under the Israeli Companies Law, shareholder approval is required for any transaction, including any grant of equity-based compensation, to a director or a controlling shareholder, but is not generally required to establish or amend an equity based compensation plan. Similarly, shareholder approval is required for a private placement that is deemed an "extraordinary private placement" or that involves a director or controlling shareholder. A "extraordinary private placement" is a private placement in which a company issues securities representing 20% or more of its voting rights prior to the issuance and the consideration received pursuant to such issuance is not comprised, in whole or in part, solely of cash or securities registered for trade on an exchange or which is not made pursuant to market conditions, and as a result of which the shareholdings of a 5% holder of the shares or voting rights of the company increases or as a result of which a person will become a holder of 5% of the shares or voting rights of the company or a controlling shareholder after the issuance.

- *Quorum* - As permitted under the Israeli Companies Law, pursuant to our articles of association, the quorum required for an ordinary meeting of shareholders consists of at least two shareholders present in person or by proxy who hold or represent at least 25% of the voting rights of our shares (and in an adjourned meeting, with some exceptions, any number of shareholders), instead of 33 1/3% of the issued share capital required under the Nasdaq Listing Rules.

- Nominations Committee - As permitted under the Israeli Companies Law, our board of directors selects director nominees subject to the terms of our articles of association which provide that incumbent directors are re-nominated for additional terms. Directors are not selected, or recommended for board of director selection, by independent directors constituting a majority of the board's independent directors or by a nominations committee comprised solely of independent directors as required by the Nasdaq Listing Rules.

Otherwise, we comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq Stock Market. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq Marketplace Rules related to corporate governance. We also comply with Israeli corporate governance requirements under the Israeli Companies Law applicable to public companies.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable

ITEM 17. FINANCIAL STATEMENTS

Not applicable

ITEM 18. FINANCIAL STATEMENTS

The financial statements required by this item are found at the end of this Annual Report, beginning on page F-1.

ITEM 19. EXHIBITS

See Exhibit Index on page 103.

Glossary of Industry Terms

Certain standards and other terms specific to our industry that are used in this Annual Report are defined below:

5-HT3 seretonin receptor inhibitors - play a role in mediating nausea and vomiting, and as such, demonstrate anti-emetic efficacy.

Bioequivalence - the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. To be considered "bioequivalent", certain standards specified by the US Food and Drug Administration must be met.

cGMP - Current Good Manufacturing Practice - Standards, procedures and guidelines designed for production quality control.

Clinical trial material (CTM) manufacturing - manufacturing of study supplies provided by the study sponsor to the clinical investigator.

CRO - a Contract Research Organization, also called a clinical research organization (CRO) is a service organization that provides outsourced pharmaceutical research services.

Diffuse large B-cell lymphoma (DLBCL- DLBCL is a B-cell type of lymphoma. With DLBCL, the cancer cells appear very large and scattered throughout (diffuse) all of the lymph node. Lymphoma is the most common blood cancer. Lymphoma occurs when cells of the immune system called lymphocytes, a type of white blood cell, grow and multiply uncontrollably. Cancerous lymphocytes can travel to many parts of the body, including the lymph nodes, spleen, bone marrow, blood, or other organs, and form a mass called a tumor.

H. pylori (*Helicobacter pylori* ***)*** - a Gram-negative bacterium found in the stomach. It was identified in 1982 by Dr. Barry Marshall and Dr. Robin Warren and is associated with peptic ulcer disease and development of gastric cancer.

IND - Investigational New Drug - a status assigned by the Food and Drug Administration to a drug before allowing its use in humans, so that experimental clinical trials may be conducted.

MAP bacterium (*Mycobacterium avium subspecies paratuberculosis* (MAP)) - an obligate pathogenic bacterium in the genus Mycobacterium.

***Mycobacterium avium subspecies paratuberculosis* (MAP)** - MAP is the causative agent of Johne disease, a chronic granulomatous ileitis occurring mainly in ruminants. MAP has been incriminated as the cause of Crohn disease in humans.

MAA - Marketing Authorization Application – An MAA is the equivalent European Union (EU) process to the U.S. new drug application (NDA – see below) process. It is an application submitted by a drug sponsor seeking permission to bring a newly developed medicinal product to the market. An MAA may be filed with the European Medicines Agency (EMA) or one or more Member States, depending on the applicable and selected procedure: centralised, mutual recognition or decentralised.

NDA - New Drug Application - an application by drug sponsors to the Food and Drug Administration for approval of a new pharmaceutical for sale and marketing in the U.S.

Ondansetron - Ondansetron is a drug in class of medications called serotonin 5-HT $_3$ receptor antagonists. Ondansetron works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.

Orphan Drug Status - the designation of Orphan Drug status to drugs that are in the process of development for the treatment of rare diseases. This status provides tax reductions and the exclusive rights to the cure for a specific condition for a period of seven years post-approval.

Bioequivalence (BE) Clinical Trial - a study the data from which is submitted to the Food and Drug Administration in support of a marketing application of a test drug that is being compared to a referenced existing (already approved) drug. Sufficient similarity between the test and the reference drug is required, according to certain standards specified by the Food and Drug Administration, which must be met.

Rizatriptan ™ - a serotonin 5-HT 1B/1D receptor agonist of the triptan class of drugs.

Stability Testing - as part of the cGMP regulations, the Food and Drug Administration requires that drug products bear an expiration date determined by appropriate stability testing. The stability of drug products needs to be evaluated over time in the same container-closure system in which the drug product is marketed.

TNFα - Tumor necrosis factor alpha is a cell signaling protein (cytokine) involved in systemic inflammation.

Triptans - serotonin 5-hydroxytryptamine (5-HT) receptor agonists drugs used for the treatment of migraine.

Sphingosine kinase-2 (SK2) - Sphigosine kinase is an enzyme catalyzes the phosphorylation of sphingosine to generate sphingosine 1-phosphate. There are two isotypes of sphingosine enzyme, SK1 and SK2. Both isotypes have a key role in variety of disease, including the development of a range of solid tumors and are promising anti-cancer therapeutic targets.

REDHILL BIOPHARMA LTD.
2015 FINANCIAL STATEMENTS

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2015 FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders of

REDHILL BIOPHARMA LTD.

We have audited the accompanying statements of financial position of RedHill Biopharma Ltd. (the "Company") as of December 31, 2015 and 2014 and the related statements of comprehensive loss, changes in equity and cash flows for each of the three years in the period ended December 31, 2015. These financial statements are the responsibility of the Company's Board of Directors and management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by the Company's Board of Directors and management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the accompanying financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2015 and 2014 and the results of its operations, changes in equity and cash flows for each of the three years in the period ended December 31, 2015, in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Tel-Aviv, Israel
February 24,, 2016

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Kesselman & Kesselman, Trade Tower, 25 Hamered Street, Tel-Aviv 6812508, Israel,
P.O Box 50005 Tel-Aviv 6150001 Telephone: +972 -3- 7954555, Fax:+972 -3- 7954556, www.pwc.com/il

REDHILL BIOPHARMA LTD.

STATEMENTS OF COMPREHENSIVE LOSS

	Note	Year ended December 31		
		2015	2014	2013
		U.S. dollars in thousands		
REVENUES:				
Licensing revenue	16	-	7,000	-
Other revenue		3	14	12
TOTAL REVENUES		3	7,014	12
COST OF REVENUE		-	1,050	-
RESEARCH AND DEVELOPMENT EXPENSES, net	17	17,771	12,700	8,100
GENERAL AND ADMINISTRATIVE EXPENSES	18	4,134	4,011	2,684
OTHER EXPENSES (INCOME)	8	100	(100)	-
OPERATING LOSS		22,002	10,647	10,772
FINANCIAL INCOME		1,124	319	158
FINANCIAL EXPENSES		212	383	14
FINANCIAL EXPENSES (INCOME), net	19	(912)	64	(144)
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR		21,090	10,711	10,628
LOSS PER ORDINARY SHARE (U.S. dollars)**:**	20			
Basic		0.19	0.12	0.17
Diluted		0.19	0.13	0.17

The accompanying notes are an integral part of these financial statements.

REDHILL BIOPHARMA LTD.

STATEMENTS OF FINANCIAL POSITION

	Note	December 31	
		2015	2014
		U.S. dollars in thousands	
CURRENT ASSETS:			
Cash and cash equivalents	5	21,516	5,892
Bank deposits	5	36,622	17,053
Prepaid expenses and receivables	6	2,372	3,074
		60,510	26,019
NON-CURRENT ASSETS:			
Bank deposits		134	76
Fixed assets	7	124	146
Intangible assets	8	6,060	2,615
		6,318	2,837
T O T A L ASSETS		66,828	28,856
CURRENT LIABILITIES:			
Accounts payable and accrued expenses	10	3,514	1,720
Payable in respect of intangible asset purchase	11a(6)	2,000	-
		5,514	1,720
NON-CURRENT LIABILITIES:			
Derivative financial instruments	14	1,237	2,125
T O T A L LIABILITIES		6,751	3,845
COMMITMENTS	11		
EQUITY:	13		
Ordinary shares		343	240
Additional paid-in capital		120,621	65,461
Warrants		1,057	1,528
Accumulated deficit		(61,944)	(42,218)
T O T A L EQUITY		60,077	25,011
T O T A L LIABILITIES AND EQUITY		66,828	28,856

The accompanying notes are an integral part of these financial statements.

REDHILL BIOPHARMA LTD.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Ordinary shares to be issued	Additional paid-in capital	Warrants	Accumulated deficit	Total equity
	U.S. dollars in thousands					
BALANCE AT JANUARY 1, 2013	143	8,020	31,469	3,273	(23,887)	19,018
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2013:						
Comprehensive loss	-	-	-	-	(10,628)	(10,628)
Exercise of warrants and options into ordinary shares, net	7	-	3,311	(1,138)	-	2,180
Issuance of ordinary shares and warrants	24	(8,020)	8,087	9	-	100
Warrants expiration	-	-	277	(277)	-	-
Share-based compensation to employees and service providers	-	-	-	-	1,255	1,255
BALANCE AT DECEMBER 31, 2013	174	-	43,144	1,867	(33,260)	11,925
BALANCE AT JANUARY 1, 2014	174		43,144	1,867	(33,260)	11,925
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2014:						
Comprehensive loss	-	-	-	-	(10,711)	(10,711)
Exercise of warrants and options into ordinary shares, net	11	-	5,696	(702)	-	5,005
Issuance of ordinary shares and warrants	55	-	15,927	1,057	-	17,039
Warrants expiration	-	-	694	(694)	-	-
Share-based compensation to employees and service providers	-	-	-	-	1,753	1,753
BALANCE AT DECEMBER 31, 2014	240	-	65,461	1,528	(42,218)	25,011

REDHILL BIOPHARMA LTD.

STATEMENTS OF CHANGES IN EQUITY

	Ordinary shares	Additional paid-in capital	Warrants	Accumulated deficit	Total equity
	U.S. dollars in thousands				
BALANCE AT JANUARY 1, 2015	240	65,461	1,528	(42,218)	25,011
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2015:					
Comprehensive loss	-	-	-	(21,090)	(21,090)
Exercise of options into ordinary shares	*	108	-	-	108
Issuance of ordinary shares, see note 13a(6)	103	54,581	-	-	54,684
Warrants expiration	-	471	(471)	-	-
Share-based compensation to employees and service providers	-	-	-	1,364	1,364
BALANCE AT DECEMBER 31, 2015	343	120,621	1,057	(61,944)	60,077

* Represents amount less than $1 thousand.

The accompanying notes are an integral part of these financial statements.

REDHILL BIOPHARMA LTD.

STATEMENTS OF CASH FLOWS

	Year ended December 31		
	2015	2014	2013
	U.S. dollars in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Comprehensive loss	(21,090)	(10,711)	(10,628)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	1,364	1,753	1,255
Unrealized gain on derivative financial instruments	(888)	(200)	-
Depreciation	36	27	24
Cost of out-licensing of intangible assets	-	50	
Write off of intangible assets	100	-	-
Fair value gains on financial assets at fair value through profit or loss	-	-	(54)
Revaluation of bank deposits	(69)	(29)	(16)
Exchange differences in respect of cash and cash equivalents	150	237	(64)
Changes in assets and liability items:			
Decrease (increase) in prepaid expenses and receivables	702	(2,586)	(290)
Increase (decrease) in accounts payable and accrued expenses	1,869	(770)	1,337
Net cash used in operating activities	(17,826)	(12,229)	(8,436)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of fixed assets	(14)	(70)	(14)
Purchase of intangible assets	(1,620)	(1,035)	(210)
Change in investment in current bank deposits	(29,500)	(7,000)	477
Purchase of non-current bank deposits	(58)	(10,000)	-
Maturity of non-current bank deposits	10,000	-	-
Proceeds from sale of financial assets at fair value through profit or loss	-	243	876
Net cash provided by (used in) investing activities	(21,192)	(17,862)	1,129
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares, warrants and derivative financial instruments, net	54,684	19,364	100
Exercise of warrants and options into shares, net of expenses	108	5,005	2,180
Net cash provided by financing activities	54,792	24,369	2,280
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	15,774	(5,722)	(5,027)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(150)	(237)	64
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	5,892	11,851	16,814
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	21,516	5,892	11,851
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	236	118	30
SUPPLEMENTARY INFORMATION ON INVESTING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Purchase of intangible assets	1,925	75	-

The accompanying notes are an integral part of these financial statements.

NOTE 1 - GENERAL:

a. General

RedHill Biopharma Ltd. (the "Company") was incorporated in Israel on August 3, 2009. The Company is focused primarily on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drug candidates for inflammatory and gastrointestinal diseases, including cancer (the "Drug Candidates").

In February 2011, the Company listed its securities on the Tel-Aviv Stock Exchange ("TASE"). Since December 2012, the Company's American Depositary Shares ("ADSs") have been listed on the NASDAQ Capital Market ("NASDAQ").

The Company's registered address is at 21 Ha'arba'a St, Tel-Aviv, Israel.

The Company is engaged in the research and development of most of its Drug Candidates and to date has out-licensed only one of its Drug Candidates. Accordingly, there is no assurance that the Company's business will generate positive cash flow. Through December 31, 2015, the Company has an accumulated deficit and its activities have been funded through public and private offerings of the Company's securities.

The Company plans to further fund its future operations through commercialization of its Drug Candidates, out-licensing certain programs and raising additional capital. The Company's current cash resources are not sufficient to complete the research and development of all of the Company's Drug Candidates. Management expects that the Company will incur more losses as it continues to focus its resources on advancing its Drug Candidates based on a prioritized plan that will result in negative cash flows from operating activities. The Company believes its existing capital resources should be sufficient to fund its current and planned operations for at least the next 12 months.

If the Company is unable to commercialize or further out-license its remaining Drug Candidates or obtain future financing, the Company may be forced to delay, reduce the scope of, or eliminate one or more of its research, development programs or commercialization related to the Drug Candidates, any of which may have a material adverse effect on the Company's business, financial condition and results of operations.

b. Approval of financial statements

These financial statements were approved by the Board of Directors on February 24, 2016.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

a. Basis for presentation of the financial statements

The financial statements of the Company as of December 31, 2015 and 2014 and for each of the three years in the period ended on December 31, 2015 have been prepared in accordance with International Financial Reporting Standards, ("IFRS"), as issued by the International Accounting Standards Board ("IASB").

The significant accounting policies described below have been applied consistently in relation to all the periods presented, unless otherwise stated.

The financial statements have been prepared under the historical cost convention, subject to adjustments in respect of revaluation of financial assets and financial liabilities at fair value through profit or loss.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company's accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the financial statements, are disclosed in note 3. Actual results could differ significantly from those estimates and assumptions.

b. Translation of foreign currency balances and transactions:

1) Functional and presentation currency

Items included in the financial statements are measured using the currency of the primary economic environment in which the Company operates (the "Functional Currency"). The financial statements are presented in U.S. dollars ("$"), which is the Company's functional and presentation currency.

2) Transactions and balances

Foreign currency transactions in currencies different from the Functional Currency (hereafter foreign currency, mostly New Israeli Shekels ("NIS")) are translated into the Functional Currency using the exchange rates at the dates of the transactions. Foreign exchange differences resulting from the settlement of such transactions and from the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recorded to the statement of comprehensive loss among financing income or expenses.

c. Cash and cash equivalents

Cash and cash equivalents include cash on hand and unrestricted short-term bank deposits with maturities of three months or less.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Fixed assets

Fixed assets items are initially recognized at acquisition cost. Fixed assets items are stated at cost less accumulated depreciation. Depreciation is computed by the straight- line method, to reduce the cost of fixed assets to their residual value over their estimated useful lives as follows:

	%
Computers	33
Office furniture and equipment	8-15

Leasehold improvements are depreciated by the straight-line method over the shorter of the term of the lease or the estimated useful life of the improvements.

e. Research and development:

1) Research and development assets acquired by the Company, the development of which has not been completed yet, are stated at cost and are not amortized; these assets are tested for impairment once a year. At the time these assets will be available for use, they will be amortized by the straight line method over their useful lives.

2) Research expenses are charged to profit or loss as incurred. An intangible asset arising from development of the Company's Drug Candidates is recognized if all of the following conditions are met:
   - It is technically feasible to complete the intangible assets so that it will be available for use;
   - Management intends to complete the intangible asset and use it or sell it;
   - There is an ability to use or sell the intangible asset;
   - It can be demonstrated how the intangible asset will generate probable future economic benefits;
   - Adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available and costs associated with the intangible asset during development can be measured reliably.

Other development costs that do not meet the above criteria are recognized as expenses as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period.

As of December 31, 2015, the Company has not yet capitalized development costs.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

3) Amounts paid to purchase intellectual property of Drug Candidates are capitalized and recorded as intangible assets. Amounts due for future payment based on contractual agreements will be accrued upon reaching the relevant milestones.

4) Research and development costs for the performance of clinical trials and manufacturing by subcontractors are recognized as expenses when incurred.

f. Impairment of non-financial assets

Depreciable assets are tested for impairment if any events have occurred or changes in circumstances have taken place which might indicate that their carrying amounts may not be recoverable. Research and development assets, the development of which has not been completed yet, are not amortized and are tested for impairment on an annual basis.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Nonfinancial assets that were subject to impairment are reviewed for possible reversal of the impairment recognized in respect thereof at each date of statement of financial position.

g. Financial assets:

1) Classification

The financial assets of the Company are classified into the following categories: financial assets at fair value through profit or loss and loans and receivables. The classification depends on the purpose for which the financial assets were acquired. The Company's management determines the classification of its financial assets at initial recognition.

a) Financial assets at fair value through profit or loss

This category includes financial assets that are managed and their performance is evaluated on a fair value basis, thus, upon their initial recognition, these assets are designated by management at fair value through profit or loss. Assets in this category are classified as current assets if expected to be settled within 12 months, otherwise, they are classified as noncurrent.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

b) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for those with maturities greater than 12 months after the statement of financial position date (for which they are classified as noncurrent assets). The loans and receivables of the Company are comprised of prepaid expenses and receivables, cash and cash equivalents and bank deposits in the statement of financial position.

2) Recognition and measurement

Regular purchases and sales of financial assets are recognized on the settlement date, which is the date on which the asset is delivered to the Company or delivered by the Company. Investments are initially recognized at fair value plus transaction costs for all financial assets not recorded at fair value through profit or loss.

Financial assets measured at fair value through profit or loss are initially recognized at fair value, and transaction costs are expensed in profit or loss. Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Financial assets at fair value through profit or loss are subsequently recorded at fair value. Loans and receivables are measured in subsequent periods at amortized cost using the effective interest method.

Gains or losses arising from changes in the fair value of financial assets at fair value through profit or loss are presented in the statement of comprehensive loss under "financial expenses (income), net".

h. Trade payables

Trade payables are obligations to pay for goods or services that have been acquired from suppliers in the ordinary course of business. Accounts payable are classified as current liabilities if payment is due within one year or less, otherwise they are presented as noncurrent liabilities.

Trade payables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

i. Warrants

Receipts in respect of warrants are classified as equity to the extent that they confer the right to purchase a fixed number of shares for a fixed exercise price. Warrants that confer the right to net share settlement do not qualify for equity classification and are classified as liabilities (see j below).

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

j. Derivative financial instruments

The derivative financial instruments of the Company represent warrants and Price Protection Rights issued to investors (see also i above and 13a(4)).

These derivative financial instruments are carried at fair value, with changes in their fair value recognized in profit or loss. The issuance costs of such instruments were directly charged to profit or loss.

k. Share capital

The Company's ordinary shares are classified as the Company's share capital. Incremental costs directly attributed to issuance of new shares or warrants are presented under equity as a deduction from the proceeds of issuance.

l. Employee benefits:

1) Pension and retirement benefit obligations

In any matter related to payment of pension and severance pay to employees in Israel to be dismissed or to retire from the Company, the Company operates in accordance with labor laws.

Labor laws and agreements in Israel and the Company's practice require the Company to pay severance pay and/or pensions to employees in Israel dismissed or retiring from their employer in certain circumstances.

The Company has a severance pay plan in accordance with Section 14 of the Israeli Severance Pay Law with the plan treated as a defined contribution plan. According to the plan, the Company regularly makes payments to severance pay or pension funds without having a legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay all employees in Israel the benefits relating to employee service in the current and prior periods. Contributions for severance pay or pension are recognized as employee benefit expenses when they are due commensurate with receipt of work services from the employee and no further provision is required in the financial statements.

2) Vacation and recreation pay

Under Israeli law, each employee in Israel is entitled to vacation days and recreation pay, both computed on an annual basis. The entitlement is based on the period of employment. The Company records a liability and an expense for vacation and recreation pay based on the benefit accumulated by each employee.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

m. Share-based payments

The Company operates a number of equity-settled, share-based compensation plans to employees (as defined in IFRS 2 "Share-Based Payments") and service providers. As part of the plans, the Company grants employees and service providers, from time to time and at its discretion, options to purchase Company shares. The fair value of the employee and service provider services received in exchange for the grant of the options is recognized as an expense in profit or loss and is recorded as accumulated deficit within equity. The total amount recognized as an expense over the vesting period of the options (the period during which all vesting conditions are expected to be met) is determined by reference to the fair value of the options granted at date of grant.

Vesting conditions are included in assumptions about the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

At the end of each reporting period, the Company revises its estimates of the number of options that are expected to vest based on the nonmarket vesting conditions. The Company recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to accumulated deficit.

When exercising options, the Company issues new shares. The proceeds, less directly-attributable transaction costs, recognized as share capital (par value) and share premium.

n. Revenue recognition

Revenue incurred in connection with the out-licensing of the Company's intellectual property is recognized when all of the following criteria have been met as of the statement of financial position:

- The Company has transferred to the buyer the significant risks and rewards of ownership of the intellectual property.
- The Company does not retain either the continuing managerial involvement to the degree usually associated with ownership or the effective control over the intellectual property.
- The amount of revenue can be measured reliably.
- It is probable that the economic benefits associated with the transaction will flow to the Company.
- The costs incurred or to be incurred in respect of the sale can be measured reliably.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

Revenue from reaching additional milestones is recognized upon achievement of the specific milestone, in accordance with the relevant agreement.

Revenue from royalties is recognized on an accrual basis in accordance with the substance of the relevant agreement.

o. Leases

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases are charged to the statement of comprehensive loss on a straight-line basis over the period of the lease.

p. Loss per ordinary share

The computation of basic loss per share is based on the Company's loss divided by the weighted average number of ordinary shares outstanding during the period.

In calculating the diluted loss per share, the Company adds to the average number of shares outstanding that was used to calculate the basic loss per share, the weighted average of the number of shares to be issued assuming all shares that have a potentially dilutive effect have been exercised into shares.

q. Deferred taxes

Deferred income tax is recognized, using the liability method, for temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the financial statements.

Deferred income tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the statement of financial position date and are expected to apply when the related deferred income tax asset will be realized or the deferred income tax liability will be settled. Deferred income tax assets are recognized only to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Since the Company is unable to assess whether it will have taxable income in the foreseeable future, no deferred tax assets were recorded in these financial statements.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

r. Standards and interpretations to existing standards that are not yet in effect and have not been early adopted by the Company:

International Financial Reporting Standard No. 9 "Financial Instruments" (hereafter -IFRS 9)

IFRS 9, 'Financial instruments', addresses the classification, measurement and recognition of financial assets and financial liabilities. The complete version of IFRS 9 was issued in July 2014. It replaces the guidance in IAS 39 that relates to the classification and measurement of financial instruments. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income and fair value through profit or loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in other comprehensive income. Further, the expected credit losses model replaces the incurred loss impairment model used in IAS 39. For financial liabilities, there were no changes to classification and measurement except for the recognition of changes in the Company's own credit risk in other comprehensive income for liabilities designated at fair value through profit or loss.
The standard is effective for accounting periods beginning on or after 1 January, 2018. Early adoption is permitted. The Company is currently assessing the impact of IFRS 9.

International Financial Reporting Standard No. 15 "Revenue from Contracts with Customers" (hereafter - IFRS 15)

IFRS 15 amends revenue recognition requirements and establishes principles for reporting information about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces IAS 18 Revenue and IAS 11 Construction Contracts and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2018. The Company is currently assessing the impact of adopting IFRS 15.

International Financial Reporting Standard No. 16 "Leases" (hereafter - IFRS 16)

IFRS 16 defines a lease as a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration. Under IFRS 16 lessees have to recognize a lease liability reflecting future lease payments and a 'right-of-use asset' for almost all lease contracts.

The standard replaces the current guidance in IAS 17. The standard is effective for annual periods beginning on or after January 1, 2019. The Company is currently assessing the impact of adopting IFRS 16.

NOTE 3 - CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS:

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The Company makes judgments and estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The material judgments, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the following financial year are in respect of impairment of intangible assets.

The Company reviews once a year or when indications of impairment are present, whether research and development assets are impaired, see also note 2f.

The Company makes judgments to determine whether indications are present that require reviewing impairment of these intangible assets.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amounts of cash generating units are based on the Company's estimates as to the development of the Drug Candidates, changes in market scope, market competition and timetables for regulatory approvals.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT:

a. Financial risk management:

1) Financial risk factors

The Company's activities expose it to a variety of financial risks: market risk (including foreign exchange risk and price risk), credit and interest risks, and liquidity risk. The Company's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Company's financial performance.

Risk management is performed by the Deputy Chief Executive Officer, Finance and Operations of the Company, who identifies and evaluates financial risks in close cooperation with the Company's Chief Executive Officer.

The Company's finance department is responsible for carrying out risk management activities in accordance with policies approved by its Board of Directors. The Board of Directors provides guidelines for overall risk management, as well as policies dealing with specific areas, such as exchange rate risk, interest rate risk, credit risk, use of financial instruments, and investment of excess cash. In order to minimize the risk exposure to market risk and credit risk, the Company invested the majority of its cash balances in highly-rated bank deposits with maturities of less than one year.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

(a) Market risks

Foreign exchange risk: the Company might be exposed to foreign exchange risk as a result of making payments to employees or service providers and investment of some liquidity in currencies other than the U.S. dollar (i.e. the Functional Currency). The Company manages the foreign exchange risk by aligning the currencies for holding liquidity with the currencies of expected expenses, based on the expected cash flows of the Company. Had the Functional Currency of the Company been stronger by 5% against the NIS, assuming all other variables remained constant, the Company would have recognized an additional expense of $12,000, $125,000 and $96,000 in profit or loss for the years ended, December 31, 2015, 2014 and 2013, respectively.

(b) Credit and interest risks

Credit and interest risks arise from cash and cash equivalents, deposits with banks, as well as receivables. A substantial portion of liquid instruments of the Company are invested in short-term deposits in highly-rated banks. The Company estimates that since the liquid instruments are mainly invested for the short term and with highly-rated institutions, the credit and interest risks associated with these balances are immaterial.

(c) Liquidity risk

Prudent liquidity risk management requires maintaining sufficient cash and the availability of funding through an adequate amount of committed credit facilities.
Management monitors rolling forecasts of the Company's liquidity reserve (comprising of cash and cash equivalents, and deposits). This is generally carried out based on the expected cash flows in accordance with practice and limits set by the management of the Company.

The Company has not yet generated significant revenue from the sale of its Drug Candidates or royalties; it is therefore exposed to liquidity risk, taking into consideration the forecasts of cash flows required to finance its investments and other activities.

As of December 31, 2015 and 2014, the Company's non-derivative financial liabilities include accounts payable, accrued expenses and payable in respect of intangible asset purchase for a period of less than 1 year.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

2) Capital risk management

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern in order to provide returns for shareholders and to maintain an optimal capital structure to reduce the cost of capital. It should be indicated that the Company has not yet generated significant revenue from the sale of its Drug Candidates or from royalties.

3) Fair value estimation

The following is an analysis of financial instruments measured at fair value using valuation methods. The different levels have been defined as follows:

- Quoted prices (unadjusted) in active markets for identical assets or liabilities (level 1)
- Inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (that is, as prices) or indirectly (that is, derived from prices) (level 2)
- Inputs for the asset or liability that are not based on observable market data (that is, unobservable inputs) (level 3)

The fair value of financial instruments traded in active markets is based on quoted market prices at dates of statements of financial position. A market is regarded as active if quoted prices are readily and regularly available from an exchange, dealer, broker, industry group, pricing service, or regulatory agency, and those prices represent actual and regularly occurring market transactions on an arm's length basis. These instruments are included in level 1.

The fair value of financial instruments that are not traded in an active market is determined by using valuation techniques. These valuation techniques maximize the use of observable market data where it is available and rely as little as possible on entity-specific estimates. If all significant inputs required to fair value an instrument are observable, the instrument is included in level 2.

If one or more of the significant inputs is not based on observable market data, the instrument is included in level 3.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

As of December 31, 2015 and 2014, the financial instruments of the Company presented at fair value are derivative financial liabilities in the amounts of $1.2 million and $2.1 million, respectively. These instruments are classified as level 3.

The following table represents the change in derivative liabilities measured at level 3 for the years ended December 31, 2014 and 2015:

	Derivative financial instruments	
	Year ended December 31	
	2015	2014
	U.S. dollars in thousands	
Balance at the beginning of the year	2,125	-
Proceeds received during the year	-	2,325
Amount recognized in profit or loss	(888)	(200)
Balance at the end of the year	1,237	2,125

The fair value of the above-mentioned derivative financial liabilities that are not traded in an active market is determined by using valuation techniques. The Company uses its judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period.

For more information regarding the derivatives, see note 14.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

b. Classification of financial instruments by groups:

	Loans and receivables
	U.S. dollars in thousands
As of December 31, 2015:	
Cash and cash equivalents	21,516
Bank deposits	36,756
Receivables (except prepaid expenses)	2,260
	60,532
As of December 31, 2014:	
Cash and cash equivalents	5,892
Bank deposits	17,129
Receivables (except prepaid expenses)	2,904
	25,925

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortized cost	Total
	U.S. dollars in thousands		
As of December 31, 2015:			
Accounts payable and accrued expenses	-	3,514	3,514
Derivative financial instruments	1,237	-	1,237
Payable in respect of intangible asset purchase	-	2,000	2,000
	1,237	5,514	6,751
As of December 31, 2014:			
Accounts payable and accrued expenses	-	1,720	1,720
Derivative financial instruments	2,125	-	2,125
	2,125	1,720	3,845

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

c. Composition of financial instruments by currency:

	U.S. Dollar	Other currencies	Total
	U.S. dollars in thousands		
As of December 31, 2015:			
Assets:			
Cash and cash equivalents	20,282	1,234	21,516
Bank deposits	36,605	150	36,756
Receivables (except prepaid expenses)	2,064	196	2,260
	58,951	1,580	60,532
Liabilities:			
Accounts payable and accrued expenses	3,465	49	3,514
Payable in respect of intangible asset purchase	2,000	-	2,000
Derivative financial instruments	1,237	-	1,237
	6,702	49	6,751
	52,249	1,531	53,781
As of December 31, 2014:			
Assets:			
Cash and cash equivalents	2,165	3,727	5,892
Bank deposits	17,036	93	17,129
Receivables (except prepaid expenses)	2,827	77	2,904
	22,028	3,897	25,925
Liabilities:			
Accounts payable and accrued expenses	1,385	335	1,720
Derivative financial instruments	2,125	-	2,125
	3,510	335	3,845
	18,518	3,562	22,080

NOTE 5 - CASH AND CASH EQUIVALENTS AND BANK DEPOSITS:

a. Cash and Cash Equivalents:

	December 31	
	2015	2014
	U.S. dollars in thousands	
Cash in bank	5,990	4,590
Short-term bank deposits	15,526	1,302
	21,516	5,892

The carrying amounts of the cash and cash equivalents approximate their fair values.

b. Short-term Bank Deposits

As of December 31, 2015, the bank deposits include deposits invested for terms of three months to one year and bear interest at annual rates of between 0.25% - 1.1%.

NOTE 6 - PREPAID EXPENSES AND RECEIVABLES:

	December 31	
	2015	2014
	U.S. dollars in thousands	
Advances to suppliers	2,040	1,840
Discount from Service Provider - see note 17	178	987
Prepaid expenses	112	170
Government institutions	42	77
	2,372	3,074

The fair value of receivables, which constitute financial assets, approximates their carrying amount.

NOTE 7 - FIXED ASSETS:

The composition of assets and accumulated depreciation, grouped by major classifications:

	Cost		Accumulated depreciation		Depreciated balance	
	December 31		December 31		December 31	
	2015	2014	2015	2014	2015	2014
	U.S. dollars in thousands					
Office furniture and equipment (including computers)	151	137	76	51	75	86
Leasehold improvements	99	99	50	39	49	60
	250	236	126	90	124	146

NOTE 8 - INTANGIBLE ASSETS:

The intangible assets represent R&D assets with respect to intellectual property rights of the Drug Candidates purchased by the Company under licensing agreements or under asset acquisition agreements. The changes in those assets are as follows:

	Year ended December 31	
	2015	2014
	U.S. dollars in thousands	
Cost:		
Balance at beginning of year	2,615	1,555
Additions during the year	3,545	1,110
Cost of out-licensing	-	(50)
Balance at end of year	6,160	2,615
Write off charge	(100)	-
	6,060	2,615

As of December 31, 2015, the Company recognized loss from writing off the initial $100,000 paid to a Danish company for the exclusive rights to a Drug Candidate intended to treat congestive heart failure, left atrium dysfunction and high blood pressure. As the Company put on hold additional investments in the Drug Candidate development, the above-mentioned amount exceeds the forecasted recoverable amount. Consequently, the Company decided to write off the entire amount and recorded a loss in the Statement of Comprehensive Loss under Other Expenses.

For further details regarding the intangible assets, see note 11.

NOTE 9 - LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT:

a. Labor laws and agreements in Israel require the Company to pay severance pay and/or pensions to an employee dismissed or retiring from their employment in certain circumstances.

b. The Company's pension liability and the Company's liability for payment of severance pay for employees in Israel for whom the liability is within the scope of Section 14 of the Severance Pay Law is covered by ongoing deposits with defined contribution plans. The amounts deposited are not included in the statements of financial position.

The amounts charged as an expense in respect of defined contribution plans in 2015, 2014 and 2013 were $95,000, $88,000 and $62,000, respectively. Of those amounts, approximately 60% were charged to general and administrative expenses and 40% to research and development expenses.

NOTE 10 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

	December 31	
	2015	**2014**
	U.S. dollars in thousands	
Trade payables	119	66
Accrued expenses	3,070	1,334
Employees and employees institutions	268	261
Government institutions	57	59
	3,514	1,720

The fair value of the accounts payable and accrued expense balances approximates their carrying amounts.

NOTE 11 - COMMITMENTS:

a. Agreements to purchase intellectual property:

1) On May 2, 2010, the Company entered into an agreement with a U.S. publically-traded company that grants the Company an exclusive license to use rights relating to a drug candidate intended to treat chemotherapy and radiotherapy-induced nausea and vomiting. Under the agreement, the Company paid the U.S. company an initial amount of $100,000, and undertook to pay the U.S. company an amount of up to $500,000, based on regulatory milestones set between the parties. Under the agreement, the Company agreed to pay the U.S. company royalties equal to 8% of Company revenues generated from the drug candidate, less certain deductible amounts as detailed in the agreement, during a period which is the shorter of: (1) expiry of the last patent granted under the license; (2) ten years from the beginning of marketing the drug candidate by the Company or any third party; and (3) the date in which the amount of all payments to the U.S. company reach $30 million. Through December 31, 2015, the Company paid the U.S. company the initial amount of $100,000.

NOTE 11 - COMMITMENTS (continued):

In 2013, the U.S. company announced that it had ceased business operations. Under the terms of the license agreement, the Company has the protection afforded to the licensee under the United States Bankruptcy Code.

On March 7, 2014, the Company entered into a licensing agreement with a U.S. university to secure certain patent rights related to the drug candidate. The Company therefore terminated the agreement with the U.S. company and licensed the patents directly from the U.S. university, the original owner of the patents. Under the agreement, the Company agreed to pay the U.S. university certain future payments.

2) On August 26, 2010, the Company entered into an agreement with a Canadian-based company which is traded in the U.S. and Canada, to co-develop a drug candidate for the treatment of migraines. Under the agreement, the Company paid the Canadian company up-front and milestone payments in the aggregate amount of $800,000, and undertook under the agreement to transfer additional amounts of up to $500,000 based on achieving milestones as agreed between the parties. In addition, the Company undertook to participate in additional drug candidate research and development costs.

   Under the agreement, the Company will pay a 60% royalty on revenues, less certain deductible amounts as detailed in the agreement, to the Canadian company for the first $2 million in revenue. For revenues beyond the $2 million, the Company will pay royalties at 20% - 40% of the Company's revenue from the drug candidate, less certain deductible amounts as detailed in the agreement. The agreement is for an indefinite period and is subject to certain termination conditions.

   Through December 31, 2015, the Company paid the Canadian company for the license of the drug candidate under the agreement a total of approximately $800,000. In addition, through December 31, 2015, the Company participated in the drug candidate research and development costs in the amount of approximately $1.3 million that was recorded in the statement of comprehensive loss under research and development expenses.

3) On August 11, 2010, the Company entered into an agreement with an Australian company in an asset purchase agreement to acquire intellectual property of the Australian company relating to three therapeutic candidates for the treatment of gastrointestinal conditions. Pursuant to the purchase agreement, the Company paid the Australian company an initial amount of $500,000 and undertook to pay future payments in the range of 7% - 20% of the Company revenues generated from the drug candidates, less certain deductible amounts as detailed in the agreement. Through December 31, 2015, the Company paid the Australian company a total of $1.5 million. See also note 16 in connection with the license agreement for one of the Drug Candidates.

NOTE 11 - COMMITMENTS (continued):

4) On June 30, 2014, the Company entered into an agreement with a German publicly-traded company that grants the Company the exclusive worldwide (excluding China, Hong Kong, Taiwan and Macao) development and commercialization rights for all indications to an oncology drug candidate. Under the terms of the agreement, the Company paid to the German company an upfront payment in the amount of $1 million and agreed to pay the German company potential tiered royalties on revenues, less certain deductible amounts as detailed in the agreement, ranging from mid-teens up to 30%. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2015, the Company paid the German company total amount of approximately $1 million.

5) On August 13, 2014, the Company entered into a binding exclusive option agreement with a private German company. Under the terms of the agreement, the Company has an option to acquire the worldwide exclusive rights of an oncology drug candidate for all indications (excluding pancreatic cancer indication in South Korea). The option was for a one year period and was extended in July 2015 by the Company for an additional year. During the option period, the Company may, at its discretion, conduct development activities with the drug candidate. The total payment, for both the option and the acquisition of the rights, should the Company elect to exercise the option, will be $100,000, as well as potential milestone payments and tiered royalties on revenues, less certain deductible amounts as detailed in the agreement, ranging from single-digit to mid-teens. Through December 31, 2015, the Company paid a total amount of $45,000 in consideration of both option periods. If the Company will exercise the option, such amount will be fully deducted from the up-front payment of $100,000, as described above.

6) On March 30, 2015, the Company entered into an agreement with a U.S.-based private company that granted the Company the exclusive worldwide development and commercialization rights for all indications to an oncology drug candidate, and additional intellectual property rights, targeting multiple inflammatory-GI and oncology disease indications. Under the terms of the agreement, the Company undertook to pay the U.S. Company an upfront payment in the amount of $1.5 million and an additional amount of $2 million which will be paid on the earlier of (i) a specific date or (ii) reaching a specific development milestone. In addition, the Company undertook to pay up to $2 million in potential development milestone payments, and potential tiered royalties on revenues, less certain deductible amounts as detailed in the agreement, starting in the low double-digits. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2015, the Company paid the U.S. Company the initial amount of $ 1.5 million and recognized an amount of $2 million as a current liability.

NOTE 11 - COMMITMENTS (continued):

b. Operating lease agreement

The Company entered into an operating lease agreement for the offices it uses. The agreement will expire on January 31, 2020. The projected yearly rental expenses are approximately $357,000 per year.

As of December 31, 2015, an amount of $134,000 was deposited with a bank to secure the lease payments.

NOTE 12 - INCOME TAX:

a. Measurement of results for tax purposes

The Company elected to compute its taxable income in accordance with Income Tax Regulations (Rules for Accounting for Foreign Investors Companies and Certain Partnerships and Setting their Taxable Income), 1986. Accordingly, the Company's taxable income or loss is calculated in U.S. dollars.

The results of the Company are measured for tax purposes in accordance with Accounting Principles Generally Accepted in Israel (Israeli GAAP). These financial statements are prepared in accordance with IFRS. The difference between IFRS and Israeli GAAP, both on an annual and a cumulative basis causes a difference between taxable results and the results reflected in these financial statements.

b. Tax rates

The income of the Company is subject to corporate tax rate. Israeli corporate tax rate for 2013 was 25%.

On August 5, 2013, the Law of Change in National Priorities (Legislative Achieve Budget for the Years 2013 and 2014), 2013, was published, which provided, inter alia, raising the corporate tax rate to a rate of 26.5% for 2014 and 2015.

In January 2016 the corporate tax rate from 2016 and thereafter was reduced to 25% (instead of 26.5%) according to a law that was approved in January 2016.

c. Carryforward losses

The balance of carryforward losses as of December 31, 2015 is $42 million. These tax carry- forward losses have no expiration date.
Deferred tax assets on losses for tax purposes carried forward to subsequent years are recognized if utilization of the related tax benefit against a future taxable income is expected. The Company has not created deferred taxes on its carryforward losses since their utilization is not expected in the foreseeable future.

NOTE 12 - INCOME TAX (continued)**:**

d. Deductible temporary differences

The amount of cumulative deductible temporary differences, other than carryforward losses (as mentioned in c. above), for which deferred tax assets have not been recognized in the statement of financial position as of December 31, 2015 and 2014, were $21 million and $13 million, respectively. These temporary differences have no expiration dates.

e. Tax assessments

The Company has not been assessed for tax purposes since its incorporation. The Company's tax assessments for the 2010 tax year are considered to be final.

NOTE 13 - EQUITY:

a. Share Capital

1) Composition

Company share capital is composed of ordinary shares of NIS 0.01 par value, as follows:

	Number of shares	
	December 31	
	2015	2014
	In thousands	
Authorized	200,000	200,000
Issued and paid	127,114	87,884

The Company's ordinary shares are traded on the TASE and the Company's ADSs are traded on the NASDAQ under the symbols "RDHL." Each ADS represents 10 ordinary shares. The last reported market price for the Company's securities on December 31, 2015 was $12.88 per ADS on the NASDAQ and $1.28 per share on the TASE (based on the exchange rate reported by the Bank of Israel for such date).

On February 16, 2016, a Special general meeting of shareholders approved the increase of the authorized share capital of the Company to 300,000,000 ordinary shares.

2) Exercise of warrants

Through February 2014 the Company received notifications with respect to the exercise of the warrants (Series 1) that had been issued as part of a public offering on the TASE, for an exercise price per ordinary share of $1.25. Accordingly, in February 2014, the Company issued 3,246,082 ordinary shares for $4.1 million, net of issuance costs. The remaining 3,905,068 unexercised warrants (Series 1) expired in February 2014 along with any right or claim whatsoever of the holders.

NOTE 13 - EQUITY (continued)**:**

During 2014, the Company received notifications of exercise with respect to the warrants that had been granted to investors under investment agreement from December 2012. Accordingly, the Company issued 682,200 ordinary shares for $964,000, net of issuance costs. On January 10, 2015, the remaining 2,558,440 unexercised warrants expired along with any right or claim whatsoever of the holders.

3) Exercise of options

During 2014, the Company received notifications of exercise with respect to options that had been issued to an employee and a consultant of the company. Accordingly, the Company issued 150,000 ordinary shares for $55,000.

During 2015, the Company received notifications of exercise with respect to options that had been issued to employees and a consultant of the Company. Accordingly, the Company issued 338,750 ordinary shares for $108,000.

4) In January 2014, the Company raised an aggregate gross amount of $8.5 million from two new investors in the form of private placements of ADSs and warrants.

The Company issued a total of 894,740 ADSs and warrants to purchase 357,896 ADSs at a purchase price of $9.5 per unit of one ADS and 0.4 warrants (the “Unit”). In addition, the agreements with the investors provided that if the Company issues new securities at a price per unit which is less than $9.5 (such lower price, the "Subsequent Offering Price"), the Company was to issue to the investors a number of additional ADSs as necessary to reduce the effective price per Unit to equal the Subsequent Offering Price (“Price Protection Right”). If ordinary shares and/or ADSs were offered with any other rights, the Subsequent Offering Price was to be calculated for each unit in such offering, consisting of one ordinary share (or ADS) plus the number of other rights per share in such offering.

The Price Protection Right applied until the Company raises a certain threshold of capital. The threshold of capital was $28 million in the agreement with the first investor and $25.5 million in the agreement with the second investor, who invested $2.5 million and signed one day later. Following additional capital raisings by the Company of $11.7 million in January 2014 and $14.4 million in February 2015, the Price Protection Rights expired. See also (6) below.

The warrants were classified as a financial liability due to a net settlement provision. In addition, the Price Protection Right represents a derivative financial instrument. These derivatives were recognized and subsequently measured at fair value through profit or loss. The gross consideration in respect of this investment amounted to $8.5 million. The issuance expenses amounted to approximately $372,000. The consideration, net of issue expenses, in the amount of approximately $8.1 million, was allocated to the various issued instruments. Out of the gross consideration, amounts of $279,000 and $2.05 million were allocated to the Price Protection Right and warrants, respectively.

NOTE 13 - EQUITY (continued)**:**

The remainder of approximately $6.2 million was allocated to ADSs. Issuance expenses in amount of $372,000 were allocated both to the liability instruments and to the equity component. Expenses allocated to the liability instruments, in amount of $102,000, were
recorded directly to the statement of comprehensive loss, and expenses in the amount of $270,000 allocated to the equity component were carried against share premium.

For information regarding the terms of the warrants, see note 14a below.

5) In January 2014, the Company raised an aggregate gross amount of $11.7 million from Israeli investors in the form of a private placement. The Company issued a total of 10,458,740 ordinary shares and warrants to purchase an additional 4,183,496 ordinary shares. The net proceeds were allocated to the issued shares and warrants, based on the fair value of each of these instruments that were recognized as equity. Issuance expenses in amount of $526,000 were allocated to equity components.

For information regarding the term of the warrants see b. below.

6) In 2015 the Company completed two underwritten public offerings:

(a) The Company completed an underwritten public offering in the U.S. of an aggregate of 1,150,000 ADSs at a price of $12.50 per ADS for gross proceeds to the Company of $14.4 million. Net proceeds to the Company from the offering, following discounts, commissions and expenses amounting to $1.2 million, were approximately $13.2 million.

As a result of the offering, the Price Protection Right, as described in (4) above, provided by the Company to investors who participated in the January 2014 private placement, is no longer valid. The change in the fair value of the Price Protection Right of $542,000 was recognized as financial income in the statement of comprehensive loss in 2015.

(b) The Company completed an underwritten public offering in the U.S. of an aggregate of 2,739,143 ADSs at a price of $16.25 per ADS generating gross proceeds to the Company of approximately 44.5$ million. Net proceeds to the Company from the offering, following underwriting discounts and other offering expenses of approximately $3 million, were approximately $41.5 million.

b. Warrants

The warrants issued under the investment agreement, as described in a(5) above, are exercisable into 4,183,496 ordinary shares, which have a three-year term and are exercisable at an exercise price of $1.4 per ordinary share.

NOTE 14 - DERIVATIVE FINANCIAL INSTRUMENTS:

a. Warrants

The warrants issued under the investment agreement, as described in note 13a(4) above, were classified as a financial liability due to a net settlement provision. These warrants are exercisable into 357,896 ADSs. The warrants have a three-year term and may be exercised either for cash or on a cashless basis at an exercise price of $11 per ADS.

b. Price Protection Right

For information regarding the Price Protection Right, see note 13a(4) above.

c. Fair value

The fair value of the warrants is computed using the Black and Scholes option pricing model. The fair value of the Price Protection Right is computed using a common valuation model, which takes into account specific scenarios. The fair value of the warrants and the Price Protection Right upon issuance was computed based on the price of an ordinary share and based on the following key parameters: risk-free interest rate of 0.13% - 0.87% and an average standard deviation of 33.38% - 53.33%. The values of the warrants and Price Protection Right as of December 31, 2014, are based on the price of an ordinary share on December 31, 2014 and based on the following key parameters: risk-free interest rate of 0.12% - 0.7% and an average standard deviation of 44.92% - 61.70%. The fair value of the warrants as of December 31, 2015, is based on the price of an ordinary share on December 31, 2015 and based on the following key parameters: risk-free interest rate of 0.66% and an average standard deviation of 49.55%.

NOTE 15 – SHARE-BASED PAYMENTS:

On May 30, 2010, a general meeting of shareholders approved the option plan of the Company for 2010 (the "Option Plan"), after being approved by the Board of Directors. It was resolved in 2015 to increase the Option Plan to allow the Company to allocate 30,000,000 options to employees and directors. The terms and conditions of the grants were determined by the Board of Directors and are according to the Option Plan.

a. Following is information on options granted in 2015:

	Number of options granted			
	According to option plan of the company		Exercise price to 1 ordinary share ($)	The fair value of options on date of grant in U.S.$ thousands (2)
Date of grant	Other than directors (1)	Total		
May 2015	300,000	300,000	1.61	218
September 2015	2,375,072	2,375,072	1.56	1,392
	2,675,072	2,675,072		1,610

1) The options will vest as follows: for employees and consultants of the Company who had provided services exceeding one year to the Company as of the grant date, the options will vest in 16 equal quarterly installments over a four-year period. For employees and consultants of the Company who had not provided services to the Company exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over the following three years in 12 equal quarterly installments. The options will be exercisable, either in full or in part, from the vesting date until the end of 7 years from the date of grant.

2) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $1.30 – $1.56, expected volatility: 51.75% – 53.30%, risk-free interest rate: 1.87% – 1.92% and expected useful life to exercise: seven years.

NOTE 15 – SHARE-BASED PAYMENTS (continued):

b. Following is information on options granted in 2014:

	Number of options granted			Exercise price to 1 ordinary share ($)	The fair value of options on date of grant in U.S.$ thousands (2)
	According to option plan of the company				
Date of grant	Other than directors (1)	To directors (1)	Total		
March 2014	1,830,016	-	1,830,016	1.48	1,260
April 2014	-	*1,760,000	1,760,000	1.48	1,203
May 2014	150,000	-	150,000	1.48	100
	1,980,016	1,760,000	3,740,016		2,563

* The options were allocated to officers who also serve as directors.

1) The options will vest as follows: for employees and consultants of the Company who had provided services to the Company for a period exceeding one year as of the date of grant, the options will vest in 16 equal quarterly installments over a four-year period. For employees and consultants of the Company who provided services to the Company for a period of less than one year as of the date of grant, the options will vest as follows: 1/4 of the options will vest one year following the grant date, and the rest over the following three years in 12 equal quarterly installments.

2) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $1.43- $1.44, expected volatility: 51.6%-52.3%, risk-free interest rate: 2.25%-2.31% and expected useful life to exercise: seven years.

NOTE 15 – SHARE-BASED PAYMENTS (continued):

c. Changes in the number of shares and weighted averages of exercise prices are as follows:

	Year ended December 31			
	2015		2014	
	Number of options	Weighted average of exercise price	Number of options	Weighted average of exercise price
Outstanding at beginning of year	18,325,016	0.78	14,735,000	0.60
Exercised	(338,750)		(150,000)	
Expired	(150,000)		-	
Granted	2,675,072	1.57	3,740,016	1.48
Outstanding at end of year	20,511,338	0.88	18,325,016	0.78
Exercisable at end of year	15,493,449	0.68	14,152,921	0.60

d. The following is information about exercise price and remaining useful life of outstanding options at year-end:

December 31, 2015			December 31, 2014		
Number of options outstanding at end of year	Exercise price range	Weighted average of remaining useful life	Number of options outstanding at end of year	Exercise price range	Weighted average of remaining useful life
20,511,338	$0.17-$1.61	3.6	18,325,016	$0.17-$1.48	4.13

e. Expenses recognized in profit or loss for the options are as follows:

Year ended December 31		
2015	2014	2013
U.S. dollars in thousands		
1,364	1,753	1,255

The remaining compensation expenses as of December 31, 2015 are $1.9 million and will be expensed in full by September 2019.

The options granted to Company employees in Israel are governed by relevant rules in Section 102 to the Israel Income Tax Ordinance (hereinafter the "Ordinance"). According to the treatment elected by the Company and these rules, the Company is not entitled to claim as tax deductions the amounts charged to employees as a benefit, including amounts recognized as payroll benefits in Company accounts for the options the employees received within the Option Plan. Options granted to option holders who are related parties of the Company are governed by Section 3(i) to the Ordinance.

NOTE 16 - REVENUES

On February 27, 2014, the Company entered into an exclusive agreement by which Salix Pharmaceuticals, Inc. ("Salix"), which was later acquired by Valeant Pharmaceuticals International, Inc., or Valeant, licensed the worldwide exclusive rights to one of the Company's therapeutic candidates, an encapsulated formulation for bowel preparation, and rights to other purgative developments. Under the license agreement, Salix paid an upfront payment of $7 million with subsequent potential milestone payments up to a total of $5 million. Salix has also agreed to pay the Company tiered royalties on net sales, ranging from low single-digit up to low double-digits. As there was no continuing managerial involvement of the Company under the agreement with Salix to develop any product based on the license and related intellectual property granted to Salix, the upfront payment of $7 million was recognized in 2014 as revenue in the statement of comprehensive loss.

Following the agreement with Salix, and pursuant to the purchase agreement from August 11, 2010, between the Company and an Australian company from which it purchased the rights sold to Salix, the Company paid to the Australian company $1 million in 2014. The amount paid was recognized as cost of revenue in the statement of comprehensive loss.

NOTE 17 - RESEARCH AND DEVELOPMENT EXPENSES, net**:**

	Year ended December 31		
	2015	**2014**	**2013**
	U.S. dollars in thousands		
Payroll and related expenses	621	573	426
Professional services	1,953	1,685	1,272
Share-based payments	842	951	753
Clinical trials	13,611	9,187	6,019
Intellectual property development	216	556	233
Other	713	382	363
Discount from Service Provider*	(185)	(634)	(966)
	17,771	12,700	8,100

* Discount provided to the Company by its Canadian service provider due to certain Canadian authorities incentives programs.

NOTE 18 - GENERAL AND ADMINISTRATIVE EXPENSES:

	Year ended December 31		
	2015	**2014**	**2013**
	U.S. dollars in thousands		
Payroll and related expenses	986	943	754
Share-based payments	522	802	501
Professional services	2,050	1,662	997
Office related expenses	173	187	131
Other	403	417	301
	4,134	4,011	2,684

NOTE 19 - FINANCIAL EXPENSES (INCOME), net**:**

	Year ended December 31		
	2015	**2014**	**2013**
	U.S dollars in thousands		
Financial income:			
Fair value gain on derivative financial instruments	888	200	-
Fair value gain on financial assets at fair value through profit or loss	-	-	54
Income from changes in exchange rates	-	-	74
Interest from bank deposits	236	119	30
	1,124	319	158
Financial expenses:			
Loss from changes in exchange rates	200	361	-
Other	12	22	14
	212	383	14
Financial expenses (income) - net	(912)	64	(144)

NOTE 20 - LOSS PER ORDINARY SHARE:

a. Basic

The basic loss per share is calculated by dividing the loss by the weighted average number of ordinary shares in issue during the period.

Set forth below is data taken into account in the computation of loss per share:

	Year ended December 31		
	2015	**2014**	**2013**
Loss (U.S. dollars in thousands)	21,090	10,711	10,628
Weighted average number of ordinary shares outstanding during the period (in thousands)	110,814	86,610	62,379
Basic loss per share (U.S. dollars)	0.19	0.12	0.17

b. Diluted

The diluted loss per share for the year ended December 31, 2013 is identical to the basic loss per share since the effect of potential dilutive shares is anti-dilutive.

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding assuming conversion of all dilutive potential ordinary shares, which is calculated using the Treasury Method. The Company has two categories of dilutive potential ordinary shares: warrants issued to investors and options issued to employees and service providers. The effect of options issued to employees and service providers is anti-dilutive.

	Year ended December 31		
	2015	**2014**	**2013**
Loss (U.S. dollars in thousands)	21,090	10,711	10,628
Adjustment for financial income of warrants	346	463	-
Loss used to determine diluted loss per share	21,436	11,174	10,628
Weighted average number of ordinary shares outstanding during the period (in thousands)	110,814	86,610	62,379
Adjustment for warrants	901	612	-
Weighted average number of ordinary shares for diluted loss per share (in thousands)	111,715	87,222	62,379
Diluted loss per share (U.S. dollars)	0.19	0.13	0.17

NOTE 21 - RELATED PARTIES:

a. Key management includes members of the Board of Directors, the Chief Executive Officer and Deputy Chief Executive Officer Finance and Operations.

	Year ended December 31		
	2015	2014	2013
	U.S. dollars in thousands		
Key management compensation:			
Salaries and other short-term employee benefits	776	628	555
Post-employment benefits	58	60	48
Share-based payments	382	726	515
Other long-term benefits	27	31	25

b. Balances with related parties:

	December 31	
	2015	2014
	U.S. dollars in thousand	
Current liabilities -		
Credit balance in "accounts payable"	264	155

EXHIBIT INDEX

The exhibits filed with or incorporated into this Registration Statement are listed in the index of exhibits below.

Exhibit Number	Exhibit Description
1.1	Articles of Association of the Registrant, as amended (unofficial English translation).
2.1	Form of Deposit Agreement among the Registrant, the Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued hereunder (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
2.2	Form of American Depositary Receipt (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
4.1*	Co- Development and Commercialization Agreement, dated August 26, 2010, by and between the Registrant and IntelGenx Corp. (incorporated by reference to Exhibit 4.3 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.2*	Side Letter Agreement, dated January 31, 2013, by and between the Registrant and IntelGenx Corp (incorporated by reference to Exhibit 4.4 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2014).
4.3*	Asset Purchase Agreement, dated August 11, 2010, by and between the Registrant and Giaconda Limited (RHB-104, 105, 106) (incorporated by reference to Exhibit 4.4 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.4*	Amendment to Asset Purchase Agreement by and between the Registrant and Giaconda Limited (RHB-104, 105, 106) dated February 27, 2014 (incorporated by reference to Exhibit 4.4 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.5*	License Agreement, dated September 15, 2011, by and between the Registrant and University of Central Florida Research Foundation (incorporated by reference to Exhibit 4.5 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.6*	License Agreement, dated February 27, 2014, by and between the Registrant and Salix Pharmaceuticals, Inc. (later acquired by Valeant Pharmaceuticals International, Inc.) (incorporated by reference to Exhibit 4.6 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.7†	Exclusive License Agreement, dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp.
4.8*	Master Service Agreement, dated April 28, 2011, by and between the Registrant and 7810962 Canada Inc. and amendment (incorporated by reference to Exhibit 4.12 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.9†	Third Amendment dated May 21, 2015 to the Master Service Agreement, dated April 28, 2011 by and between the Registrant and 7810962 Canada Inc.

4.10* Second Amendment to Master Services Agreement, dated May 29, 2013 by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.9 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2014).

4.11* Clinical Services Agreement, dated June 15, 2011, by and between the Registrant and 7810962 Canada Inc. and amendment (regarding RHB-104) (incorporated by reference to Exhibit 4.15 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).

4.12 Change Order #4.1 dated August 9, 2015 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc.

4.13† Change Order #5 dated May 21, 2015 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc.

4.14* Second Amendment to Clinical Services Agreement, dated January 19, 2014, by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.13 of the Annual Report on Form 20-F/A filed with the Securities and Exchange Commission on July 7, 2014).

4.15* Third Amendment to Clinical Services Agreement, dated December 7, 2014, by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.14 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).

4.16* Fourth Amendment to Clinical Services Agreement, dated December 17, 2014, by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.15 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).

4.17* Clinical Trials Global Master Service Agreement, dated December 27, 2012 by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) (incorporated by reference to Exhibit 4.22 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).

4.18 Global Master Service Agreement amendment, dated June 20, 2014 by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) (incorporated by reference to Exhibit 4.23 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).

4.19	Amendment No. 2 dated May 13, 2015 to the Clinical Trials Global Master Service Agreement, dated December 27, 2012 by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104).
4.20*	Master Agreement Work Order, dated May 13, 2014, by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) (incorporated by reference to Exhibit 4.24 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.21†	Amendment No. 1 dated December 30, 2015 to the Master Agreement Work Order, dated May 13, 2014, by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104).
4.22†	Change Specification Form by and between Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) dated June 6, 2015.
4.23	Form of Letter of Exemption and Indemnity adopted on July 2013 (unofficial English translation) (incorporated by reference to Exhibit B to Exhibit 99.1 to Form 6-K disseminated with the Securities and Exchange Commission, dated June 26, 2013).
4.24	2010 Stock Option Plan, as amended (incorporated by reference to Exhibit 4.27 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.25	Securities Purchase Agreement, dated December 30, 2013 by and between the Registrant and OrbiMed Israel Partners Limited Partnership (together with Form of Warrant attached as Exhibit A) (incorporated by reference to Exhibit 4.17 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2014).
4.26	Securities Purchase Agreement, dated December 31, 2013 by and between the Registrant and Broadfin Healthcare Master Fund, LTD (together with Form of Warrant attached as Exhibit A) (unofficial English translation) (incorporated by reference to Exhibit 4.18 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2014).
4.27	Underwriting Agreement, dated February 10, 2015, between the registrant and Wells Fargo Securities, LLC as representative of the several Underwriters (incorporated by reference to Exhibit 1.1 to the Form 6-K submitted to the Securities and Exchange Commission on February 13, 2015).
4.28	Underwriting Agreement, dated July 16, 2015, between the Registrant and Nomura Securities International, Inc. as representative of the several Underwriters (incorporated by reference to Exhibit 1.1 to the Form 6-K submitted to the Securities and Exchange Commission on July 21, 2015).
12.1	Certification by Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification by Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13	Certification by Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of Independent Registered Public Accounting Firm.

* Confidential treatment granted with respect to certain portions of this Exhibit.

† Portions of this exhibit have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

SIGNATURE

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

REDHILL BIOPHARMA LTD

By: /s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: Chief Executive Officer and Chairman of the Board of Directors

By: /s/ Ori Shilo
Name: Ori Shilo
Title: Deputy Chief Executive Officer, Finance and Operations

Date: February 25, 2016

Exhibit 1.1

These Articles of Association are an unofficial translation of the Articles of Association in Hebrew adopted by the Company.

The Articles of Association will take effect upon the public issuance of the Company

Articles of Association

of

Redhill Biopharma Ltd.
("Company")

Table of Contents

1. Introduction

1.1 In these Articles, each of the terms set forth below shall have the meaning set forth opposite it:

Law -	The provisions of any law applicable in the State of Israel.
Administrative Proceeding -	A proceeding pursuant to Chapter H3 (Imposing Monetary Sanction by the ISA), H4 (Imposing Administrative Enforcement Measures by the Administrative Enforcement Committee) and/or I1 (Conditioned Arrangement for Avoidance of Taking Action of for Stopping Action) of the Securities Law, as amended from time to time
The Companies Law -	The Companies Law, 5759 – 1999; or any provision of law superseding same.
The Securities Law -	The Securities Law, 5728 – 1968; or any provision of law superseding same.
Business Day -	A day on which most of the banks in Israel are open for the performance of transactions.
Writing -	Print and any other form of imprinting words including documents transmitted in writing via facsimile, by telegraph, telex, email, computer or in any other electronic means of communication, creating or allowing the creation of any copy and/or printed output of the document.
Securities -	As defined in Section 1 of the Securities Law.
Incapacitated -	A person declared incapacitated pursuant to the Legal Capacity and Guardianship Law, 5722 – 1962.
Companies Ordinance -	The Companies Ordinance [New Version], 5743 – 1983, or any provision of law superseding same.
Simple Majority -	A majority of over one half of the votes of the shareholders entitled to vote who have voted in person or by proxy or by means of a voting paper, other than abstainees.
A majority of 75% -	A majority of 75% or more of the votes of the shareholders entitled to vote who have voted in person or by proxy or by means of a voting paper, other than abstainees.
Articles of Association -	The Company's articles of association as per the wording herein or as duly modified, from time to time, either expressly or under any law.
The Companies Regulations -	Regulations enacted by virtue of the Companies Law and/or by virtue of the Companies Ordinance.
Securities Regulations -	Regulations enacted by virtue of the Securities Law.
Related Corporation -	A corporation controlling the Company directly and/or indirectly and/or any corporation directly and/or indirectly controlled by such corporation and/or any corporation controlled by the Company, directly and/or indirectly.

1.2 In these Articles, reference to any organ or officeholder is to organs or officeholders of the company.

1.3 The provisions of sections 3-10 of the Interpretation Law, 5741 – 1981, shall also apply, *mutatis mutandis*, to the interpretation of these Articles, where there is no other provision in respect of such matter and where such matter or the context thereof, contain nothing which does not comply with such applicability.

Save for the provisions of this Article, any word or term in these Articles shall have the meaning imparted to them in the Companies Law, and where there is no such meaning in the Companies Law, then the meaning imparted to them in the Companies Regulations, and where there is no such meaning, then the meaning imparted to them in the Securities Law, and where there is no such meaning, then the meaning imparted to them in the Securities Regulations and where there is no such meaning, then the meaning imparted to them in any other law, all where the meaning imparted as aforesaid is not in conflict with the context where such word or expression appears or with the purpose of the relevant provision in these Articles.

In case of reference in these Articles to a provision of law, and such provision has been revised or revoked, such provision shall be deemed valid and as though it were part of the Articles, unless in consequence of such revision or cancellation, such provision has no effect.

The provisions of these Articles are designed to add to and contract out the provisions stipulated in the Companies Law. In the event that any of the provisions of these Articles is in contravention of that permitted under law, the provisions of these Articles shall be interpreted to the extent possible in accordance with the provisions of the law.

2. **A Public Company**

The Company is a public company.

3. **Donations**

The Company may make donations, even if the donation is not made as part of commercial considerations.

4. **Company's Objectives**

The Company shall engage in any lawful business.

5. **Limitation of Liability**

The liability of the shareholders of the Company is limited, each of them to full payment of the amount that he has undertaken to pay for the shares allocated to him at the time of the allocation.

6. **Amendments to the Articles of Association**

The Company may amend any of the provisions of these Articles or substitute these Articles for other Articles, by means of a resolution passed by the a simple majority at a general meeting, apart from the provisions of Sub-Articles 14.1, 14.2, 19.1 and 19.2 herein, the amendment or replacement of which is subject to a resolution to be passed by a majority of 75% at a general meeting.

Chapter Two - The Share Capital of the Company

7. **Share Capital**.[1]

7.1 The Company's registered share capital is NIS 3,000,000, divided into 300,000,000 registered Ordinary Shares of NIS 0.01 par value each (hereinafter: "**share", "ordinary share", "shares" or "ordinary shares",** as the case may be). Each share confers a right to receive invitations to participate in and vote at the general meetings. A shareholder shall have one vote for every fully paid up share that he holds. All Shares have equal rights *inter se* with respect to dividend, distribution of bonus shares or any other distribution, capital refund and participation in distribution of surplus of Company assets upon liquidation.

7.2 The provisions of these Articles in relation to shares, shall also apply, *mutatis mutandis*, to other securities to be issued by the Company.

8. **Issuance of Shares and Other Securities**

8.1 No Priority Right - the existing shareholders of the Company shall not have a priority right, a right of preference, or any other right whatsoever to acquire the Company's securities. The board of directors may, at its exclusive discretion, first offer the Company's securities to all or any of the current shareholders.

8.2 Redeemable Securities

The Company may issue redeemable securities, with rights attached to them and subject to such terms and conditions as shall be prescribed by the board of directors.

8.3 Commissions - the Company may pay any person a commission (including underwriting fees) in consideration of underwriting services, marketing or distribution of the Company's securities, either conditionally or unconditionally, on such terms and conditions as shall be prescribed by the board of directors. Payment as aforementioned in this Article can be made either in cash or in securities of the Company, or some of them in one way and some of them in another way.

[1] Subject to the provisions of Section 46.B. of the Securities Law, pursuant to which so long as the Company's shares are listed for trading on the Stock Exchange, the Company's share capital will consist of one class of shares.

8.4 The board of directors may introduce distinctions between holders of the Company's securities in relation to the terms and conditions of allocation of the Company's securities and the rights attached to such securities and may also vary such terms and conditions, including waiving some of them. The board of directors may further issue calls to the holders of securities for payment of the money that has not yet been paid for the securities held by them.

8.5 Any payment on account of a share shall be credited initially on account of the nominal value and only then on account of the premium for each share, unless otherwise prescribed in the terms of the allocation.

8.6 A shareholder will not be entitled to his rights as a shareholder, including to a dividend, unless he has paid the amounts in full in accordance with the terms of the allocation, with the addition of interest, linkage and expenses, if there were any, and all if not otherwise prescribed in the terms of the allocation.

8.7 The board of directors may forfeit as well as sell, re-allocate or otherwise transfer any security as it shall decide, in respect of which the full consideration has not been paid, including for nil consideration.

8.8 The forfeiture of a security shall result, at the time of such forfeiture, in the revocation of any right in the Company and any claim or demand against it in relation to such security, except for such rights and obligations as are excluded from this rule in accordance with these Articles or which the law confers on or imposes on a former shareholder.

9. **The Register of Shareholders of the Company and Issue of Share Certificates**

9.1 The secretary of the Company or whoever is appointed for such purpose by the board of directors of the Company shall be responsible for keeping a Register of the Company's Shareholders. A shareholder is entitled to receive from the Company, free of charge, within two months after the allocation or the registration of the transfer (unless the terms of the issue stipulate another period of time), one certificate or a number of certificates, at the Company's discretion, in respect of all the shares that are registered in his name, which shall specify the number of shares, and any other detail that is important in the opinion of the board of directors. In the event of a jointly held share, the Company shall not be required to issue more than one certificate to all the joint holders, and delivery of such a certificate to one of the joint holders shall be deemed to be delivery to all of them.

9.2 The board of directors may close the register of shareholders for a total period of up to 30 days annually.

9.3 Every certificate shall bear the seal or stamp of the Company or its printed name and shall bear the signature of one director and the Company secretary, or of two directors or of any other person who has been appointed by the board of directors for such purpose.

9.4 The Company may issue a new certificate *in lieu of* a certificate that was issued and was lost, defaced, or destroyed, on the basis of such proof and guarantees as the Company may require, and after payment of an amount that shall be prescribed by the board of directors and the Company may also, in accordance with a resolution of the board of directors, replace existing certificates with new certificates free of charge subject to such conditions as the board of directors shall stipulate.

9.5 Where two or more persons are registered as the joint holders of a share, each of them may confirm receipt of a dividend or other payments for such share and his confirmation will bind all holders of such share.

9.6 The Company is entitled to recognize a holder of a share as a trustee and to issue a share certificate in the name of the trustee provided that the trustee has notified the Company of the identity of the beneficiary of the trust. The Company will not be bound to or be required to, recognize a right that is based on the rules of equity or a right that is subject to a condition, or a future right or a partial right to a share, or any other right in relation to a share, other than the absolute right of the registered holder in respect of any share, unless this is done on the basis of a judicial decision or in accordance with the requirements of any law.

10. **Transfer of the Company's Shares**[2]

10.1 The Company shares are transferable.

10.2 No transfer will be registered of shares that are registered in the register of shareholders in the name of a registered shareholder, unless an original, signed deed of transfer of the shares has been submitted to the Company (hereinafter: "**deed of transfer"**), unless otherwise stipulated by the board of directors of the Company. The deed of transfer shall be drawn up in the form set out hereunder or in such other format as is as similar as possible to it or in another format which shall be approved by the board of directors.

Deed of Transfer

I, _____ Identity Card No. / Corporate No. _____ (hereinafter: **"the transferor**") of _____ hereby transfer to _____ Identity Card No. / Corporate No. _____ (hereinafter: "**the transferee**") of _____ in consideration of the sum of NIS _____ that he has paid to me, _____ shares, each having a nominal value of NIS _____, which are marked by the numbers _____ to _____ inclusive, of _____Ltd. (hereinafter: "**the Company**"), and they shall be in the possession of the transferee, his estate administrators, guardians, and his duly authorized representatives, in accordance with the conditions under which I personally held the shares at the time of signature of this deed, and I, the transferee, agree to accept the said shares in accordance with the conditions set out above and subject to the Company 's Articles, such as they are from time to time.
In Witness Whereof we have signed, this __ day of the month of _____, in the year _____

Transferor -
Name: _____
Signature: _____

Transferee
Name: _____
Signature: _____

Witness to the Transferor's Signature:
Name: _____, Advocate
Signature: _____

Witness to the Transferee's Signature:
Name: _____, Advocate
Signature: _____

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[2] So long as the Company shares are listed for trading on the stock exchange, the Company shares will be registered in the name of the nominee company and the share transfer will be carried out via the nominee company and not as prescribed in Sub-Articles 10.1-10.4 of these Articles.

Neither a transfer of non-fully paid up shares or of shares over which the Company has a lien or a charge shall be valid unless it has been approved by the board of directors, which may, at its absolute discretion and without giving any reasons, refuse to register such a transfer.

The board of directors may refuse a transfer of shares as aforesaid and the board of directors may also make such a transfer of shares conditional on an undertaking by the transferee, in such scope and in such manner as the board of directors shall stipulate, or settle the transferor's liabilities in respect of such shares or the liabilities in respect of which the Company has a lien or a charge over such shares.

10.3 The transferor shall continue to be deemed to be the holder of the shares being transferred until such time as the name of the transferee is registered in the Company's register of shareholders.

10.4 A deed of transfer shall be submitted to the registered office of the Company for registration together with the certificates of registration of the shares that are about to be transferred (if such certificates have been issued) and any other proof which the Company shall require as to the title of the transferor to such shares or his right to transfer them.

10.5 A joint shareholder who wishes to transfer his right in a share but is not in possession of the share certificate, will not be bound to attach the share certificate to the transfer deed provided that in the transfer deed it is stated that the transferor is not in possession of the share certificate in respect of the share in which his right is being transferred and that the share being transferred is held jointly with others, together with their particulars.

10.6 The Company may require payment of a fee for registration of the transfer of such an amount or at such rate as the board of directors shall determine from time to time.

10.7 Upon the death of a holder of shares in the Company, the Company will recognize guardians, estate administrators or executors, and if there are no such persons, the lawful heirs of the shareholder, as parties with the sole right to the shares of the shareholder, after the entitlement thereto is substantiated in such manner as shall be determined by the board of directors.

10.8 In the event that a deceased shareholder held shares jointly with others, the Company will recognize the survivor as a shareholder in respect of the said shares, unless all the joint holders of the share have notified the Company in writing prior to the death of one of them, of their wish that the provisions of this Article shall not apply, provided that this shall not absolve the estate of a joint holder of a share from any obligation whatsoever that the joint holder would have had in respect of such share had he not passed away.

10.9 A person who acquires a right to shares by virtue of being a guardian, estate administrator, heir of a shareholder, a receiver, liquidator or trustee in bankruptcy of a shareholder or in accordance with any other legal provision, may, if and when he proves his right as such may be required by the board of directors, be registered as the shareholder or may transfer such shares to another person, subject to the provisions of the Articles in relation to a transfer.

10.10 A person who acquires a right to a Share as a result of a transfer thereof by operation of law, will be entitled to a dividend and to the other rights in respect of such share and he may also accept and give receipts for a dividend or for other payments payable in respect of such share; however, he will not be entitled to receive notices regarding the general meetings of the Company (insofar as such a right exists), and to participate at or vote at such meetings in connection with such share or to exercise any right whatsoever, which the share confers, except as aforesaid, until after he is registered in the register of shareholders.

11. **Bearer Share Warrant**

The Company will not issue bearer share warrants.

12. **Lien on Shares**

12.1 The Company shall have a first charge and a lien over all the shares that are not fully paid up, which are registered in the name of any shareholder, and over the proceeds of sale thereof, in relation to monies (whether or not the time for payment thereof has fallen due), payment of which has already been called or which are to be paid at a fixed time in respect of such shares. The Company shall also have a first charge over all the shares (except fully paid up shares) that are registered in the name of any shareholder as security for monies that are due from him or from his assets, whether his liability is individual or jointly with others. The said charge shall also apply over such dividends as have been declared from time to time in respect of such shares.

12.2 The board of directors may sell the shares to which the charge applies for the purpose of realizing the charge and lien, or any part thereof, in any manner as it sees fit. No such sale shall proceed until after written notification has been given to such shareholder as to the intention of the Company to sell them, and the amounts have not been paid within fourteen days after such notification. The net proceeds of any such sale, after payment of the sale expenses, shall be utilized in discharging the debts or obligations of such shareholder and the balance (if any remains) shall be paid to him.

12.3 Where a sale of shares has occurred in order to realize a charge or a lien by the *prima facie* exercise of the powers vested as aforesaid, the board of directors may register such shares in the register of shareholders, in the name of the purchaser, and the purchaser will be under no obligation to examine the propriety of the transaction or the way in which the purchase price is used. Following registration of the said shares in the register of shareholders in the name of the purchaser, no person shall have the right to challenge the validity of the sale.

13. **Alteration of Share Capital**[3]

The general meeting may resolve at any time to take one of the following actions, provided that a resolution of the general meeting as aforesaid has been adopted by a simple majority.

13.1 Increase of the Registered Share Capital

To increase the registered share capital of the Company, irrespective of whether or not all the shares registered at that time have been issued. The increased capital will be divided into ordinary shares with equal rights.

13.2 Consolidation and Division of Share Capital

To consolidate and re-divide some or all of its share capital into shares of a greater or smaller nominal value than that which is specified in the Articles. In a case in which, as a result of such consolidation, shareholders whose shares have been consolidated are left with fractions of shares, the board of directors may, if it receives approval thereto from the general meeting in the resolution as to consolidation of capital as aforesaid:

A. Sell the aggregate of all the fractions, and for this purpose appoint a trustee in whose name the share certificates containing the fractions shall be issued, and the trustee shall sell the said fractions, and the proceeds received less commissions and expenses shall be distributed to eligible shareholders. The board of directors will be entitled to decide that shareholders who are entitled to the consideration, which is less than an amount that it shall stipulate, will not receive a consideration from the sale of the said fractions, and their share in the sale proceeds shall be distributed among such shareholders who are entitled to a consideration that exceeds the stipulated amount, *pro rata* to the consideration to which they are entitled;

B. To allocate to all holders of shares in respect of whom the consolidation and the re-division leaves them with a fraction of a share, shares of the class of shares which, before such consolidation, are fully paid up, in such a number that their consolidation with the fraction will be sufficient for one complete consolidated share, and such an allocation shall be deemed as being effective immediately prior to such consolidation;

C. Determine that shareholders shall not be entitled to receive a consolidated share in respect of a fraction of a consolidated share, which derives from the consolidation of half or less of the number of shares whose consolidation creates one consolidated share, and they shall be entitled to receive a consolidated share in respect of a fraction of a consolidated share which derives from the consolidation of more than half of the number of shares whose consolidation creates one consolidated share.

In the event that an action taken in accordance with sub-paragraphs (b) or (c) above requires the issue of additional shares, payment therefor shall be made in the manner in which bonus shares may be repaid. Consolidation and division as aforesaid shall not be deemed to be a variation of the rights of the shares forming the subject of the consolidation and division.

[3] Subject to the provisions of Section 46.B. of the Securities Law, pursuant to which so long as the Company's shares are listed for trading on the Stock Exchange, the Company's share capital will consist of one class of shares.

13.3 Cancellation of Un-allocated Registered Share Capital

To cancel registered share capital which has not yet been allocated provided that the Company is under no obligation to allocate such shares.

13.4 Split of Share Capital

To split some or all of the Company's share capital, into shares with a smaller nominal value than that which is prescribed in the articles of association by division of some or all of the Company shares, at that time.

Chapter Three - General Meetings

14. **Powers of the General Meeting**

14.1 Subjects within the authority of the General Meeting

Resolutions of the Company in respect of the following matters shall be passed by the general meeting:

14.1.1 Changes to the Articles.

14.1.2 Exercise of the powers of the board of directors, provided that the general meeting has decided by a majority of 75% of the votes of shareholders who are entitled to vote and have voted either in person or by proxy, that the board of directors is incapable of exercising its powers and further that the exercise of its powers is essential for the proper management of the Company.

14.1.3 Approval of actions or transactions requiring approval of the general meeting pursuant to the provisions of Sections 255 and 268 to 275 of the Companies Law.

14.1.4 Any decision that, by law or under the Articles, must be passed by a resolution of a general meeting.

14.1.5 Any power which, by law, is vested in the general meeting.

14.2 Power of the General Meeting to Transfer Powers between the Company's Organs

The general meeting may by a majority of 75% of the votes of shareholders who are entitled to vote and have voted either in person or by proxy, assume such powers as are vested in another organ and may also transfer powers that are vested in the general manager to the authority of the board of directors, and all either in respect of a particular matter or for a particular period of time which shall not exceed the period of time required under the circumstances.

15. **Annual and Special General Meetings**

15.1 Notice of a General Meeting

The Company is not obliged to give notice of a general meeting to shareholders except in so far as this is mandatory by law.

The notice of a general meeting shall specify the place and the time for the convening of the meeting, its agenda, a summary of the proposed resolutions and any other detail as may be required under law.

16. **Proceedings at General Meetings**

16.1 Quorum

No general meeting may proceed unless a quorum is present at the time of the deliberation. Two shareholders who are present in person or by proxy and who hold or represent at least twenty five percent (25%) of the voting rights in the Company shall constitute a quorum. For the purpose of a quorum, a shareholder or his proxy, who also acts as proxy for other shareholders, shall be deemed to be two or more shareholders, depending on the number of shareholders that he represents.

16.2 Postponement of the General Meeting in the Absence of a Quorum

Where half an hour has elapsed from the time designated for the meeting and no quorum is present, the meeting shall be postponed to the business day following the day of the meeting, at the same time and at the same place or to such other day, time and place as shall be prescribed by the board of directors in a notification to the shareholders. The Company shall give notice, via an immediate report, of postponement of the meeting and the time of the holding of the adjourned meeting.

Where no quorum is present at such adjourned meeting as aforesaid, at least one shareholder, who is present either in person or by a proxy, shall be deemed as a quorum, except where such meeting has been called at the demand of shareholders.

16.3 Chairman of the General Meeting

The Chairman of the board of directors shall chair any general meeting, and, in his absence, it shall be chaired by whoever is appointed for such purpose by the board of directors. In the absence of a chairman, or if he has not appeared at the meeting after 15 minutes from the time designated for the meeting, the shareholders present at the meeting shall, in person or by proxy, elect one of the directors or the officeholders of the Company present at the meeting as chairman, or if no director or officeholder is present, or where all of them refuse to chair the meeting, one of the shareholders present, or one of the officeholders present, shall be elected to chair the meeting.

The chairman of the meeting shall not have an additional or casting vote.

The decision by the chairman that a resolution at the general meeting was passed unanimously or by a specific majority or was rejected and the minutes of the general meeting signed by the chairman shall serve as *prima facie* evidence of that stated therein.

17. **Votes of Shareholders**

17.1 Majority - resolutions at the general meeting shall be passed by a simple majority unless another majority is required by law or in accordance with the provisions of Articles 6, 14.1.2, 14.2, 19.1, 19.2.5 and 19.2.6 of these Articles. Checking the majority will be carried out by means of counting of votes, where each shareholder will have one vote per each share held by him.

17.2 Confirmation of title - a shareholder must furnish the Company with confirmation of title at least two business days prior to the date of the general meeting. The Company may waive such requirement.

17.3 Vote of a legally incapacitated party - a legally incapacitated party may only vote by a trustee, natural guardian or other legal guardian. Such persons may vote either in person or by proxy.

17.4 Vote of joint holders of a share - where two or more shareholders are the joint holders of a share, one of them shall vote, either in person or by proxy. Where more than one joint holder wish to participate in a vote, only the first of the joint holders will be able to vote. For such purpose the first of the joint holders shall be deemed to be the person whose name is recorded first in the register of shareholders.

17.5 The manner of voting and the counting of votes shall be done in accordance with the provisions of the Companies Law. A resolution at a general meeting shall be passed if it has received such majority as it is required to receive under law or in accordance with the provisions of these Articles.

18. **Appointment of a Voting Proxy**

18.1 Voting by Proxy

A shareholder may appoint a proxy to participate in and vote in his place, either at a particular general meeting or generally at the general meetings of the Company, provided that the written document authorizing the appointment of a proxy has been delivered to the Company at least 48 hours prior to the date of the general meeting, unless the Company has waived such requirement. A proxy need not be a shareholder of the Company.

If such proxy is not for a particular general meeting, a proxy that has been deposited prior to one general meeting shall also hold good for other subsequent general meetings.

The foregoing shall also apply to a shareholder that is a corporation and which appoints a person to participate in and vote in its place at the general meeting.

18.2 Format of the Proxy

The proxy shall be signed by the shareholder or by the person who is duly authorized in writing for such purpose, and where the appointing party is a corporation it shall be signed in such manner as binds such corporation. The Company may require that it be furnished with written confirmation to its satisfaction as to the fact of the due authority of the signatories to bind such corporation. A proxy shall be drawn up in the form specified hereunder. The Company secretary or the board of directors of the Company may, at their discretion, accept a proxy in a different form, including in the English language, provided that the variations are not fundamental. The Company will only accept an original proxy or a copy of the proxy, provided that the same is duly authenticated by a notary or by an attorney at law holding an Israeli license.

Proxy

To: **Date: _____**
[Name of Company
Corporate address:]
Dear Sir or Madam;

Re: Annual / special general meeting of _____ (the "Company")
to be held on _____(The "Meeting")

I the undersigned _____, Identity Card/Registration No. _____, of _____Street _____ being the registered holder of _____(*) ordinary shares of NIS____ par value each, hereby empower _____ Identity Card No. (**)_____ and/or _____ Identity Card No. _____and/or _____Identity Card No. _____to participate in and vote on my behalf and instead of me at the aforementioned meeting and at any adjourned meeting of the aforesaid meeting of the Company/at any general meeting of the Company, until I notify you otherwise.

_____
Signature

(*) A registered shareholder may issue a number of proxies, each of them in reference to another quantity of shares of the Company held by him, provided that he shall not issue proxies for a quantity of shares that is greater than the quantity of shares held by him.

(**) In the event that the proxy does not hold an Israeli Identity Card, both the passport number and the country of its issue shall be stated instead.

18.3 Validity of Proxy

A vote in accordance with a proxy shall be lawful even if the appointing party has previously died or has become legally incapacitated or has become bankrupt or, in the event of a corporation - has been wound up, or has cancelled the proxy, or transferred the share in respect of which it was given, other than if notification in writing that such an event has occurred has been received at the registered office of the Company prior to the meeting.

18.4 Disqualification of Proxies

Subject to the provisions of any law, the Company secretary will be entitled at his discretion, to disqualify proxies if a reasonable concern exists that they are forged or that they have been furnished in respect of shares for which other proxies have been issued.

18.5 Voting by Voting Papers

In accordance with these Articles and the provisions of the Companies Law and the regulations enacted thereunder, the Company shareholders shall be given the option to vote at general meetings of the Company by means of voting papers, on all such matters as are obligatory by law as well as on such matters in respect of which the board of directors shall decide from time to time to allow a vote by means of voting papers.

Chapter Four - The Board of Directors

19. **Appointment of Directors and Termination of Their Office**

19.1 The number of directors - the number of directors of the Company shall not be less than five (5) and not more than seven (7) (not including the outside directors whose appointment is required under law), unless otherwise decided by the general meeting by a majority of 75%.

19.2 Appointment of Directors at an Annual Meeting and their Replacement

19.2.1 The Company directors serving in office (who are not outside directors), will be divided into three groups, one third each, which will hereinafter be referred to as: the "**First third to the Third Third**"). If the number of directors is not a multiplication of three, each of the two groups - the first third to the second third - will include another number, being a number which is closest to and more than a third, while the group of the third third will consist of the remaining directors (who are not outside directors). The initial division into thirds will be carried out pursuant to the board of directors' resolution with respect to such division, and the rule that will apply is that the division be carried out in accordance with the director's seniority on the board of directors, the most senior directors being included in the first third, and so forth. Should the number of directors vary, the number of directors in each group will vary in accordance with the aforesaid rule.

19.2.2 At the first annual meeting of the Company shareholders to be held after the Company has become a public company (in 2011), the office of the directors included in the first third will terminate and they will be put up for re-appointment at that meeting.

At the second annual meeting of the Company shareholders to be held after the Company has become a public company (in 2012), the office of the directors included in the second third will terminate and they will be put up for re-appointment at that meeting.

At the third annual meeting of the Company shareholders to be held after the Company has become a public company (in 2013), the office of the directors included in the third third will terminate and they will be put up for re-appointment at that meeting.

At the three subsequent annual general meetings the aforesaid mechanism will reapply, and so on and so forth.

Any director elected as aforesaid, will be elected for a three-year term (unless his office is terminated in accordance with the provisions of these Articles), so that every year the office of a group of one third of the board of directors will terminate, as aforesaid.

The elected directors shall assume their office commencing from the end of the meeting at which they were elected unless a later date is stipulated in the resolution on their appointment.

19.2.2 The appointment of members of the board of directors (who are not outside directors), will be carried out by the shareholders present at the meeting, in person or by proxy, or by means of a voting paper, by a simple majority of the votes of the shareholders as aforesaid.

19.2.4 If a director who was put up for re-appointment at the general meeting convened to deliberate same is not re-elected, the Company will convene another general meeting, at which another proposed director will be put up for the approval of the meeting. Notwithstanding the foregoing, the office of the director who has not been re-appointed or his alternate (insofar as he has appointed an alternate in accordance with the provisions of these Articles), will expire on the earlier of: (1) The additional general meeting as aforesaid; or (2) seventy days from the date of the annual general meeting as aforesaid in Sub-Article 19.2.2 above. It shall further be clarified that a director appointed as aforesaid will belong to the group of the third to which the director he replaced belonged, so that his office will expire on the date of the general meeting at which the office of the other directors of that third group will expire.

19.2.5 The general meeting may, at any time, by a majority of 75%, dismiss a director and it may decide at that time to appoint another person in his place by a majority of 75%. A director whose dismissal is on the agenda of the meeting will be given a reasonable opportunity to present his position before such meeting.

19.2.6 A special meeting of the Company may appoint directors for the Company *in lieu of* directors whose office has terminated and also in any case in which the number of members of the board of directors falls below the minimum that has been stipulated in these Articles or by the general meeting by a majority of 75% of the shareholders' votes. It should be clarified that a director appointed as aforesaid will belong to the group of the third to which the director he replaced belonged, so that his office will expire on the date of the general meeting at which the office of the other directors of that third group will expire.

19.2.7 The foregoing provisions of Sub-Articles 19.2.1 - 19.2.6 shall not apply to the appointment and term in office of outside directors, in respect of whom the provisions of the Companies Law shall apply.

19.2.8 Subject to the provisions of the law in relation to the expiry of the office of a director, but notwithstanding the provisions of Section 230 of the Companies Law, the office of a director shall not be terminated, other than as provided in this Article.

19.3 Appointment of Directors by the Board of Directors

The board of directors may appoint a director or additional directors for the Company, whether in order to fill an office that has become vacant for any reason whatsoever or whether in the capacity of a director or additional directors, provided that the number of directors shall not exceed the maximum number of members of the board of directors. Any director so appointed shall serve up to the first annual meeting held subsequent to his appointment. In the event that the number of directors has fallen below the minimum number of directors, as prescribed in Sub-Article 19.1 above, the remaining directors may only act to convene a general meeting of the Company for the purpose of appointing the vacant positions of directors and up to the date of such meeting, act to conduct the Company's affairs in connection with matters that are pressing.

19.4 Date of Commencement of the Office of a Director - the elected directors shall assume their offices commencing at the end of the general meeting at which they were elected or on the date of their appointment by the board of directors as provided above in Sub-Article 19.3, as the case may be, unless a later date is prescribed in the resolution on their appointment.

19.5 Alternate Director - subject to the provisions of the law, a director may from time to time appoint an alternate director for himself (hereinafter: "**alternate director**"), dismiss such an alternate director, and may also appoint another alternate director *in lieu of* any alternate director whose office has been vacated for any reason, either for a specific meeting or permanently.

19.6 A Director's Proxy - any director and any alternate director may appoint a proxy who shall participate and vote in their name at, any meeting of the board of directors or of a board of directors' committee. Such an appointment may be general or for the purpose of one or a number of meetings. Where a director or an alternate director is present at such a meeting the proxy may not vote *in lieu of* the director who appointed him. Such an appointment shall be valid in accordance with the contents thereof or until its revocation by the appointor. A director or an alternate director of the Company may serve as a proxy as aforesaid.

19.7 Termination of the Office of a Director - in the event of a director's position becoming vacant, the remaining directors may continue acting for as long as the number of remaining directors does not fall below the minimum number of directors that has been determined in these Articles or prescribed by the general meeting. If the number of directors has fallen below the foregoing, the remaining directors may only act in order to convene a general meeting of the Company.

19.8 Holding a Meeting by means of Communication and Without Convening

At a meeting that has been held by the use of any means of communication, it is sufficient that all of the directors who are entitled to participate in the proceedings and in a vote, shall be able to hear each other.

The board of directors may also pass resolutions without actually convening, provided that all of the directors who are entitled to participate in the discussion and to vote on the matter put forward for resolution have agreed not to meet to discuss such matter. Where resolutions have been passed as aforesaid, minutes of such resolutions shall be prepared, including the resolution not to convene and shall be signed by the chairman of the board of directors. The provisions of these Articles shall apply *mutatis mutandis* to such a resolution. A resolution that has been passed in accordance with this Article shall be valid in all respects as though it had been passed at a duly convened and conducted meeting of the board of directors.

19.9 Remuneration of Members of the Board of Directors - subject to the provisions of the Companies Law the Company may remunerate the Directors for fulfilling their functions as directors.

20. **Chairman of the Board of Directors**

20.1 Appointment - the board of directors shall elect one of its members to serve as chairman of the board of directors and will also designate the term in which he is to serve in his office, in the appointing resolution. If not stipulated otherwise in the resolution as to his appointment, the chairman of the board of directors shall serve in such capacity until another person is appointed in his place or until he ceases serving as a director, whichever is the earlier.Where the chairman of the board of directors has ceased serving in office as a director of the Company, the board of directors, at the first board of directors meeting held subsequently, shall elect a new chairman.

20.2 No Casting Vote - In the event of a tie of votes in a resolution of the board of directors, neither the chairman of the board of directors nor any person that has been elected to conduct the meeting, shall have an additional vote.

21. **Directors' Actions**

21.1 Convening a Meeting of the Board of Directors

Any notification of a meeting of the board of directors may be given verbally or in writing provided that such notification is given at least three business days prior to the date designated for the meeting, unless at least 75% of the members of the board of directors, their alternates or their proxies have agreed to shorten the said period of time. The aforesaid notwithstanding, the board of directors may convene for a meeting without notice only in urgent cases and with the consent of a majority of the directors.

Notification as aforesaid shall be given in writing, by facsimile, by electronic mail or by other means of communication and all to such address or the facsimile number, electronic mail address or the address to which notifications can be sent by other means of communication, as the case may be, which the Director furnished to the Company upon his appointment, or in a subsequent written notification to the Company and shall include reasonable details regarding the issues brought up for discussion at the meeting

Where an alternate or a proxy has been appointed, notification shall be given to such alternate or proxy unless the director has given notice that he wishes that notice shall also be given to him.

21.2 Quorum - the quorum for meetings shall be a majority of members of the board of directors who are not precluded by law from participating in a meeting, or any other quorum as will be prescribed by a majority of the members of the board of directors from time to time.

21.3 Validity of Actions of the Directors in the case of a Disqualified Director - All such actions as have been taken in good faith at a meeting of the board of directors or by a committee of the board of directors or by any person acting as a director shall be valid, even if it is subsequently discovered that there was a flaw in the appointment of a director or of such a person acting as aforesaid, or that they or one of them was disqualified, as though such a person had actually been duly appointed and was qualified to be a director.

21.4 Committees of the Board of Directors

Subject to the provisions of the Companies Law, the board of directors may appoint board of directors' committees.

The committees of the board of directors shall report to the board of directors their resolutions or recommendations on a regular basis, as shall be prescribed by the board of directors. The board of directors may cancel the resolution of a committee that has been appointed by it; however, such cancellation shall not affect the validity of any resolution of a committee, pursuant to which the Company acted, *vis-à-vis* another person, who was not aware of the cancellation thereof. Decisions or recommendations of the committee of the board of directors which require the approval of the board of directors will be brought to the directors' attention a reasonable time prior to the discussion at the board of directors.

22. **Validity of Actions and Approval of Transactions**

22.1 Subject to the provisions of any law, all such actions as have been taken by the board of directors or by a committee of the board of directors or by any person acting as a director, or as a member of a committee of the board of directors, or by the general manager, as the case may be, shall be valid even if it is subsequently discovered that there was any flaw in the appointment of the board of directors, a committee of the board of directors, the director who was a member of the committee or the general manager, as the case may be, or that any of the aforesaid officeholders was disqualified from serving in his position.

22.2 Subject to the provisions of the Companies Law:

22.2.1 If a person holds shares in the Company and if a person is an officeholder of the Company, a stakeholder, or an officeholder of any other corporation, including a corporation in which the Company is a stakeholder, or which is a shareholder of the Company, it shall not disqualify the officeholder from serving as an officeholder of the Company. Likewise, an officeholder shall not be disqualified from serving as an officeholder of the Company due to his contractual engagement or due to the contractual engagement of any corporation as aforesaid with the Company in any matter whatsoever and in any manner whatsoever.

22.2.2 The office of a person as an officeholder in the Company shall not disqualify him and/or a relative of his and/or another corporation in which he is a stakeholder from entering into transactions in which the officeholder has a personal interest in any way with the Company.

22.2.3 An officeholder may participate in and vote at discussions in respect of the approval of transactions or acts in which he has a *prima facie* personal interest, as prescribed in Sub-Articles 22.2.1 and 22.2.2.

22.3 Subject to the provisions of the Companies Law, a general notice that is given to the board of directors by an officeholder or a controlling shareholder of the Company with regard to his personal interest in a particular entity, while giving details of his personal interest, shall amount to disclosure on the part of the officeholder or the controlling shareholder to the Company with regard to his personal interest as aforesaid, for the purpose of the entering into any transaction which is not exceptional, with such an entity.

Chapter Five – Officeholders, Secretary, Internal Auditor and Auditor

23. **General Manager**

23.1 The board of directors may, from time to time, appoint a general manager for the Company and may further appoint more than one general manager. The board of directors may further dismiss the general manager or replace him at any time it deems fit, subject to the provisions of any agreement between him and the Company. The general manager will be responsible for the day-to-day management of the Company's affairs within the framework of the policy determined by the board of directors and subject to its directives.

23.2 The general manager will have all the powers of management and performance that were vested, pursuant to the Law or these Articles, or by virtue thereof, in another organ of the Company, apart from such powers as have been transferred from him to the board of directors. The general manager will be supervised by the board of directors.

23.3 The general manager may, subject to the approval of the board of directors, delegate some of his powers to another, who is his subordinate; the approval may be general and in advance.

23.4 Without derogating from the provisions of the Companies Law and any law, the general manager will submit to the board of directors, reports on such issues, on such dates and in such scope as shall be determined by the board of directors, either by means of a specific resolution or within the ambit of the board of directors' procedures.

23.5 The general manager will give notice to the chairman of the board of directors, without delay, of any exceptional matter that is material to the Company. If the Company has no chairman of the board of directors or if the chairman of the board of directors is unable to fulfill his function, the general manager will give a notice to that effect to all members of the board of directors.

23.6 The general manager may from time to time appoint officeholders for the Company (apart from directors and general manager), for permanent, temporary or special functions, as the general manager finds fit and the general manager may further terminate the services of one or more of the foregoing at any time.

24. **Internal Auditor**

24.1 The Company's board of directors will appoint an internal auditor, at the recommendation of the audit committee.

24.2 The officer in charge of the internal auditor at the organization will be the chairman of the board of directors.

24.3 The internal auditor will submit for the approval of the audit committee a proposed annual or periodic work plan and the audit committee will approve it with such amendments as it finds fit.

25. Secretary

The board of directors may appoint a Company secretary, on such terms as it shall deem appropriate, and appoint a deputy secretary and determine the scope of their functions and their authorities. Where a Company secretary has not been appointed, the general manager, or whoever he designates to this end, and in the absence of a general manager, whoever is empowered for such purpose by the board of directors, shall perform the secretary's functions that are prescribed under any law, in accordance with these Articles and in accordance with a resolution of the board of directors.

The Company secretary will be responsible for all the documents that are kept at the registered office of the Company and for maintaining all the registers that the Company maintains by law.

26. **Auditor**

26.1 Subject to the provisions of the Companies Law, the general meeting may appoint an auditor for a period that exceeds one year, as the general meeting shall decide.

26.2 The board of directors, following receipt of the audit committee's or the financial statement committee's (as determined by the board of directors) recommendations shall determine the remuneration of the Company's auditor for audit work as well as his remuneration for other services that are not audit work, unless otherwise determined by the general meeting of the Company.

Chapter Six - Preservation of the Capital of the Company and its Distribution

27. **Distribution and Allocation of Bonus Shares**

The Company's resolution on distribution of dividend, bonus shares or any other distribution, including any distribution that does not comply with the profit test prescribed in the Companies Law and the terms thereof, shall be passed by the board of directors of the Company.

28. **Dividends and Bonus Shares**

28.1 Right to a Dividend or to Bonus Shares

28.1.1 A dividend or bonus shares shall be distributed to whoever is registered in the register of shareholders of the Company on the date of the resolution as to such distribution or on such other date as shall be prescribed in such resolution. [4]

28.2 Payment of the Dividend

28.2.1 The board of directors may resolve that the dividend be paid, in whole or in part, in cash or by means of distribution of assets in kind, including in securities or in any other manner, at its discretion.

The Company's board of directors may, before resolving to distribute any dividend, allocate out of the profits, any amounts as it shall deem fit for a general fund or a reserve fund for the distribution of dividend, distribution of bonus shares or for any other purpose whatsoever, as the board of directors shall resolve at its discretion.

Pending the realization of the said funds, the board of directors may invest any sums so allocated and the monies in the funds in any investment whatsoever, as it shall deem fit, deal with such investments, alter them or make any other use thereof, and it may subdivide the reserve fund into special funds and use any fund or any part thereof for the Company's affairs, without holding it separately from the other assets of the Company, all at the discretion of the board of directors and under such terms as it shall determine.

28.2.2 The Method of Payment[5]

If no other provisions have been prescribed in the resolution as to distribution of the dividend it will be permissible to pay any dividend, after deduction of the requisite tax under any law, by check to the beneficiary only, which shall be sent by registered mail to the registered address of the shareholder that is entitled to it, or by bank transfer. Any such check shall be drawn in favor of the person to whom it has been sent. A dividend in kind shall be distributed as stipulated in the distribution resolution.

In the event of joint registered shareholders, the check shall be sent to the shareholder whose name is recorded first in the register of shareholders in relation to the joint ownership.

Sending of a check to a person whose name, on the effective date, is registered in the register of shareholders as the holder of a share, or in the event of joint holders - of one of the joint holders, shall constitute discharge in respect of all the payments made in relation to such share.

[4] It shall be clarified that so long as the Company shares are listed for trading on the Stock Exchange, any dividend or bonus shares will be distributed to whoever is registered in the register of shareholders of the Company on the effective date determined on the date of the resolution.

[5] It should be clarified that so long as the Company shares are listed for trading on the Stock Exchange the provisions of this Sub-Article 28.2.2 shall not apply.

The Company may resolve that a check below a certain amount, shall not be sent and amounts of the dividend that should have been paid as aforesaid shall be treated as unclaimed dividend.

The Company may offset against the dividend to which a shareholder is entitled, any debt of such shareholder to the Company, whether or not the time for payment thereof has fallen due.

28.2.3 Unclaimed Dividend

The board of directors may invest any amount of dividend that has not been claimed for a period of one year after having been declared, or use it otherwise for the benefit of the Company until it is claimed. The Company will not be compelled to pay interest or linkage in respect of an unclaimed dividend.

After one year has elapsed from the due date of any unclaimed dividend, the Company may use the unclaimed dividend as aforesaid for any purpose whatsoever and the shareholder who is entitled to such unclaimed dividend will have no claim and/or demand in relation thereto.

28.3 Method of Capitalization of Profits into Capital Funds and Distribution of Bonus Shares

28.3.1 Funds

The board of directors may, at its discretion, set aside into special capital funds, any amount out of the Company's profits, or arising from a revaluation of its assets, or its *pro rata* stake in the revaluation of assets of its affiliated companies and determine the designation of such funds. The board of directors may also cancel such funds.

28.3.2 Distribution of Bonus Shares – Subject to the provisions of the Companies Law, the board of directors may resolve to allocate bonus shares and render share capital as part of the Company's profits, within the meaning thereof in Section 302 (b) of the Companies Law, from premium on shares or from any other source contained in its equity, referred to in its last financial statements, in such sum as shall be determined by the board of directors and which shall not fall below the nominal value of the bonus shares.

Allocated bonus shares shall be deemed as fully repaid.

The board of directors resolving to allocate bonus shares may resolve that the Company will transfer to a special fund designated for future distribution of bonus shares, such amount as the rendering thereof into share capital will be sufficient to allocate to whoever, at that time, for any reason whatsoever, has a right to purchase shares in the Company (including a right exercisable only on a subsequent date), bonus shares which would have been due to him had he exercised the right to purchase the shares on the eve of the effective date for the right to receive the bonus shares (hereinafter, in this Article: the "**effective date**"). If after the effective date, the holder of the said right should exercise his right to purchase all or any of the shares, the Company will allocate bonus shares to him, having a par value and to which he would have been entitled had he exercised the right to purchase the shares which he actually purchased, on the eve of the effective date. The bonus shares will entitle their owners to participate in distribution of dividends as of the date designated by the board of directors. For the purpose of determining the amount to be transferred to the said special fund, any amount transferred to this fund for previous distributions of bonus shares shall be treated as having already been capitalized, where shares entitling the holders of the right to purchase shares, have been allocated therefrom, for bonus shares.

For the purpose of distribution of bonus shares, the board of directors may, as it sees fit, resolve any difficulty that might arise and make adjustments, such as deciding that fractions of a share shall not be distributed, issue certificates in respect of an aggregate quantity of share fractions, sell such fractions and pay the proceeds from the sale thereof to those entitled to receive the fractions of the bonus shares and may also decide that cash payments shall be made to the shareholders, or that fractions of a lesser value than a stipulated amount (and if not stipulated then amounts which are less than NIS 50) shall not be brought into account in making such adjustments. Notwithstanding the foregoing, a shareholder will be entitled to apply to the Company and ask that such payment be made to him at the Company's offices.

29. **Acquisition of Company Shares**

The Company may acquire its own securities. Where the Company has acquired securities as aforesaid it may cancel them.

Chapter Seven - Exemption, Indemnification and Insurance of Officeholders

30. **Exemption of Officeholders**

The Company may exempt an officeholder therein, in advance or *post factum,* from some or all of his liability for damage as a result of breach of a duty of care *vis-à-vis* the Company, to the maximum extent that is permissible under any law.

31. **Indemnification of Officeholders**

The Company may indemnify its officeholders to the maximum extent permissible under any law. Without derogating from the generality of the foregoing, the following provisions shall apply:

31.1 The Company may indemnify an officeholder therein in respect of a liability, payment or expense imposed on him or that he has incurred as a result of an action, which he took by virtue of his being an officeholder of the Company, as follows:

31.1.1 Any financial liability imposed on him in favor of another person under a judgment, including a judgment entered under a settlement or an award approved by a court.

31.1.2 Reasonable litigation fees, including lawyer's fee, incurred by the officeholder due to any investigation or proceeding conducted against him by any authority competent to conduct an investigation or proceeding, at the end of which no indictment was filed against him and no financial liability was levied on him as an alternative for a criminal proceeding, or at the end of which no indictment was filed against him but a financial liability was levied as an alternative for a criminal proceeding in an offense not requiring proof of *mens rea* or in connection with a monetary sanction.

31.1.3 Reasonable litigation expenses, including lawyer's fees paid by the officeholder, or with which he was charged by the Court, in a proceeding filed against him by the Company or on its behalf or by any other person, or in criminal charges from which he was acquitted, or in criminal charges in which he was convicted of an offense which does not require proof of *mens rea*.

31.1.4 A payment for the party harmed by the breach, as aforesaid in Section 52(54)(a)(1)(a) of the Securities Law (the "**Party Harmed by the Breach**").

31.1.5 Expenses incurred by an officer in connection with an Administrative Proceeding conducted in his matter, including reasonable litigation expenses, including legal fees.

31.1.6 Any other liability or expense for which it is permitted and/or will be permitted by law to indemnify an officeholder.

31.2 Advance Indemnification

The Company may give an undertaking in advance to indemnify an officeholder for a liability, payment or expense as specified above in Sub-Article 31.1.1., provided that such advance indemnity undertaking shall be limited to such events as, in the opinion of the board of directors, are anticipated in view of the Company's actual activity at the time of giving the indemnity undertaking, and to such amount or criterion as the board of directors have determined to be reasonable under the circumstances of the case, and further provided that such undertaking shall state the events that in the opinion of the board of directors are anticipated in view of the Company's actual activity at the time of giving such undertaking as well as the amount or criterion that the board of directors have determined to be reasonable in the circumstances of the case. And the Company may also give an indemnity undertaking in advance to an officeholder in respect of liabilities or an expense as specified in Articles 31.1.2, 31.1.3, 31.1.4, and 31.1.5 above.

31.3 Retroactive Indemnification

The Company may indemnify an officeholder therein *ex post facto*.

32. **Officeholders' Insurance**

32.1 The Company may insure its officeholders to the maximum extent permitted under any law. Without derogating from the generality of the foregoing, the Company may enter into a contract for insuring the liability of an officeholder in the Company in respect of a liability or a payment that may be imposed on him as a result of an action that he has taken in his capacity as officeholder in the Company, in any of the following cases:

32.1.1 Breach of the duty of care to the Company or to any other person;

32.1.2 Breach of a fiduciary duty *vis-à-vis* the Company, provided that the Officeholder acted in good faith and had reasonable grounds to assume that his act would not compromise the Company's best interests;

32.1.3 Financial liability imposed on him in favor of another person;

32.1.4 Payment to the Party Harmed by the Breach;

32.1.5 Expenses incurred by an officer in connection with an Administrative Proceeding conducted in his matter, including reasonable litigation expenses, including legal fees;

32.1.6 Any other event for which it is permitted and/or will be permitted pursuant to the law to insure the liability of an officeholder.

33. **Exemption, Indemnification and Insurance - General**

33.1 It is neither the intention of the foregoing provisions in relation to exemption, indemnification and insurance, nor will there be any future intention, to restrict the Company in any way from entering into a contract in relation to exemption, insurance or indemnification of the parties specified hereunder:

33.1.1 A person who is not an officeholder of the Company, including employees, contractors or consultants of the Company who are not officeholders of the Company;

33.1.2 Officeholders in other companies. The Company may enter into a contract in relation to exemption, indemnification and insurance of officeholders in companies under its control, related companies and other companies in which it has any interest, to the maximum extent permitted under any law, and in this context the foregoing provisions in relation to exemption, indemnification and insurance of officeholders in the Company shall apply, *mutatis mutandis*.

33.2 It should be clarified that in this Chapter, an undertaking in relation to exemption, indemnification and insurance of an officeholder as aforesaid may also be valid after the office of such officeholder in the Company has terminated.

Chapter Eight - Merger, Winding Up and Reorganization of the Company

34. **Merger**

34.1 The requisite majority for approval of a merger by the general meeting shall be a simple majority.

35. **Liquidation**

35.1 If the Company is wound up, whether voluntarily or otherwise, the liquidator may, with the approval of a general meeting, distribute *in specie* parts of the Company's assets among the shareholders, and he may, with like approval, deposit such part of the Company's assets with trustees for the benefit of the shareholders, as the liquidator, with such approval, shall deem appropriate.

35.2 Subject to special rights of shares, where shares have been issued with special rights, the Company's shares shall have equal rights *inter se* in relation to the amounts of capital that have been paid or that have been credited as paid in respect of the nominal value of the shares, in connection with the surrender of capital and participation in a distribution of surplus assets of the Company upon liquidation.

36. **Reorganization of the Company**

36.1 Upon the sale of assets of the Company, the board of directors, or the liquidators (in the case of liquidation) may, if they have been duly authorized to do so in a resolution that has been passed by a simple majority at the general meeting of the Company, accept shares that are either fully or partially paid up, debentures or securities of another company, either Israeli or foreign, whether it has been incorporated or is about to be incorporated, for the purchase of all or any of the Company's assets, and the directors (if the Company's profits so allow) or the liquidators (in case of a liquidation), may distribute, among the shareholders, the shares or securities as aforesaid or any other assets of the Company without realizing them, or deposit them with trustees on behalf of the shareholders.

36.2 The general meeting may, by a resolution to be passed by the general meeting of the Company by a simple majority, decide as to a valuation of the securities or assets as aforesaid at such price and in such manner as the general meeting shall decide, and all the shareholders will be bound to accept any valuation or distribution that has been authorized as aforesaid and to waive their rights in this context, except, in the event that the Company is about to be wound-up or is in the process of winding-up, for such legal rights (if any) which, under the provisions of the law, cannot be amended, revised, or contracted out.

Chapter Nine - Notifications

37. **Notices**

37.1 A notification or any other document may be delivered by the Company to any shareholder who appears in the register of shareholders of the Company, either personally or by sending by registered mail addressed in accordance with the registered address of such shareholder in the register of shareholders or to such address as the shareholder has notified in writing to the Company as his address for the delivery of notifications, or by publication of notices in two newspapers in Israel, or by means of publishing an immediate report on the Magna system.

37.2 All notices to be given to the shareholders shall, in relation to shares that are jointly held, be given to such person whose name appears first in the register of shareholders and any notification that is given in such manner shall be sufficient notification to all the joint shareholders.

37.3 Any notification or other document which is delivered or sent to a shareholder in accordance with these Articles shall be deemed to have been duly delivered and sent in respect of all the shares held by him (whether as regards Shares held by him alone or by him jointly with others), even where such shareholder has passed away at that time or became insolvent, or an order has been issued for its winding up, or a trustee or liquidator or receiver has been appointed for his shares (whether or not the Company was aware of the occurrence of such event), until another person is registered in the register of shareholders instead of him as the holder thereof, and delivery or sending of a notification or document as aforesaid shall be deemed to be sufficient delivery or dispatch to any person who has a right to such shares.

37.4 Any notification or other document that has been sent by the Company in the mail to an address in Israel shall be deemed to have been delivered within 48 hours from the day on which the letter containing such notification or document was dispatched at the post office or within 96 hours in the event that the address is overseas, and for the purpose of proving delivery, it shall be sufficient to prove that the letter containing the notification or the document was duly addressed and was dispatched at the post office. Any notice or document delivered by means of notifications in newspapers or via an immediate report on the Magna system, will be deemed to have been delivered on the date of publishing the notice or on the date of publishing the immediate report as aforesaid.

37.5 The Company is not obliged to give notice of a general meeting to shareholders except in so far as this is mandatory by law. The notice of a general meeting shall specify the place and the time for the convening of the meeting, its agenda, a summary of the proposed resolutions and any other specification as is required under law.

37.6 Accidental omission in giving notice of a general meeting to any shareholder or non-receipt of a notification as to a meeting or other notification by any shareholder shall not invalidate a resolution that has been passed at such meeting, or cause the invalidation of processes based on such notification.

37.7 Notices to directors may be given in any manner to be determined by the board of directors.

37.8 Any shareholder and any member of the board of directors may waive his right to receive notification, or his right to receive notification within a specific period of time, and may agree that a general meeting of the Company or a meeting of the board of directors, as the case may be, shall convene and be held despite his not having received notification or despite such notification not having been received by him within the required time.

* * *

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMIITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

EXCLUSIVE LICENSE AGREEMENT

THIS EXCLUSIVE LICENSE AGREEMENT is made and entered into as of March, __ 2015 (the "**Effective Date**"), by and between Apogee Biotechnology Corp., a Pennsylvania corporation ("**Apogee**") and RedHill Biopharma Ltd., an Israeli company ("**RedHill**"). Apogee and RedHill each may be referred to herein individually as a "Party," or collectively as the "Parties".

WHEREAS, Apogee represents that it is the sole and exclusive owner of and has the right to grant a license to RedHill in respect of the Licensed Intellectual Property and Technology (as defined below), all on the terms set forth below;

WHEREAS, Apogee wishes to license to RedHill all Apogee's rights in and to ABC294640 and [****] (as those terms are defined below)and all Licensed Intellectual Property and Technology, and RedHill wishes to receive such license from Apogee, to develop and commercialize products for all indications and for all uses, all on the terms set forth below; and

WHEREAS, the license to be granted shall be granted on an exclusive basis as more fully set out below.

NOW THEREFORE, THE PARTIES HERETO AGREE AS FOLLOWS:

1. DEFINITIONS

1.1 For purposes of this Agreement, the following terms shall have the following meanings:

"**ABC294640**" means the small molecule Sphingosine Kinases (SK2) inhibitor which is known as ABC294640, in all formulations, doses, forms and combinations.

[****].

"**Affiliate**" of a person means any other person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such first person. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" will mean the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of fifty percent or more of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity) of the other organization or entity or by contract relating to voting rights or corporate governance, or otherwise.

"**Bankruptcy Event**" means a company (i) becomes insolvent or admits inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within [****] days or is not dismissed or vacated within [****] days after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; or (v) has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

"**Business Day**" means a day that is not a Saturday or Sunday or any other day on which banks in the United States and/or Israel are authorized or required by law to be closed.

"**Combination Product**" means a product which comprises (a) a Product and (b) at least one other active ingredient or medical device, which, if administered or used independently of such Product, would have a clinical, diagnostic or therapeutic effect.

"**Commercialization Partner**" means a Sublicensee primarily responsible for commercial distribution and/or commercial promotion of a Product for sale.

"**Commercially Reasonably Efforts**" means, with respect to the development, regulatory, manufacturing, licensing and commercialization of ABC294640, the efforts and resources that are consistent with those utilized by a similarly situated biopharmaceutical company for its own internally discovered technology of similar commercial potential at a similar stage of development, taking into consideration its safety and efficacy, the cost to develop, the competitiveness of alternative technology, the nature and extent of their market exclusivity, the likelihood of regulatory approval, its profitability and all other relevant factors.

"**Field of Use**" means any and all indications and uses, including therapeutic, diagnostic and other human and/or animal uses.

"**First Commercial Sale**" means the first commercial transaction for which consideration is received by RedHill, its Affiliates or Sublicensees for the sale, use, lease, transfer or other disposition of a Product to or for the benefit of a third party, after Regulatory Approval has been granted by a Regulatory Authority responsible for the jurisdiction in which such first commercial transaction takes place; provided, that First Commercial Sale shall not include a transfer of the Product for testing purposes and/or a sale for experimental, promotional, compassionate named patient or test market purposes.

"**Generic Product**" means, with respect to any Product, any product that (a) is sold by a third party (i.e., other than RedHill or its Affiliates) that is not a Sublicensee of RedHill, under a Regulatory Approval granted by a Regulatory Authority to a third party; (b) is approved for one or more indications that are the same (or substantially the same) as one or more of the indications for which the Product is approved; and (c) is approved in reliance, in whole or in part, on the prior approval (or on safety or efficacy data submitted in support of the prior approval) of the Product as determined by the applicable Regulatory Authority, including any product authorized for sale in the U.S. pursuant to Section 505(b)(2) or Section 505(j) of the Act (21 U.S.C. 355(b)(2) and 21 U.S.C. 355(j), respectively), in the European Union pursuant to a provision of Articles 10, 10a or 10b of Parliament and Council Directive 2001/83/EC as amended (including an application under Article 6.1 of Parliament and Council Regulation (EC) No 726/2004 that relies for its content on any such provision), or in any other country or jurisdiction pursuant to all equivalents of such provisions. A product licensed or produced by RedHill or its Affiliates (i.e., an authorized generic product) will not constitute a Generic Product.

"**Licensed Know-How**" means all right, title and interest of Apogee and/or its Affiliates in and to technology, assets, intellectual property, trade secrets, inventions and invention disclosures and know-how whatsoever, including, for the avoidance of doubt, as is necessary and/or useful in any way whatsoever for the development and/or commercialization of Products in the Field, including ABC294640 and [****] and all analogs, including, all analogs of ABC294640 and all analogs of [****] and all information whether patentable or not and physical objects related to Products or such analogs or that are otherwise necessary or useful to manufacture, have manufactured, and commercialize Products, including product data, product-related results and information, including clinical data, analytical test results, non-clinical pharmacology and safety data, other R&D data, Regulatory Documentation, manufacturing and formulation information of a like nature, copies of external service and other contracts and documentation, information and correspondence relating to the development, marketing approval, marketing, manufacture and other commercialization, all to the fullest extent known to, generated by, vested in (or licensed to) and/or controlled by Apogee and/or any of its Affiliates as of the Effective Date including the classes and types of Licensed Know-how listed in **Annex B** of this Agreement. For the avoidance of doubt, Licensed Know-How does not include the Patents.

"**Licensed Intellectual Property and Technology**" means the Patents and the Licensed Know-How.

"**Net Sales**" means the gross amounts actually received by RedHill or its Affiliates in respect of the sale of a Product by RedHill or its Affiliates, less, and following recovery of, the following items to the extent not already reflected in the gross amounts invoiced (collectively, the "**Recognized Deductions**"):

(i) allowances or credits granted to and taken by customers (including wholesalers) including for damaged product, rejections, returns (including as a result of recalls), in respect of inventory management and stocking allowances and prompt payment and trade, cash and volume discounts;
(ii) amounts incurred resulting from government (or any agency thereof) mandated rebate programs;
(iii) freight, transport, packing, postage and insurance charges;
(iv) taxes, including value added tax, tariffs or import/export or customs, duties;
(v) rebates, charge backs and discounts paid or credited;
(vi) bad debts;
(vii) reasonable quantities of samples if no amounts are invoiced therefor; and any other payment which reduces gross revenue and is permitted to be deducted in calculating net sales in accordance with generally accepted accounting principles.

Even if there is overlap between any of the Recognized Deductions, each individual item shall be deducted only once in the overall Net Sales calculation.

Notwithstanding the foregoing, for the purposes of this definition, the transfer of a Product by RedHill or one of its Affiliates to another Affiliate of RedHill or to a Sublicensee for resale is not a sale.

For Net Sales of a Product sold or supplied as a "Combination Product", the Net Sales of such a Combination Product in a country will be determined by multiplying the Net Sales of such Combination Product in such country by the fraction of A/A+B, where A is the average unit selling price during the period in respect of which Net Sales are being calculated of the Product sold separately in that country and B is the total average unit selling price during the period in respect of which Net Sales are being calculated of the other product or device included in the Combination Product, when sold separately in that country. If neither the Product nor the other product or device included in the Combination Product are sold separately during the period in respect of which Net Sales are being calculated, then the Parties shall, considering the costs incurred by RedHill bringing about the Combination Product, in good faith negotiate the value of the other product or device included in the Combination Product that are to be deducted from the Net Sales of the Combination Product in determining the Net Sales of the Product contained in the Combination Product, it being agreed that absent such mutual agreement as to the proportion of such Combination Product to be attributed to the Product, the Parties shall mutually appoint an independent expert to determine such proportion.

"**Patents**" means all U.S. and non-U.S. patents and patent applications, including those listed in **Annex A**, and (a) any substitutions, divisions, continuations, continuations-in-part (but only to the extent that they cover the same invention claimed in the foregoing), reissues, renewals, registrations, confirmations, re-examinations, extensions, supplementary protection certificates and the like, and any provisional applications, of any such U.S. and non-U.S. patents or patent applications, (b) any patents issuing from any applications filed after the Effective Date and that claim priority from any of the aforesaid patents or patent applications or from which any of such patents or patent application claim priority, in respect of all of which Apogee or any of its Affiliates is as of the date of this Agreement or during the term of this Agreement becomes owner or controller.

"**person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

"**Product(s)**" means any product, including ABC294640 and [****], and all analogs, including, all analogs of ABC294640 and all analogs of [****], in each case in all current and future formulations, doses, forms and combinations whatsoever, for human and animal use, the manufacture, use, offer for sale, sale or importation of which by RedHill would, absent the License (as defined below), infringe a Valid Claim in a jurisdiction in the Territory where such a Valid Claim exists.

"**Regulatory Approval**" means (a) in the United States approval by the US FDA of an NDA (New Drug Application), or the equivalent application for marketing approval, and satisfaction of any related applicable US FDA registration and notification requirements (if any) and (b) in a market other than the United States, approval by regulatory authorities having jurisdiction over such country of a single application or set of applications equivalent to an NDA and satisfaction of any related applicable regulatory and notification requirements (if any).

"**Regulatory Authority**" means any applicable government entity regulating or otherwise exercising authority with respect to the development and commercialization of a Product.

"**Regulatory Documentation**" means all applications, registrations, licenses, authorizations and approvals (including all Regulatory Approvals), all correspondence submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority), all supporting documents and all clinical studies and tests, including the manufacturing batch records for Product to be assigned, relating to a Product, and all data contained in any of the foregoing, including all regulatory drug lists, advertising and promotion documents, adverse event files and complaint files.

"**Regulatory Exclusivity**" means, with respect to any country, an additional market protection, other than Patent protection, granted by a Regulatory Authority in such country which confers an exclusive commercialization period during which RedHill, its Affiliates or its Sublicensees have the exclusive right to market, price, and sell a Product in such country through a regulatory exclusivity right, such as new chemical entity exclusivity, new use or indication exclusivity, new formulation exclusivity, orphan drug exclusivity, pediatric exclusivity, or any applicable data exclusivity.

"**Royalty Term**" means the period, on a country by country and Product by Product basis, commencing on the date of the First Commercial Sale in such country and ending on the later of:

(i) the expiration of the last to expire Patent [****] that covers a Product in such country, [****]; and

(ii) in a country that provides Regulatory Exclusivity for a Product, the expiration of such Regulatory Exclusivity.

"**Sublicense**" means a sublicense from RedHill or its Affiliates to any other person under the License granted pursuant to this Agreement and the term "**Sublicensee**" shall be construed accordingly and shall include any Commercialization Partner. Any Sublicense may include the right to grant further Sublicenses. For the avoidance of doubt, a RedHill Affiliate shall not be considered a Sublicensee.

"**Sublicense Consideration**" means all consideration actually received in respect of a Product by RedHill or its Affiliates from Sublicensees, including payments (x) as upfront or milestone payments in respect of a Sublicense ("**Sublicense Milestone Consideration**") and (y) as royalties on account of sales of a Product effected by such Sublicensees, including, as to Commercialization Partners, purchase price paid and all other consideration by them to RedHill or its Affiliates for Product ("**Sublicense Sales Consideration**"), excluding in all instances, (i) loan proceeds paid to RedHill by a Sublicensee in an arms'-length, full recourse debt financing to the extent that such loan is not forgiven; and (ii) equity (and conditional equity, such as warrants, convertible debt and the like) investments in RedHill or any Affiliate thereof by a Sublicensee up to the amount of the fair market value of the equity purchased on the date of the investment; (iii) patent prosecution costs incurred or which shall be incurred by RedHill; (iv) the cost and financing of research and/or development activities or services performed or to be performed by RedHill or expended or to be expended by RedHill; and (v) marketing expenses which have been or shall be expended by RedHill.

"**Valid Claim**" means a claim of any issued and unexpired patent included in the Patents whose validity, enforceability, or patentability has not been affected by any of the following: (a) lapse, abandonment, revocation, dedication to the public, or disclaimer; (b) a holding, finding, or decision of invalidity, unenforceability, or non-patentability by a court, governmental agency, national or regional patent office, or other appropriate body that has competent jurisdiction; or (c) admission of invalidity or unenforceability through reissue, disclaimer or otherwise. If a claim of a pending patent application has not been issued as a claim of an issued patent within five (5) years after the earliest priority date for such claim, then such claim shall cease to be a Valid Claim unless and until such claim becomes an issued claim of an issued patent.

"**Territory**" means the entire world.

1.2 **Interpretation**. As used in this Agreement, any reference to gender shall include all genders and any reference to the plural shall include the singular, and the singular shall include the plural. When a reference is made in this Agreement to a section, such reference shall be to a section of this Agreement, unless otherwise clearly indicated to the contrary. Whenever the words "include," "includes" or "including" are used in this Agreement they shall be deemed to be followed by the words "without limitation." The words "hereof," "herein" and "herewith" and words of similar import shall, unless otherwise stated, be construed to refer to this Agreement as a whole and not to any particular provision of this Agreement, and annex, article, section, paragraph, exhibit, annex and schedule references are references to the annex, articles, sections, paragraphs, exhibits, annexes, and schedules of this Agreement, unless otherwise specified. The captions contained in this Agreement are for convenience only and shall not be deemed a part hereof or affect the interpretation or construction of any provision hereof.

2. LICENSE GRANT

2.1 **Scope of License**. Subject to the terms and conditions of this Agreement, Apogee hereby grants to RedHill an exclusive (including as to Apogee itself), worldwide and, subject to the termination rights herein, irrevocable and perpetual, license under the Licensed Intellectual Property and Technology (the "**License**").

2.2 **Sublicenses**. The License is Sublicensable (and further Sublicensable, including through multiple tiers) in whole or in part, to third parties in accordance with the terms of this Agreement. The granting of Sublicenses shall be at RedHill's sole and exclusive discretion and RedHill shall have the sole and exclusive power to determine the identity of any Sublicensee, the applicable licensee fees or royalty rates, if any, and other terms and conditions of any Sublicense. For the avoidance of doubt, RedHill shall be entitled to conduct or to perform any activity in respect of a Product by means of any third party sub-contractor, and such conduct, in and of itself, shall not automatically be considered to be a grant of a Sublicense hereunder. RedHill shall have the right to exercise such License through its Affiliates, provided, however, that RedHill shall remain responsible for the compliance by its Affiliates with the applicable terms of this Agreement. For the avoidance of doubt, the payment obligations with respect to RedHill shall apply in the same manner to each Affiliate, and as a result, Net Sales shall include Net Sales by an Affiliate and the occurrence of any milestone with respect to an Affiliate shall trigger the same milestone payment obligations as would be applicable if such milestone had occurred with respect to RedHill.

2.3 **Registration**. RedHill shall have the right, on its own account and at its own expense, to register as the exclusive licensee of the rights in and to the Licensed Intellectual Property and Technology for the purpose of developing, manufacturing, commercializing, making, using, selling, offering for sale and importing Products in the Territory and Apogee shall, at the sole expense of RedHill, execute all documentation reasonably requested by RedHill and otherwise cooperate with RedHill in order to ensure such registration.

2.4 **Limitations on Other Licenses**. During the Term, Apogee shall not, without RedHill's prior written consent, grant any rights or licenses or transfer any data or know-how to any third party that conflict with the RedHill's rights granted under this Agreement.

3. DATA AND PRODUCT TRANSFER

3.1 **Know-How**. Following the Effective Date in accordance with the schedule annexed hereto as **Annex C**, Apogee will (i) make reasonably available to RedHill the Licensed Know-How, and (ii) provide to RedHill either hard or electronic copies, with such medium determined at Apogee's discretion, of the Licensed Know-How, as shall be reasonably necessary for RedHill to develop, manufacture and commercialize Products in accordance with the License granted under this Agreement. Following the Effective Date, Apogee will, at no cost to RedHill, provide RedHill with all additional information under its control relating to Products, including commercially reasonable assistance in replying to inquiries by RedHill in respect of the information and data provided and exercise of the License and otherwise in connection with the development of Products.

3.2 **Product**. Within [****] Business Days following the Effective Date, Apogee will transfer to RedHill Ex Works Apogee's plant (Incoterms 2000), at no cost to RedHill other than reasonable transportation costs approved in advance by RedHill from such Ex Works point, no less than [****] owned by or in the possession of Apogee. It is expressly agreed that, subject to the relevant provisions of this Agreement regarding RedHill's overall control and responsibility for all development activities, but notwithstanding the License granted hereunder, any remaining portion of [****] (active ingredients and excipients in all forms, both expired and unexpired, as well as such finished product, both expired and unexpired) in the possession or control of Apogee at the Effective Date, may be used and are dedicated solely to Apogee's planned [****], provided such [****] are mutually agreed upon by the Parties, it being understood that RedHill will be the [****]. It is further agreed that in the event Apogee and/or an [****], RedHill agrees to use commercially reasonable efforts to manufacture and provide [****]. For the avoidance of doubt, [****].

3.3 Without derogating from any other obligations of Apogee under this Agreement, Apogee shall provide RedHill with timely ongoing quarterly reports regarding all studies, [****] and other activities conducted by Apogee with ABC294640 and [****].

3.4 **General Assistance**. Following the Effective Date and throughout the development process, to the extent reasonably necessary for RedHill to develop, manufacture and commercialize Products in accordance with this Agreement, Apogee will provide RedHill with commercially reasonable general assistance, cooperation, guidance and the like, including making its employees reasonably available for consultation and in replying to inquiries by RedHill in respect of the Licensed Know-How provided and reasonable cooperation with RedHill and support of RedHill's submissions of Product for approval with any and all Regulatory Authorities.

3.5 **Technical Transfer Assistance.** To the extent reasonably necessary for RedHill to develop, manufacture and commercialize Products in accordance with this Agreement, Apogee undertakes to provide reasonable assistance to RedHill in sharing technical information included within the Licensed Know-How to a contract manufacturing organization chosen by RedHill. For the avoidance of doubt, RedHill may share all such assistance with its Sublicensees.

3.6 **Consideration.** In consideration of the agreements of Apogee pursuant to Section 3.4 and Section 3.5, Apogee will be compensated according to a rate and expense reimbursement budget to be pre-approved (in writing) by RedHill.

4. DILIGENCE

4.1 **Authority; Obligations**. Following the Effective Date, RedHill shall have sole authority for the development, regulatory, manufacturing, licensing and commercialization of Products in the Field in the Territory. Notwithstanding the foregoing, RedHill will make a good faith, continuous and diligent effort using Commercially Reasonable Efforts to prepare, initiate and complete the clinical development of ABC294640 in accordance with relevant industry standards, obtain and maintain regulatory approvals necessary to commercialize ABC294640 for application for at least one indication in a jurisdiction chosen by RedHill in its sole discretion, and promptly after receipt of such regulatory approval in each applicable market, manufacture, market, promote and sell such Product in each such market as chosen by RedHill in its sole discretion, all in accordance with relevant industry standards (the "**Diligence Obligation**"), all subject to the termination provisions of this Agreement. For the avoidance of any doubt, the failure to meet the Diligence Obligation due to reasons that are beyond RedHill's control do not constitute a breach of the Diligence Obligation. Apogee's sole and exclusive remedy for a breach of the Diligence Obligation by RedHill shall be to terminate this Agreement as provided below.

4.2 **No Warranty**. For the avoidance of doubt, nothing contained in this Agreement shall be construed as a warranty by RedHill that any development or any commercialization to be carried out by it in connection with this Agreement will actually achieve its aims or any other results and RedHill makes no warranties whatsoever as to any results to be achieved in consequence of the carrying out of any such development. Furthermore, RedHill makes no representation to the effect that the commercialization of tany Product, or any part thereof, will succeed, or that it shall be able to sell Products in any quantity.

5. REPORTS

5.1 Until the end of all Royalty Terms, RedHill agrees as follows:

5.1.1 **Development Reports**. To keep Apogee informed with respect to activities and progress regarding the development, commercialization, sublicensing, and government approvals of Products. RedHill will provide written semi-annual development reports within [****] days following the close of each six calendar-month period.

5.1.2 **First Commercial Sale Report**. To report to Apogee the date of the First Commercial Sale of each Product in the first jurisdiction in which it occurs, together with the name of the country in which such First Commercial Sale occurred within [****] Business Days following such First Commercial Sale.

5.1.3 **Royalty Reports**. With respect to each Royalty payment pursuant to Section 6.3, on a calendar quarterly basis within [****] days following the end of each March, June, September and December, to deliver to Apogee written reports with respect to the period covered by the Royalty payment the amount of consideration received from Net Sales, Sublicense Sales Consideration, Sublicense Milestone Consideration, and Sublicense Sales Consideration received from Commercialization Partners, including the Recognized Deductions applicable in computing Net Sales and the deductions applicable in computing Sublicense Consideration, and the total Royalties due based on Net Sales, Sublicense Sale Consideration, Sublicense Milestone Consideration, and Sublicense Sales Consideration received from Commercialization Partners.

5.2 **Confidentiality of Reports**. Any and all information, data or reports supplied by RedHill pursuant to the provisions of this Section 5 shall be treated as RedHill's Confidential Information and subject to the confidentiality obligations set forth in Section 11 of this Agreement.

5.3 **Final Report**. If this Agreement is terminated for any reason during any Royalty Term, RedHill shall deliver a final report and associated Royalty payment to Apogee within [****] days after such termination. Except as provided above, following termination, RedHill shall have no further reporting obligations under this Section 5.

6. FINANCIAL PROVISIONS

6.1 **Up-Front Payment**. Within [****] Business Days after the Effective Date and against receipt of an appropriate invoice from Apogee, RedHill will pay Apogee a non-refundable, up-front, one-time cash license fee of One Million Five Hundred Thousand US Dollars ($1,500,000).

6.2 **Milestone Payments**. RedHill will pay to Apogee the following one-time milestone payments (such payments are due only once in respect of each milestone event actually achieved and are not payable per Product, per indication, per generation or per country) after first achievement of each of the applicable milestones in respect of the first Product achieving such milestone, whether on the part of RedHill or an Affiliate, as follows:

6.2.1 [****] days following *the earlier of* (i) [****] and (ii) [****] following the Effective Date: Two Million US Dollars ($2,000,000).

6.2.2 Within [****] days following [****].

6.2.3 Within [****] days following the [****].

6.2.4 Within [****] days following a [****].

6.3 **Royalty Payments**. During the Royalty Terms, RedHill will pay Apogee royalties (each a "**Royalty**" and collectively, the "**Royalties**") as follows:

6.3.1 Net Sales.

6.3.1.1 A Royalty equal to [****] of the first [****].

6.3.1.2 A Royalty equal to [****] of [****].

6.3.2 Sublicense Sales Consideration.

6.3.2.1 A Royalty equal to [****] of the [****].

6.3.2.2 A Royalty equal to [****].

6.3.3 Sublicense Milestone Consideration. A royalty equal [****] RedHill or an Affiliate.

6.3.4 Commercialization Partner Sublicense Consideration. Notwithstanding the terms of subsections 6.3.2 and 6.3.3 above, in the event that RedHill or an Affiliate grants a Sublicense to a Commercialization Partner during the [****] months following the Effective Date, RedHill shall pay Apogee a Royalty equal to [****] of all [****] RedHill or an Affiliate [****]. For the avoidance of doubt, all Sublicense Sales Consideration subject to this subsection 6.3.4 shall be included in calculating cumulative aggregate Sublicense Sales Consideration for the purposes of subsection 6.3.2 and 6.3.3 above.

6.4 **No Double Payment**. For the avoidance of doubt, Royalties shall be payable only once in respect of any sum received by RedHill; i.e., either (x) as a Royalty on Net Sales pursuant to Section 6.3.1, if the sum received by RedHill was in payment for a sale of Product by RedHill or its Affiliates; (y) as a Royalty on Sublicense Sales Consideration, pursuant to Section 6.3.2, if the sum received by RedHill was a royalty paid by a Sublicensee to RedHill in respect of a sale of Product made by such Sublicensee; or (z) as a Royalty on Sublicense Milestone Consideration, pursuant to Section 6.3.3, if the sum received by RedHill was a Royalty paid by a Sublicensee to RedHill as an upfront or milestone payment.

6.5 **Royalty Stacking**. RedHill may deduct from any Royalty due under this Agreement any royalties RedHill is required to pay to any third party pursuant to any agreement entered into by RedHill after the date hereof, and that is actually paid by RedHill to such party, in respect of the use of such third party's intellectual property rights that may reasonably be considered to be infringed by the manufacture, use or sale of a Product in its current formulation as of the date hereof.

6.6 **Due Dates for Payment; Late Payments**. All payments due pursuant to the provisions of Section 6.3 shall be due and payable to Apogee on a calendar quarterly basis within [****] days following the end of the applicable quarter. All payments will be made against receipt of an appropriate invoice from Apogee for same; provided that RedHill notifies Apogee in writing of the occurrence of the event requiring payment. In the event such payment may require approval of any governmental authority, RedHill undertakes to file for approval promptly following the Effective Date and to effectuate prompt payment following receipt of the necessary approval. In addition to any other remedies available to Apogee, any failure by RedHill to make a payment within [****] days after the date when due shall obligate RedHill to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to Apogee at a rate per annum equal to [****] per month, or the highest rate allowed by applicable law, whichever is lower.

6.7 **Payment Method**. Any amounts due to Apogee under this Agreement will be paid in U.S. dollars, by wire transfer in immediately available funds to the most recent account designated in writing at least [****] days in advance by Apogee.

6.8 **Currency; Foreign Payments**. If any currency conversion will be required in connection with the calculation of any payment hereunder, such conversion will be made by using the exchange rate for the purchase of U.S. dollars as published in *The Wall Street Journal*, Eastern Edition, on the date of the payment. If at any time legal restrictions prevent the prompt remittance of any payments in any jurisdiction, RedHill may notify Apogee and make such payments by depositing the amount thereof in local currency in a bank account or other depository in such country in the name of Apogee or its designee, and RedHill will have no further obligations under this Agreement with respect thereto.

6.9 **Taxes**. RedHill may deduct from amounts it is required to pay Apogee pursuant to this Agreement an amount equal to that required by applicable law to be withheld by RedHill for or due on account of any taxes (including VAT to the extent applicable, but other than taxes imposed on or measured by net income of RedHill) or similar governmental charge imposed by any jurisdiction based on such payments to Apogee ("**Withholding Taxes**") and such payment shall be deemed as payment to Apogee in accordance with this Agreement. RedHill will provide Apogee a certificate evidencing payment of any Withholding Taxes.

6.10 **Continuing Right**. Following the expiration of the Royalty Term in any country, RedHill shall be entitled to continue to exploit the License in the Field in such country with respect to Products without having to pay Royalties or make any other payment to Apogee in respect of such activities.

7. RECORDS RETENTION AND AUDIT

7.1 **Record Retention**. Until the expiry of the Royalty Terms, RedHill will maintain (and will ensure that its Affiliates maintain) complete and accurate books, records and accounts that fairly reflect Net Sales and Sublicense Consideration in the relevant jurisdiction, in sufficient detail to confirm the accuracy of Royalty payments made hereunder, which books, records and accounts will be retained for [****] years after the end of the period to which such books, records and accounts pertain. For the avoidance of doubt, RedHill has no (a) duty of trust or other fiduciary relationship with Apogee regarding the maintenance of the records or the calculation and reporting of royalties or (b) obligations to maintain any records except in accordance with its own document retention policy.

7.2 **Audit.** Apogee will have the right, at its own cost, to have an independent certified public accounting firm of nationally recognized standing, reasonably acceptable to RedHill and who agrees to be bound by a customary undertaking of confidentiality at least as restrictive as those in this Agreement, have access during RedHill's normal business hours, and upon reasonable prior written notice, to RedHill's records as may be reasonably necessary to verify the accuracy of RedHill's Royalty Reports, for any period ending not more than [****] months prior to the date of such request; *provided, however*, that Apogee will not have the right to conduct more than one such audit in any calendar year or more than one such audit covering any given time period. The accounting firm shall not in any way be compensated (in whole or in part) contingent on the outcome of the audit. The accounting firm will disclose to Apogee only the results of its audit and not any other information. Any such audit shall not unreasonably interfere with the business of RedHill. Apogee shall provide to RedHill a copy of the audit report within [****] days of its receipt thereof. Without derogating from the foregoing, Apogee's audit rights shall be conducted no later than [****] following the final payment under this Agreement. The costs of the audit are the responsibility of Apogee provided that in the event that there is a shortfall of more than [****] in the payment due, and provided such [****] or more shortfall is resolved if applicable in accordance with section 7.3, the audit costs and all related travel costs up to a maximum cap of [****] will be covered by RedHill within [****] days of billing.

7.3 **Payment of Additional Amounts**. If the audit report shows that payments made by RedHill are in excess of the required payment, Apogee shall pay RedHill the excess amount within [****] days after the date it provides the copy of the audit report to RedHill. If the audit report shows that additional payments are owed by RedHill under this Agreement, RedHill shall, at its own cost, have an additional [****] to conduct an additional (second) audit to verify Apogee's audit results, and, assuming the two audits reconcile, RedHill shall make such additional payments within [****] days after the date on which such second accounting firm's written report is delivered to RedHill. If the results of the two audits do not reconcile, the Parties shall, unless otherwise agreed, appoint a third independent auditor, who – on basis of the audit results achieved by the first two auditors and such additional investigations and reviews, which the third auditor may find to be required – shall conduct a third and final audit the result of which shall be applied by the Parties. The Parties shall equally share the costs of for the third audit to be conducted, unless the third audit substantially confirms the results of either party's individual audit in which case the audit costs and all related travel costs of such audit shall be paid by the other party hereto up to a maximum cap of [****].

7.4 **Sublicensee Audits.** To the extent RedHill or its Affiliates conducts any audit of a Sublicensee, RedHill or its Affiliate shall promptly provide the contents of such audit report to Apogee to the extent relevant to calculate any payments owing to Apogee under Section 6 of this Agreement. If an audit report shows that additional payments are owed by a Sublicensee to RedHill or its Affiliates, RedHill or its Affiliate shall pay all additional amounts owing to Apogee for such additional payments made by Sublicensee within [****] days after RedHill or its Affiliate receives such payment from the Sublicensee. If an audit report shows that excess payments were made by a Sublicensee to RedHill or its Affiliates, Apogee shall refund to RedHill or such Affiliate all amounts paid to Apogee for such excess payments made by Sublicensee within [****] days after RedHill or its Affiliate makes repayment to the Sublicensee.

7.5 **Confidentiality**. Apogee will treat all information subject to review under this Section 7 in accordance with the confidentiality provisions of Section 11 below.

8. REPRESENTATIONS AND WARRANTIES

8.1 **By Both Parties**. Each Party hereby represents, warrants and covenants to the other Party as of the Effective Date as follows:

8.1.1 Such Party (a) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (b) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

8.2.2 Such Party has obtained all necessary consents, approvals and authorizations of all governmental authorities and other parties required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder have been obtained.

8.2.3 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable law or any provision of the articles of incorporation, bylaws or any similar instrument of such Party, as applicable, in any material way, and (b) do not conflict with, violate, or breach or constitute a default or require any consent not already obtained under, any contractual obligation or court or administrative order by which such Party is bound.

8.2 **By Apogee**. Apogee hereby further represents, warrants, and covenants to RedHill as of the Effective Date as follows:

8.2.1 The patents and patent applications identified on Annex A are all the patents and patent applications owned or controlled by Apogee or any of its Affiliates, or in which Apogee or any of its Affiliates has a licensable interest. Apogee undertakes that if there are any additional patents or related rights owned or controlled by Apogee or any of its Affiliates or in which Apogee or any of its Affiliates has a licensable interest, Apogee or its Affiliates hereby grant a license to RedHill, its Affiliates, and any Sublicensee on the terms of the License hereunder.

8.2.2 Apogee has the sole legal and/or beneficial title to and ownership of the Patents and is the record owner of all patent applications and patents that comprise the Patents as is necessary to fulfill its obligations under this Agreement and to grant the License to RedHill pursuant to this Agreement, and the Licensed Intellectual Property and Technology is free and clear of any liens, encumbrances, claims or security interests of any kind (including prior license grants) that would interfere, or the exercise of which would interfere, with RedHill exercising the licenses or rights granted hereunder.

8.2.3 Apogee has not, and during the Term shall not, grant any rights to the Licensed Intellectual Property and Technology that conflict with the rights granted to RedHill hereunder, and no third party has any rights whatsoever (including the right to receive royalties or any other compensation) under the Licensed Intellectual Property and Technology to develop, use, sell, offer for sale or import any Product.

8.2.4 To Apogee's knowledge, the Licensed Know-How has not been misappropriated and is non-infringing. The exercise by RedHill of the License will not by itself infringe upon the patent or other intellectual property rights of any third party, and no actions, suits, claims, disputes, or proceedings concerning the Licensed Intellectual Property and Technology are currently pending or to Apogee's knowledge have been threatened. Furthermore, to Apogee's knowledge, there are no legal actions or proceedings by a third party (including employees or former employees of Apogee) contesting the ownership or validity of the Licensed Intellectual Property and Technology or ABC294640 or [****] or any part thereof.

8.2.5 No additional licenses to any patents (including patents owned or controlled by third parties) or knowhow are required to develop, manufacture, use or sell any Product.

8.2.6 Apogee has not brought or threatened any claim against any third party alleging infringement of any Patent, nor, to its knowledge, is any third party infringing or, to its knowledge, preparing or threatening to infringe any patent, or practicing any claim of any patent application, comprising a Patent.

8.2.7 Apogee has not received written notification of any interference, opposition, or reexamination proceedings against any of the Patents.

8.2.8 Apogee has complied with applicable regulations in submitting, prosecuting, and maintaining the Patents, in particular the duty of good faith and candor pursuant to U.S. patent law (including 37 C.F.R. 1.56) and analogous applicable foreign laws.

8.2.9 Apogee has no knowledge of any circumstances that would require a court to conclude that RedHill's current or planned commercialization of any Product, infringes or will infringe any valid patent rights of others as of the date hereof.

9. LIMITATION OF LIABILITY.

Except in the case of a fraud or willful misrepresentation, breach of confidentiality obligations and indemnification for payments to third parties under Section 13, in no event shall either Party be liable to the other or any of its Affiliates for any consequential, incidental, indirect, special, punitive or exemplary damages (including lost profits, business or goodwill) suffered or incurred by such other Party or its Affiliates, whether based upon a claim or action of contract, warranty, negligence or tort, or otherwise, arising out of or relating to this Agreement.

10. PATENTS

10.1 **Patent Prosecution and Maintenance**

10.1.1 **Prosecution of Patents**.

As between the parties, RedHill undertakes and shall have the first right, at its own expense, to prosecute and maintain the Patents using counsel of its choice, in the jurisdictions and to the extent that RedHill shall deem appropriate at its sole discretion. All such filings shall be for the benefit of Apogee and shall identify Apogee as the owner of the inventions described in the applications. RedHill will provide Apogee with copies of all relevant documentation and will keep Apogee apprised of status and respond to Apogee's inquiries in that regard so that Apogee will be informed of the continuing prosecution. In the event RedHill decides not to file, to abandon, or otherwise elects not to prosecute and maintain any Patents in any jurisdiction in the Territory, RedHill shall provide Apogee with written notice at least [****] days prior to the date such abandonment would become effective or the next prosecution and maintenance deadline in the applicable jurisdiction, whichever is sooner, in order to allow Apogee, in its sole discretion, to continue the prosecution and maintenance of such Patents without a loss of rights at Apogee's own expense. If Apogee elects to continue prosecution and maintenance, RedHill shall execute such documents and perform such acts as Apogee shall reasonably request for Apogee to perform such prosecution or maintenance.

10.1.2 **RedHill's Requests**. Apogee shall use reasonable efforts to amend any Patent application to include claims or any other changes reasonably requested by RedHill to protect any Product contemplated to be sold under this Agreement. Moreover, Apogee will reasonably cooperate in the preparation, filing, prosecution, and maintenance of the Patents, including, to the extent necessary for such activities, taking commercially reasonable efforts to do the following: (a) promptly executing all papers and instruments and requiring employees to execute such papers and instruments as reasonable and appropriate so as to enable RedHill to file, prosecute, and maintain the Patents in any country; (b) promptly informing RedHill of matters known to Apogee that could reasonably be expected to adversely affect the preparation, filing, prosecution, or maintenance of any Patents; and (c) providing reasonable access to relevant documents and other evidence, making its employees available at reasonable business hours. This Section 10.1.2 shall likewise apply to RedHill if Apogee assumes any of RedHill's activities pursuant to Section 10.1.1.

10.2 **Patent Enforcement**.

10.2.1 **Infringement Notice**. If Apogee or RedHill knows or suspects that any Patent is being infringed by a third party's activities, it will promptly notify the other Party in writing. In addition, if Apogee or RedHill knows or suspects that any Licensed KnowHow is being misappropriated by a third party's activities, it will promptly notify the other Party in writing. Such notices shall specify in reasonable detail the nature of such actual or suspected infringement or misappropriation.

10.2.2 **RedHill Enforcement**. RedHill will have the sole, exclusive and first right, but not the obligation, to remove such infringement and/or misappropriation and to control all litigation to remove such infringement and/or misappropriation, all as RedHill shall deem appropriate in its sole discretion. RedHill will provide Apogee with copies of all relevant documentation so that Apogee will be informed of the continuing action and may comment upon such documentation sufficiently in advance of any initial deadline for filing a response, provided, however, that if Apogee has not commented upon such documentation in a reasonable time for RedHill to sufficiently consider Apogee's comments prior to a deadline, or RedHill must act to preserve the action, RedHill will be free to act without consideration of Apogee's comments, if any. RedHill shall, subject to recovery under Section 10.2.5, be solely responsible for all costs and expenses of such litigation undertaken by RedHill. If RedHill does not commence an infringement or misappropriation action within [****] days after learning of the infringement or misappropriation, Apogee may commence an action against such infringement or misappropriation pursuant to Section 10.2.3 below.

10.2.3 **Apogee Enforcement**. In the event Apogee does, at its discretion, undertake any infringement or misappropriation action, Apogee will provide RedHill with copies of all relevant documentation so that RedHill will be informed of the continuing action and may comment upon such documentation sufficiently in advance of any initial deadline for filing a response, provided, however, that if RedHill has not commented upon such documentation in a reasonable time for Apogee to sufficiently consider RedHill's comments prior to a deadline, or Apogee must act to preserve the action, Apogee will be free to act without consideration of RedHill's comments, if any. Apogee shall, subject to recovery under Section 10.2.5, be solely responsible for all costs and expenses of such litigation undertaken by Apogee.

10.2.4 **Co-operation**. The Parties will provide reasonable assistance to each other, including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the prosecuting Party to maintain the action.

10.2.5 **Recovery**. Any amounts recovered in connection with or as a result of any action contemplated by Sections 10.2.2 and 10.2.3, whether by settlement or judgment, will be used to reimburse the Parties for their reasonable costs and expenses in making such recovery (which amounts will be allocated pro rata if insufficient to cover the totality of such expenses), and any remainder received by RedHill in excess of the reasonable costs and expenses in making such recovery will be treated as Net Sales and payments will be due in respect of same pursuant to this Agreement.

10.3 **Patent License**

In the event that either or both of Apogee or RedHill are sued by a third party alleging that the commercialization of a Product infringes upon any intellectual property rights of such third party, the Party being so sued shall immediately give the other Party notice of same and the Parties shall thereafter proceed as provided in Section 13.

Neither Party shall, without the consent of the other Party, which shall not be unreasonably delayed or withheld, enter into any settlement or compromise or consent to any judgment in respect of any claim related to rights licensed to RedHill under this Agreement, unless such settlement, compromise or consent includes an unconditional release of the other Party from all liability arising out of the claim and does not otherwise limit or impair the other Party's rights.

11. CONFIDENTIALITY

11.1 **Disclosure and Use Restriction**. The Parties agree that, during the Term of this Agreement and thereafter, each Party will (a) use the same degree of care to maintain the secrecy of the Confidential Information (as such term is defined below) of the other Party that it uses to maintain the secrecy of its Confidential Information of like kind, (b) use the Confidential Information only to accomplish the purpose of this Agreement, and (c) limit internal dissemination of the Confidential Information to its and its Sublicensees' and Affiliates' respective directors, officers, employees, consultants, representatives or agents, whose duties justify the need to know such information, and then only provided that such individuals are bound by obligations of confidentiality and non-use at least as equivalent in scope to those set forth in this Agreement.

11.2 **Confidential Information**. "**Confidential Information**" means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, which may include data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. Notwithstanding the foregoing, information or know-how of a Party shall not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how:

(i) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party as evidenced by written records;

(ii) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such receiving Party as evidenced by written records;

(iii) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such receiving Party other than as a result of an act or omission by the receiving Party in breach of this Agreement;

(iv) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the disclosing Party not to disclose such information or know-how to others; or

(v) was independently discovered or developed by such receiving Party, as evidenced by their written records, without the use of Confidential Information belonging to the disclosing Party and prior to any subsequent disclosure by the receiving Party.

All Licensed Know-How shall be deemed to be Confidential Information of Apogee; provided that RedHill shall be entitled to disclose and use any Licensed Know-How in the exercise of its rights under this Agreement on the terms provided in Section 11.3, including clause (iv) thereof.

11.3 **Authorized Disclosure**. Notwithstanding the provisions of Section 11.1 above, a Party shall be entitled to disclose the Confidential Information of the other Party hereto to the extent that such disclosure is:

(i) made in response to a valid order of a court of competent jurisdiction; *provided,* however, that such Party will first (to the extent practicably possible) have given notice to such other Party and given such other Party a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided further* that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;

(ii) otherwise required by law or stock exchange rule; *provided, however*, that the disclosing Party will provide such other Party with notice of such disclosure in advance thereof to the extent practicably possible and to the extent permitted, will redact from such disclosure the other party's Confidential Information or designate the same as trade secret;

(iii) made by such Party to Regulatory Authorities as necessary for the development or commercialization of a medicinal product, including any Product, in a country, as required in connection with any filing, application or request for Regulatory Approval or as required by applicable securities laws and regulations, subject to the limitations in Section 11.3(ii); or

(iv) made by such Party in the course of submitting financial accounts to relevant authorities as per local statutory requirements or to existing or potential acquirers; existing or potential collaborators; investment bankers; existing or potential investors, merger candidates, partners, venture capital firms or other financial institutions or investors for purposes of obtaining financing; or, bona fide strategic potential partners; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Agreement.

12. PRESS RELEASES

Press releases or other similar public communication by either Party relating to the terms of this Agreement (but not, for the avoidance of doubt, unless reference is made to the other Party or the terms of this Agreement, with respect to activities in exercise of its rights under this Agreement) must be approved in advance by the other Party, which approval will not be unreasonably withheld or delayed, except for those communications required by applicable law, regulation or securities exchange rule (including a public offering prospectus), disclosures of information for which consent has previously been obtained, and information of a similar nature to that which has been previously disclosed publicly with respect to this Agreement each of which will not require advance approval, but will be provided to the other Party as soon as practicable after the release or communication thereof. For the avoidance of doubt, the Parties may issue press releases regarding the fact that this Agreement has been signed and the nature of the Agreement so long as they do not describe the specific provisions hereof without approval from the other party.

13. INDEMNIFICATION

13.1 **Indemnification of Apogee**. RedHill will defend and hold Apogee and its Affiliates, and each of their respective directors, officers, employees and agents ("**Apogee Parties**") harmless, from and against any and all liability, suits, investigations, claims or demands by a third party to the extent arising from or occurring as a result of or in connection with (a) the negligence or willful misconduct on the part of RedHill in performing any activity contemplated by this Agreement, (b) breach by RedHill of any representations, warranties, or covenants set forth in this Agreement, and/or (c) the development, testing, use, manufacturing, promotion, sale or other disposition of a Product; except to the extent the liability or loss arises from the (i) negligence or willful misconduct on the part of an Apogee Party; or (ii) breach by Apogee of any representations, warranties or covenants set forth in this Agreement. RedHill shall, in addition, indemnify Apogee against any losses, damages or liabilities from such claims (including reasonable attorneys' fees and expenses) by paying the amount of any judgment awarded against Apogee in connection with such claims.

13.2 **Indemnification of RedHill**. Apogee will defend and hold RedHill, its Affiliates, and their respective directors, officers, employees and agents ("**RedHill Parties**"), harmless, from and against any and all liability, suits, investigations, claims or demands by a third party to the extent arising from or occurring as a result of or in connection with (a) negligence or willful misconduct on the part of Apogee; or (b) breach by Apogee of any representations, warranties, or covenants set forth in this Agreement, except to the extent the liability or loss arises from or occurs as a result of or in connection with (i) negligence or willful misconduct on the part of a RedHill Party; (ii) breach by RedHill of any representations, warranties, or covenants set forth in this Agreement. Apogee shall, in addition, indemnify RedHill against any losses, damages or liabilities from such claims (including reasonable attorneys' fees and expenses) by paying the amount of any judgment awarded against RedHill in connection with such claims.

13.3 **Conditions to Indemnity**. Each Party's agreement to indemnify and hold the other harmless is conditioned upon the indemnified Party (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within [****] days after the indemnified Party has knowledge of such claim, demand or action, (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand and not making any admission or otherwise adversely affecting the indemnifying party's interest, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation of and defense of any such claim or demand; and (iv) the indemnifying Party not compromising or settling such claim or demand without the indemnified Party's prior written consent (such consent shall not be unreasonably withheld or unduly provided), unless avoiding such settlement prejudices the position of the indemnifying party and/or its insurers or unless such settlement includes as an unconditional term thereof the giving by the claimant or plaintiff to such indemnified Party a complete release from all liability in respect of such claim or litigation; provided that, if the Party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (i), the indemnifying Party shall only be relieved of its indemnification obligation to the extent it is prejudiced by such failure and provided further that the indemnified Party is not obligated to notify the indemnifying Party of claims, demands and/or actions made directly against the indemnifying Party only. Notwithstanding the foregoing, if in the reasonable judgment of the indemnified party, such suit or claim involves an issue or matter which could have a materially adverse effect on the business, operations or assets of the indemnified party, the indemnified party may waive its rights to indemnity under this Agreement and control the defense or settlement thereof, but in no event shall any such waiver be construed as a waiver of any indemnification rights such indemnified party may have at law or in equity.

14. TERM AND TERMINATION

14.1 **Term**. Unless earlier terminated in accordance with the provisions of this Article 14, the term of this Agreement (the "**Term**") will become effective on the Effective Date and will continue in full force and effect until terminated in accordance with the terms hereof.

14.2 **Termination**.

14.2.1 **Termination for Breach**. Subject to the limitations set forth in Sections 6.10 and 14.2.3, failure by a Party to comply with any of its material obligations contained herein will entitle the Party not in default to give to the defaulting Party notice specifying the nature of the material breach, requiring the defaulting Party to make good or otherwise cure such material breach, and stating its intention to invoke the provisions of Section 14.3 if such material breach is not cured. If such material breach is not capable of cure or if such material breach is capable of cure and is not cured within (a) within [****] days of the date payment is due for late payments pursuant to Section 6.6, or (b) [****] days after the receipt of such notice (or, if such material breach is capable of cure but cannot be cured within such [****]-day period, if the defaulting Party does not commence actions to cure such material breach within such period and thereafter diligently continue such actions to achieve full compliance as soon thereafter as is reasonably possible, but such material breach is not cured with an additional [****]-day period), the Party not in default will be entitled, without limiting any of its other rights conferred on it by this Agreement (except as expressly set forth herein), to terminate this Agreement by providing written notice to the breaching Party.

14.2.2 **Voluntary Termination**. Subject to Section 14.3.4 below, RedHill shall be entitled, in its sole discretion, to terminate this Agreement at any time on [****] days written notice to Apogee, without the need to pay Apogee any compensation in respect of such termination,. In addition, subject to the limitations set forth in Section 6.10, Apogee shall be entitled, in its sole discretion, to terminate this Agreement in the event of a Bankruptcy Event with respect to RedHill.

14.2.3 **Limited Rights of Termination**. For the avoidance of doubt, it is hereby expressly agreed that outside the scope of Sections 14.2.1 and 15.12 Apogee shall have no right to terminate this Agreement. For the avoidance of doubt, Apogee shall not be entitled to terminate this Agreement for any reason whatsoever once all Royalty Terms have expired.

14.3 **Consequences of Termination**

14.3.1 **License**. Upon early termination of this Agreement, all rights granted to RedHill under Section 2.1 will terminate; provided that RedHill shall have a period of [****] days after the date of termination to sell-off Product, subject to Royalties on such sales being duly paid to Apogee.

14.3.2 **Continuation following Apogee's Bankruptcy**. The Parties agree that in the event that Apogee becomes insolvent or makes a filing under bankruptcy or similar laws in any jurisdiction, RedHill shall have the protection afforded to the licensee under the United States Bankruptcy Code, including the protections set forth in 11 U.S.C §365(n) or its equivalent in any other jurisdiction which allows the licensee, upon rejection of the license agreement by the debtor-licensor or its representative, the option to either retain the licensee's rights in the intellectual property under the existing contract while continuing to pay royalties, or to treat the executory contract as terminated.

14.3.3 **Return of Information and Materials**. Upon termination of this Agreement, each Party will promptly return to the other all Confidential Information of the other Party (except one copy of which may be retained for archival and compliance purposes).

14.3.4 **Accrued Rights**. Termination or expiration of this Agreement for any reason will be without prejudice to any rights or financial compensation that will have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration will not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

14.3.5 **Survival**. This Section 14.3 and Sections 6, 7, 8, 9, 11, 13 and 15 of this Agreement will survive expiration or termination of this Agreement for any reason.

15. MISCELLANEOUS

15.1 **Assignment**. Without the prior written consent of the other Party hereto, neither Party will sell, transfer, assign, delegate, pledge or otherwise dispose of, whether voluntarily, involuntarily, by operation of law or otherwise, this Agreement or any of its rights or duties hereunder; provided, however, that (i) either Party hereto may assign or transfer this Agreement or any of its rights or obligations hereunder without the consent of the other Party to any Affiliate, or to any third party successor in interest with which it has merged or consolidated, or to which it has transferred all or substantial part of its assets or stock to which this Agreement relates. Any purported assignment or transfer in violation of this Section 15.1 will be void *ab initio* and of no force or effect.

15.2 **Severability.** Should any term or provision of this Agreement be or become invalid or unenforceable or should this Agreement contain an omission, the validity or enforceability of the remaining terms or provisions shall not be affected. In such case, subject to the next following sentence, the Parties shall immediately commence to negotiate in good faith in order to replace the invalid or unenforceable term or provision by such other valid or enforceable term or provision which comes as close as possible to the original intent and effect of the invalid or unenforceable term or provision, or respectively, to fill the omission by inserting such term or provision which the Parties would have reasonably agreed to, if they had considered the omission at the date hereof. In the event that any term or provision as aforesaid is invalid, void or unenforceable by reason of its scope, duration or area of applicability or some similar limitation as aforesaid, then the court making such determination shall have the power to reduce the scope, duration, area or applicability of the term or provision so that they shall be enforceable to the maximum scope, duration, area or applicability permitted by applicable law which shall not exceed those specified in this Agreement or to replace such term or provision with a term or provision that comes closest to expressing the intention of the invalid or unenforceable term or provision.

15.3 **Governing Law.** This Agreement will be governed by and construed in accordance with the laws of England and Wales, without reference to any rules of conflicts of laws and the courts of London, England shall have exclusive jurisdiction of disputes regarding this Agreement and the Parties hereby submit to the jurisdiction of such courts.

15.4 **Notices**. All notices or other communications that are required or permitted hereunder will be in writing and delivered personally with acknowledgement of receipt, sent by electronic mail (provided receipt is acknowledged), facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight courier as provided herein), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Apogee, to:

Apogee Biotechnology Corp.
1214 Research Blvd.
Suite 2014
Hershey Center for Applied Research
Hummelstown, PA 17036, U.S.A
Fax: + 1 717 531 4758

If to RedHill, to:

RedHill Biopharma Ltd.
21 Ha'arba'a Street
Tel-Aviv 64739
Israel
Fax: +972 (3) 541 3144

or to such other address as the Party to whom notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed to have been given (i) when delivered, if personally delivered, (ii) on the Business Day (on the receiving end) after dispatch, if sent by nationally-recognized overnight courier (third Business Day if sent internationally), (iii) on the third Business Day following the date of mailing, if sent by mail (fifth Business Day if sent internationally) and (iv) on the First Business day (on the receiving end) after being sent by facsimile or by if sent by electronic mail followed by facsimile. It is understood and agreed that this Section 15.4 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

15.5 **Entire Agreement; Modifications.** This Agreement sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby, including the Non-Binding Term Sheet between the Parties dated December 31, 2014. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge will be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties.

15.6 **Relationship of the Parties**. It is expressly agreed that the Parties will be independent contractors of one another and at no time will either Party make commitments or incur any charges or expenses for or on behalf of the other Party. The relationship between the Parties will not constitute a partnership, joint venture, agency or employer-employee relationship for financial, tax, legal or other purposes.

15.7 **Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. Any such waiver will not be deemed a waiver of any other right or breach hereunder.

15.8 **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

15.9 **No Third Party Beneficiaries.** The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other parties.

15.10 **Expenses**. Except as expressly provided herein, each Party shall each bear its own legal, accounting and other expenses in connection with this Agreement and the transactions contemplated hereby.

15.11 **Further Assurances.** Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary to carry out the provisions and purposes of this Agreement.

15.12 **Force Majeure**. Neither party shall be responsible to the other for failure or delay in performing any of its obligations under this Agreement or for other non-performance hereof but only to the extent that such delay or non-performance is occasioned by a cause beyond the reasonable control and without fault or negligence of such party, including earthquake, fire, flood, explosion, discontinuity in the supply of power, court order or governmental interference, act of God, strike or other labor trouble, act of war or terrorism and provided that such party will inform the other party as soon as is reasonably practicable and that it will entirely perform its obligations immediately after the relevant cause has ceased its effect. If any such force majeure event continues for a continuous period of 12 months, the Party whose performance is not prevented by such event may terminate this Agreement with immediate effect by providing the other Party with written notice. This Section 14.15 shall not apply to any obligation of a party to make a payment hereunder.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Apogee Biotechnology Corp.

Signature: /s/ Charles D. Smith
Name: Charles D. Smith
Title: President and CEO
March 30, 2015

RedHill Biopharma Ltd.

Signature: /s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO
March 30, 2015

Signature: /s/ Ori Shilo
Name: Ori Shilo
Title: Deputy CEO, Finance and Operations
March 30, 2015

ANNEX A

PATENTS

[****]

Exhibit 4.9

AMENDMENT # 3

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMIITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

AMENDMENT TO THE MASTER SERVICE AGREEMENT FOR REDHILL BIOPHARMA LTD.'S RHB R&D PROGRAM

BY AND BETWEEN: **RedHill Biopharma Ltd.**, with principle place of business at **21 Ha'arba'a St. Tel-Aviv 64739, Israel** (herein referred to as the "Client"),

AND: **7810962 Canada Inc (doing Business under the name "InSymbiosis")**, a body politic and corporate, duly incorporated according to the laws of Canada and with principle place of business at 245 Victoria Ave, Suite 100, Montreal, Quebec, H3Z 2M6, Canada, (herein referred to as the "Provider"),

The Client and the Provider are, in this Agreement, sometimes individually referred to as "Party" and collectively as the "Parties".

WHEREAS on 28 April 2011**,** the Client and the Provider entered into a Master Service Agreement in relation to the Client's RHB R&D Program (the "MSA");

WHEREAS WHEREAS the MSA was scheduled to terminate on April 28, 2015 as per amendment 2 and the parties hereby agree to formally extend the term of the MSA until April 28, 2016 (the "Extended Period"); and

WHEREAS the Parties have agreed to certain terms and conditions, the whole as is fully set forth below.

NOW, THEREFORE, THE PARTIES HERETO AGREE AS FOLLOWS:

1. Unless specifically set out otherwise in this agreement (the "AMENDMENT AGREEMENT"), the terms of the MSA shall continue to apply.

2. The parties hereby agree to formally extend the term of the MSA until April 28, 2016.

3. During the term of the Agreement, PROVIDER will charge CLIENT a monthly project management fee of $US [****]. This monthly project management fee will be payable each quarter, in advance, upon lawful invoice to be provided by the PROVIDER to the CLIENT within 21 days of the beginning of the relevant quarter according to the following payment schedule:

- Payment 1: May 2015 to July 2015
- Payment 2: August 2015 to October 2015
- Payment 3: November 2015 to January 2015
- Payment 4: February 2015 to April 2016

IN WITNESS WHEREOF, the parties hereto have executed this Amendment Agreement as of the date first herein above mentioned.

REDHILL BIOPHARMA Ltd.

/s/ Dror Ben-Asher
Per: Dror Ben-Asher
Title: CEO
Date: May 21, 2015

/s/ Ori Shilo
Per: Ori Shilo
Title: VP Finance and Operation
Date: May 21, 2015

PARTY OF THE FIRST PART

7810962 Canada Inc.

Per: Alain Guimond
Title: Senior Director of R&D
Date: 12May2015

PARTY OF THE SECOND PART

Exhibit 4.12

Changed Order 4.1 to Clinical Services Agreement

Sponsor's study drug RHB-104

This CO#4.1 to the Clinical Services Agreement signed 15 June 2011 ("**Clinical Services Agreement**"), is by and among:

(1) RedHill Biopharma Ltd., having its principle place of business at 21 Ha'arba'a St., Tel Aviv 64739, Israel (hereafter "**SPONSOR**");

(2) 7810962 Canada Inc., a Canadian corporation, having its principal office at 245 Victoria Ave, Suite 100, Montreal, Quebec, H3Z 2M6, Canada (hereinafter "**MANAGER**");

WHEREAS, "SPONSOR" mandated "MANAGER" to enter into a subcontract with inVentiv Health Clinical to act as a CRO for its Study (as defined in the Clinical Services Agreement) with an expected termination date of March 2013; however, the study as of the Amendment Effective Date is ongoing;

WHEREAS, FURTHER as due to the initial term of the Clinical Services Agreement being only 2 years, the parties have omitted from the calculation of professional fees an applicable annual inflation rate therein;

WHEREAS, FURTHER the parties now wish to include inflation to account for the extended term;

WHEREAS, FURTHER PharmaNet GmbH has assigned all of their rights, title and interest in and to the Agreement as of 1 July 2014 to inVentiv Health UK as part of an internal reorganization; and

NOW THEREFORE, in exchange of mutual consideration the sufficiency of which is hereby acknowledged, the parties hereto agree to the following amendment(s) to the Agreement:

1. As of 1 January 2015 an inflation rate of 2% per year will be included in the calculation of the professional fees agreed upon in the Clinical Services Agreement.

2. Except as amended herein, the Clinical Services Agreement remains in full force and effect.

IN WITNESS WHEREOF, this change Order 4.1 has been executed by the parties hereto through their duly authorized officers and is effective as the last date below.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd.

/s/ Ori Shilo
Name: Ori Shilo
Title: Deputy CEO

Date: August 9, 2015

For 7810962 Canada Inc.

/s/ Alain Guimond
Name: Alain Guimond PhD
Title: Senior Director of R&D
Date: 06Aug2015

RedHill Biopharma Ltd.

/s/ Uri Hananel Aharon
Name: Uri Hananel Aharon
Title: Chief Accounting Officer

Date: August 9, 2015

Exhibit 4.13

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMIITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

Change Order 5 to Clinical Services Agreement

Client's study drug RHB-104

This Change Order 5 ("**Change Order**") to the Clinical Services Agreement signed 15 June 2011 ("**Clinical Services Agreement**"), is by and among:

(1) RedHill Biopharma Ltd., having its principle place of business at 21 Ha'arba'a St., Tel Aviv 64739, Israel (hereafter "**SPONSOR**");

(2) 7810962 Canada Inc., a Canadian corporation, having its principal office at 245 Victoria Ave, Suite 100, Montreal, Quebec, H3Z 2M6, Canada (hereinafter "**MANAGER**");

WHEREAS, "SPONSOR" mandated "MANAGER" to enter into a subcontract with inVentiv Health Clinical to act as a CRO for its Study (as defined in the Clinical Services Agreement);

Is hereby made effective as of September 11, 2015 ("**Effective Date**") and the parties hereby agree as follows:

1. Change Order 5 to Clinical Services Agreement.

   This Change Order constitutes an amendment to the Clinical Services Agreement pursuant to section 3.0 therein. As such, this Change Order is subject in all respects to the terms and provisions of the Clinical Services Agreement.

2. Scope of Work

   In addition to the Services to be provided in the above-referenced Clinical Services Agreement, Manager will cause inVentiv Health Clinical to perform additional Services for Client's study drug RHB-104, in accordance with the Summary of Changes attached hereto and incorporated herein as Exhibit A.

3. Compensation

   Under this Change Order, inVentiv Health Clinical's Professional Fees have increased by the amount of USD [****], the pass-through costs have increased by USD [****]. The total costs of the Clinical Services Agreement have increased to USD [****].

Payment due to inVentiv Health Clinical for the Services provided under this Change Order shall be made pursuant to the Agreement and the revised unit Payment Schedule attached hereto and incorporated herein as Exhibit B.

4. Project Period

The term of this Change Order shall commence on the date of its execution and shall continue until the Services as described in the Clinical Services Agreement are completed, unless this Change Order or corresponding Clinical Services Agreement are terminated early in accordance with the Clinical Services Agreement.

By their signatures below, the parties hereto agree to the terms of this Change Order and represent that they are authorized to enter into this Change Order on behalf of their respective companies.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd.

/s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO

Date: October 20, 2015

/s/ Ori Shilo
Name: Ori Shilo
Title: Deputy CEO

Date: October 20, 2015

For 7810962 Canada Inc.

/s/ Alain Guimond
Name: Alain Guimond
Title: Sr. Director of R&D

Date: October 19, 2015

Study Assumption Changes

Changes to the parameters and assumptions for the study are defined below. Unless otherwise noted, activities will be performed according to the original contract.

Change Order 5 for 7810962 Canada Inc. /Red Hill Biopharma Ltd.

Overview of major level changes

- **Protocol v8 Amendment**
- **DM-Dose Admin page created for future DSUR preparation requested by RHB Medical Director**
- **Interim IM approved 26Jan15 by RHB**
- **Israel & ANZ Investigator Meeting**
- **Update eCRF to** [****] **and** [****] **based on** [****] **in Protocol v8 and** [****] **with** [****]
- **DM-DSUR report programming for 2015 submission to FDA**
- **Protocol v8 eCRF Changes**
- [****] **& ANZ DM & Safety Monitoring**

1.1 Revised Costs

Costs for this study are presented below in two categories, pass-through costs and professional fees.

1.1.1 Pass-Through Costs

Pass-through costs are in US dollars and include those expenses listed below. inVentiv Health Clinical will invoice Client for actual costs in these areas, it being understood that any pass-through costs in excess of the amounts set out below will require the Client's prior written approval. inVentiv Health Clinical will use its best efforts to keep actual costs to reasonable levels through adherence to inVentiv Health Clinical's travel policy and prudent negotiation with outside providers. Pass-through costs are presented in the table below:

Task	Current (USD)	Change Order #5	Assumption Changes influencing the change in the budget	Additional comments
Site Visit Travel	$[****]	$[****]	No change	
Investigators' Meeting Organisation	$[****]	$[****]	No change	
Kick-off Meeting Travel/Attendance	$[****]	$[****]	No change.	
Shipping/Photocopying	$[****]	$[****]	Printing of Protocol v8, Investigator Brochure #10; Mini-protocols; Annotated Protocol v8 eCRF document; Pharmacy manuals; Quest lab chart tool; I/E laminated pocket cards; Protocol v8 IWRS Guidelines; [****] Guidelines DVD	
Translation	$[****]	$[****]	Protocol v8 French and Spanish ICFs; French CSSi materials and I/E cards; Study Rationale Slides to French:; Dossier items translation to English	
Regulatory Fees	$[****]	$[****]	No change	
Ethics Committee Fees	$[****]	$[****]	Protocol v8 and [****] materials	
EDC Studies/3G Cards	$[****]	$[****]	No change	
DSMB member fees	$[****]	$[****]	No change	
EDC Fees (Oracle)	$[****]	$[****]	No Change	
CRA Face to Face Meeting Travel expenses	$[****]	$[****]	No change	
Pass Through Costs	**$[****]**	**$[****]**		

1.1.2 Investigator Grants Costs

Investigator Grants	**Current (NA USD)**	**NA (USD)**	**Assumption Changes influencing the change in the budget**	**Additional Comments**
	$[****]	$[****]	No Change	Estimate only. Will be paid based on actual costs as approved by the Client.

1.1.3 Professional Fees

Based on the parameters and assumptions outlined in the original proposal, inVentiv Health Clinical fees are categorised by major activity in the table below and in USD:

Task	**Current (US Dollars)**	**Change Order #5**	**Assumption Changes influencing the change in the budget**	**Additional comments**
Pre-study Activities				
Case Report Form Preparation/Review	$[****]	$[****]	-CRF Pages/book change from 180 to 182 -Number of unique pages from 30 to 34 for visit schedule; ECG procedures, and Study Drug Administration pages	Sr. Data Analyst, India [****] hrs; Manager DM [****] hrs - N/A; Database Programmer India [****] hours; Sr. CRA Israel - [****] hr.
Data Management Plan Preparation/Review	$[****]	$[****]	-CRF Pages/book change from [****] to [****] -Number of unique pages from [****] to [****] for visit schedule; ECG procedures, and Study Drug Administration pages	DM Data Manager NA[****] hrs Sr. Data Analyst, India [****] hrs Database Programmer NA [****] hour
Informed Consent Preparation/Review	$[****]	$[****]	Protocol v8 consents revised for USA, Canada, and Israel; central IRBs; and specific for [****] sites	Israeli GSSU SS specialist- [****] hrs for country-specific changes and [****] site specific ICFs GSSU Mgr. NA = [****] hrs to review and prepare Protocol v8 Country Specific and central IRB ICFs; GSSU SS Specialist - [****] hrs for [****] hrs /site ICF for [****] sites

Task	Current (US Dollars)	Change Order #5	Assumption Changes influencing the change in the budget	Additional comments
IRB/Ethics Committee Interactions	$[****]	$[****]	Protocol v8, IB#10, Protocol v8 ICF; and [****] materials submissions	Israeli GSSU SS specialist - [****] hrs for [****] site specific submissions; GSSU SS specialist- [****] hrs ([****]hrs/site for [****] sites)
Investigators' Meetings	$[****]	$[****]	Three investigator meetings attended in North America, Israel, and Australia	[****] hours NA CRA ([****] CRAs at [****] hours avg/each for travel and meeting) [****] hours for Clinical Project Monitoring Lead NA (CMPL) for prep, travel, and meeting [****] hours for Sr. PM NA for prep, travel, and meeting [****] for Medical Director APA (ANZ IM) [****] hours for Data Manager NA (ANZ IM) [****] hrs for one CRA API (Israel IIM) Medical Director WE [****] hours (Israel IIM)
Investigator Site Contract	$[****]	$[****]	Changes in the protocol visit schedule and procedures required contract amendments for [****] sites	Sr. Contracts Associate =[****] hours ([****] hrs/site contract amendments); PM = [****] hours
Investigator Recruitment	$[****]	$[****]	No change	No change
Project Feasibility	$[****]	$[****]	No change	No change
Project Plan Preparation/Review	$[****]	$[****]	No Change	No change

Task	Current (US Dollars)	Change Order #5	Assumption Changes influencing the change in the budget	Additional comments
Protocol Preparation/Review	$[****]	$[****]	Review of Protocol V8 by Medical Directors, CRAs, Data Management, Regulatory Affairs; Safety Group, and Statisticians	Sr CRA Israel [****] hr. Sr. Data Analyst India [****] hr. Data Analyst India [****] hr. Manager (PM & DM) 12 hours NA [****] Medical Director NA 6 hours [****] Sr Regulatory Associate North America [****] hr. [****] for Protocol v8 review and conference calls in 2014; NA CMPL [****] hours [****] hrs WE Medical Director [****] for Protocol v8 prep and review in 2014, includes interactions with RHB and ISB team members NA CRA [****] hours NA Safety Associate II [****] hr. NA Director Reg Affairs [****] hr. NA Reg Affairs Associate [****] hr. NA Principal Statistician [****] hr. NA Manager [****] hours ([****] PM & [****] DM) NA Medical Director [****] hour Sr. Database Programmer India [****] hours
Randomization Schedule Preparation	$[****]	$[****]	Protocol v8 required changes to the randomization plan for assigning study drug according to biologics use.	[****] hours Statisticians (Principal Statisticians in NA and India, [****] hours X[****] for discussion and review of randomization changes prior to Protocol v8 finalization) and (Principal Statisticians in NA and India, [****] hours X[****] preparation of revised randomization schedule in 2015 after Protocol v8 was finalized)
Study-Specific Form Preparation	$[****]	$[****]	No change	No change
Training - Project-Specific	$[****]	$[****]	Training required for CRA team, and CMPLs for the Dose Administration eCRF page,	Sr. CRA - [****] hrs - N/A ([****] hrs X [****] CRAs); NA CMPL = 1 hr. ([****] hrs X [****]);
Translations	$[****]	$[****]	Revised Protocol v8 ICFs, [****] materials; I/E pocket cards sent to translation service	NA GSSU Manager - [****] HR
PROMIS	$[****]	$[****]	No change	No change
Monitoring/Site Management				
Data Clean-up	$[****]	$[****]	Protocol v8 decreased the number of patient visits while increasing the number of unique pages	Decreased number of patient visits and while adding more eCRFs

Task	Current (US Dollars)	Change Order #5	Assumption Changes influencing the change in the budget	Additional comments
Investigator Grant Administration	$[****]	$[****]	No change	The number of costed grants remains at [****] payments.
Laboratory Report Review	$[****]	$[****]	No Change	. No Change
Serious/Significant Adverse Event Management	$[****]	$[****]	Addition of [****] sites in [****]- [****] sites in Australia, and [****]sites in New Zealand and two CROs increased costs for [****]	Safety Manager NA - [****] hrs Safety Associate II NA- [****] hrs Safety Project Coordinator NA- [****] hrs
Site Management	$[****]	$[****]	Attendance at Site Teleconferences for Protocol v8; follow-up for IWRS changes conversations; follow-up for conference call training; follow-up for receipt of updated Central Lab manuals & supplies	Israeli Sr. CRA [****] hrs; NA PM – [****] hrs; CMPL – [****] hrs [****]; NA CRA [****] hr. ([****] hr. /site X [****] sites).
Remote Monitoring of Site Data	$[****]	$[****]	No Change	No Change
Site Visits - Pre-study Visits	$[****]	$[****]	No change	No change
Site Visits - Initiation Visits	$[****]	$[****]	No change	Current costing remains at [****] SIVs. Only costs for visits actually performed will be paid. Reconciliation of costs and visits will be performed at project end
Site Visits - Routine Visits conducted on site	$[****]	$[****]	No change	Current costing remains at [****] RMVs. Only costs for visits actually performed will be paid. Reconciliation of costs and visits will be performed at project end
Site Visits - Close-out Visits at each site at Study End	$[****]	$[****]	No change	Current costing remains at [****] COVs. Only costs for visits actually performed will be paid. Reconciliation of costs and visits will be performed at project end
Study Master File/Project File Set-up and Maintenance	$[****]	$[****]	Filing of Protocol v8 and Investigator Brochure #10 Investigator signature pages and IRB approval documents	NA GSSU Specialist [****] hrs/site X [****] sites = [****] hrs
Patient/Site Recruitment	$[****]	$[****]	No change	No change

Task	Current (US Dollars)	Change Order #5	Assumption Changes influencing the change in the budget	Additional comments
Client/CRO meeting	$[****]	$[****]	RHB/Israeli Study Coordinator Meeting held in February 2015	Israeli CRA [****] hours
Regulatory	$[****]	$[****]		
Regulatory Documentation Preparation/Review	$[****]	$[****]	No change	No change
Project Management /Project Tracking	$[****]	$[****]		
Financial Project Management	$[****]	$[****]	Additional financial management for payment of printer, translator, and Ethics Committee fees for Protocol V8 changes and [****] materials.	Manager, PM, NA [****] hr.
Project Management	$[****]	$[****]	Protocol v8 and [****] materials weekly updates and action items for site IRB status and approvals and investigator protocol v8 and investigator brochure sign off pages. Includes notification to [****] of approvals	Israeli GSSU Specialist – [****] hr.([****] hr./ site X [****] sites) NA GSSU Specialist – [****] hrs ([****]/ site X [****] sites)
Project Tracking / Communications	$[****]	$[****]	Review of weekly updates for Protocol v8 IRB approvals and to pending action items. Includes notifications to IWRS.	NA PM - [****] hrs NA CMPLs [****] hrs
Vendor Management	$[****]	$[****]	-Add [****] CRO and CRO for [****] for DM and Safety - Increase the number of vendors to 8. -Printer interaction for Protocol v8 printing	Revised costing includes 8 vendors.
Data Management				
Database Archiving	$[****]	$[****]	No change	No change
Data Cleanup (DM)	$[****]	$[****]	Addition of [****] sites in [****], [****] sites in Australia, and [****] sites in New Zealand and two CROs and increase of 30 patients from 240 to 270 patients increases data clean-up costs	Data Analyst India [****] hrs NA DM Manager [****] hrs

Task	Current (US Dollars)	Change Order #5	Assumption Changes influencing the change in the budget	Additional comments
Data Management: Database Quality Control Inspection	$[****]	$[****]	-CRF Pages/book change from [****] to [****] pages -Number of unique pages from [****] to [****]	Data Analyst India - [****] hrs Quality Associate II, NA - [****] hrs
Database Design	$[****]	$[****]	-CRF Pages/book change from [****] to [****]-# of unique pages from [****] to [****]; -Addition of [****] sites in [****], [****] sites in Australia, and [****] sites in New Zealand and two CROs -Increase of 30 patients from 240 to 270 patients -Revisions to format Adverse Event data listings for 2015 Data Safety Update Report (DSUR) for FDA submission.	NA Data Manager - [****] hrs NA Data Services PM - [****] hrs NA Sr. DB Programmer, [****] hrs DB Programmer India – [****] hrs Sr. Data Analyst, India [****] hrs
Dictionary Coding	$[****]	$[****]	No Change	No Change
Edit Check Programming	$[****]	$[****]	Change in eCRF pages for Protocol v8, ECG visits, Study Drug Administration, and DSUR data results in 8 additional edit checks from[****] to [****] in total	Sr. Data Analyst, India [****] hrs Sr. Database Programmer India - [****] hrs DM Data Mgt Manager NA = [****] hr. Principal Statistician NA [****] hrs Sr. D/B Programmer NA = [****] hrs Manager, PM, NA [****] hr.
Electronic Data Import	$[****]	$[****]	The number of data imports increased from [****] to [****]	Sr. Database Programmer India - [****] hrs Sr. Data Analyst, India [****] hrs
Case Report Form Data/Document Transfers	$[****]	$[****]	No change	
EDC Fees	$[****]	$[****]	No Change	
Statistical Analysis and Table Generation	$[****]	$[****]		

Task	Current (US Dollars)	Change Order #5	Assumption Changes influencing the change in the budget	Additional comments
Electronic Data Transfer	$[****]	$[****]	No Change	
Interim Analysis/Report Preparation and Review	$[****]	$[****]	No Change	
Statistical Analysis Plan Preparation/Review	$[****]	$[****]	No Change	
Table Generation	$[****]	$[****]	No Change	
Table/Listings Review	$[****]	$[****]	No Change	
Clinical Study Report	$[****]	$[****]		
Clinical Study Report Preparation/Review	$[****]	$[****]	No Change	
Team Meetings	$[****]	$[****]		
Project Team Meetings - Internal Meetings	$[****]	$[****]	- GSSU team for updates about IRB approvals, protocol v8 questions, amendment and updated IB sign-off page -DM Manager and Sr. DB Programmer meeting about Protocol v8 eCRF changes	NA GSSU Manager [****] hr. Sr. Database Programmer India [****] hours Data Manager NA [****] hours
Project Team Meetings - Client Teleconferences	$[****]	$[****]	- Sponsor conference call with Israeli Sr, CRA about Protocol v8 changes. -Sponsor conference call with PM and DM Manager about DSUR data	Israeli Sr. CRA [****] hrs PM and Data Manager NA [****] hours ([****] hour each) - reduced rates decreased the total amount.
Project Team Meetings - Kick-off Meeting	$[****]	$[****]	Project Team Meetings - Kick-off Meeting with [****] and [****]	NA Director - [****] hours NA Managers X[****] ([****] DM [****] CM) - [****] hrs Sr. Project Coordinator [****] hours
Total Direct Costs	**$[****]**	**$[****]**		

Total Costs

Category	Total Costs($)		
	Current Contract (USD)	Change in Scope # 5 (USD)	Revised Total (USD)
Pass-Through Costs	$[****]	$[****]	$[****]
Investigator Grants Costs	$[****]	$[****]	$[****]
Professional Fees	$[****]	$[****]	$[****]
Discount	-$[****]	$[****]	-$[****]
Revised Professional Fees	**$**[****]	**$**[****]	**$**[****]
Grand Total	**$**[****]	**$**[****]	**$**[****]

1. PAYMENT TERMS

A. Service Fees: [****]

B.

2. Pass Through Costs:

(a) CO#2: Twenty percent (20%) of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling $[****], were paid on execution of Change Order #2. Prepayment for Out of Pocket Expenses (to be drawn down once paid and replenished once 75% depleted). This process to continue until the end of the study.

(b) CO#3: Twenty percent (20%) of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling $[****], were paid on execution of Change Order #2. Prepayment for Out of Pocket Expenses (to be drawn down once paid and replenished once 75% depleted). This process to continue until the end of the study.

(c) CO#4: This one-time payment of $[****] (exclusive of funds for investigator grants), was paid on execution of Change Order #4.

(d) CO#5: This is a one-time payment of $[****] (exclusive of funds for investigator grants), that will be due and payable upon execution of this Agreement.

(e) Actual pass-through expenses, as provided in the expenses estimate, will be billed as incurred by inVentiv Health Clinical

(f) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

3. Investigator Grants:

(a) Twenty percent (20%) of the estimated total of the grant payments of the study, totaling $ [****], were paid on execution of Change Order #2. Prepayment for Investigator Grants (to be drawn down once paid and replenished once 75% depleted). This process to continue until the end of the study.

(b) inVentiv Health Clinical will submit invoices in advance for estimated amounts to be paid to investigators during the next quarter to ensure that adequate funds are available to pay investigator grants

(c) inVentiv Health Clinical will not make payments to investigators without having sufficient funds available in advance.

(d) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

4. Payment Conditions:

(a) For all Services, pass through expenses and investigator grants invoiced, payments are due net thirty (30) days from invoice date as set forth in Terms, Item 2 of the Agreement. In the event of a dispute, all undisputed portions of the invoice(s) are due within the above stated terms

(b) Payments shall be made in the currency identified above and shall be made free of any applicable local withholding taxes, charges or remittance fees. Invoices will be inclusive of applicable taxes as determined by local laws and regulations

(c) inVentiv Health Clinical reserves the right to charge interest against any unpaid overdue balance at the rate of one and a half percent (0.5%) per month

(d) All services and pass-through payments should be sent via wire or Automated Clearing House (ACH).

Exhibit 4.19

CLINICAL TRIALS GLOBAL MASTER SERVICES AGREEMENT
AMENDMENT NO. 2

This Amendment No. 2 is made effective as of the date last signed below ("Amendment No. 2 Effective Date") by and between RedHill Biopharma, Ltd. ("Client") and Quest Diagnostics Clinical Laboratories, Inc. ("Quest Diagnostics"). This Amendment No. 2 amends the Clinical Trials Global Master Services Agreement dated 27-December-2012 (the "Agreement") as amended by Amendment No. 1 effective June 20, 2014 ("Amendment No.1") to which both Client and Quest Diagnostics Client are parties. Client and Quest Diagnostics shall be referred together as the "Parties".

1. The purpose of this Amendment No. 2 is to extend the Term set forth in section 3.1 of the Agreement.

2. The Parties agree to replace the first sentence of section 3.1 to read as follows:

   "This Agreement shall be effective as of the Effective Date, and shall continue in full force and effect through August 1, 2017, unless otherwise terminated as provided herein (the "Term")."

3. All other terms and conditions of the Agreement and Amendment No. 1 shall remain in full force and effect.

The Parties agree to this Amendment No. 2 by their authorized signatures below.

REDHILL BIOPHARMA LTD.

/s/ Ori Shilo /s/ Uri Hananel Aharon
Signature

Name Printed: Ori Shilo and Uri Hananel Aharon

Title: Deputy CEO and Chief Accounting Officer

Date: May 11, 2015

QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC.

/s/ Christopher Fikry
Signature

Name Printed: Christopher Fikry, M.D.

Title: Vice President, Clinical Trials

Date: May 13, 2015

CONFIDENTIAL

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMIITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

MASTER AGREEMENT WORK ORDER
AMENDMENT #1

Protocol # RHB-104-01 (MAP and Other Analysis)

Effective Date: date of last signature below

RedHill Biopharma
21 Ha'arba'a St.
Tel-Aviv Israel 64739

WHEREAS, RedhIll Biopharma Ltd. and Quest Diagnostics Clinical Laboratories, Inc. are parties (together the "Parties") to a Clinical Trials Global Master Services Agreement dated 27-December-2015 (the "Agreement") and have also entered into a Work Order on 10-Oct-2013 pursuant to Protocol RHB-104-01 (the "Work Order").

WHEREAS, Quintiles Laboratories and Quest Diagnostics have formed the company Q Squared Solutions (Quest) LLC, to provide certain laboratory services (including central and bio-analytical laboratory services).

WHEREAS, pursuant to the joint venture described in the above recital, Q Squared Solutions (Quest) LLC will hereinafter perform the Services under the Agreement, and all references to Quest Diagnostics Clinical Laboratories, Inc. in the Agreement, the Work Order and this Amendment #1 shall reflect Q Squared Solutions (Quest) LLC (hereinafter "Q Squared") following the effective date of this Amendment.

NOW THEREFORE, the Parties agree as follows:

1. The purpose of this Amendment #1 to the Work Order is to revise the budget, update the project term and to provide services by Q Squared Solutions.

2. The Term of the Agreement shall now be as follows:
Effective Date: 10-Oct-2013 End Date: [****]

3. The Budget has been updated to reflect :
- the addition of Australia and New Zealand;
- an estimate for optional [****]use in the US only;
- the addition of [****];
- updated [****], [****], [****]
- that Israel and [****]shipping costs from sites direct [****]have been line itemed until Quest is notified to begin shipping directly and the budget will be updated with these costs at that time;
- outbound shipping of [****]is included - estimating [****]per site;
- the inclusion of[****];
- the addition of [****]: [****], [****], [****], [****], [****], [****];
- additional updates made to [****], [****] per client request;
- the addition of [****]

- and a revised [****] sample volume;
- add [****]([****] sites/[****] screen/[****] randomized);
- remove [****] patients from [****] to move to [****];
- update visit names;
- study amendment fee;
- update to [****];
- [****];
- [****];
- Add [****], [****] to be sent to [****];
- change to [****];
- New kit for [****];
- costs added for [****];
- extend DNA storage length to 10 years.

4. The revised Estimated Central Laboratory Budget is attached hereto as Attachment #1, is incorporated herein by reference, and shall replace the Attachment #1 of the Work Order.

5. The study value is revised as follows:

Document	Change Value	Total Study Contracted Value*
Original Work Order	$0.00	$[****]
Amendment #1	$[****]	$[****]

*RedHill shall be invoiced for actual tests performed and services rendered.

6. All other terms and conditions of the Work Order and the Clinical Trials Global Master Services Agreement (the "Agreement") shall remain in full force and effect. In the event of any conflict between the terms of the Agreement, the Work Order, and this Amendment, the terms of this Amendment shall control.

7. The parties hereto agree to this Amendment #1 as of the effective date by authorized signature below.

REDHILL BIOPHARMA LIMITED

/s/ Dror Ben Asher /s/ Ori Shilo
Authorized Signature

Dror Ben-Asher Ori Shilo
Name Printed

CEO Deputy CEO
Title

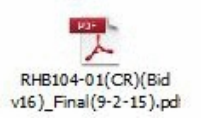
December 29, 2015
Date

Q SQUARED SOLUTIONS (QUEST) LLC

/s/ Terrence D. Burke
Terrence D Burke
Authorized Person

December 30, 2015
Date

Attachment # 1
Protocol # RHB-104-01 (MAP and Other Analysis)



[The Quest Diagnostics Budget Version #16, dated 2-Sep-2015, is attached hereto, is incorporated herein, contains 27 printed pages, and shall be printed in full for contract signature]

CONFIDENTIAL

Q^2 Solutions, a Quintiles Quest Joint Venture
Central Laboratory Services Budget

Q^2 Solutions, a Quintiles Quest Joint Venture (JV), brings together the clinical trials laboratory operations of the two parent organizations to provide biopharmaceutical customers with the diverse capabilities and end-to-end services required in the rapidly evolving biopharmaceutical industry. The new organization creates a global laboratory network that combines Quintiles' scale, clinical trial expertise, and diverse therapeutic experience with Quest Diagnostics' operational, scientific and quality excellence, supply-chain network and informatics to promote greater innovation, quality and value for biopharmaceutical customers.

RedHill Biopharma Limited
RHB-104-01 (CR)
Version 16
2-Sep-15

Prepared for: [****]
[****]
[****]
[****]
[****]

Tel: [****]

Email: [****]

by: [****]
[****]
[****]
[****]
[****]
[****]

Tel: [****]
Fax: [****]
Email: [****]

2-Sep-15

Patrick L. McLean
Product Manager
RedHill Biopharma Limited
21 Ha'arba'a St.
Tel-Aviv Israel 64739

Regarding: **Centralized Clinical Laboratory and Related Support Services for Protocol RHB-104-01 (CR)**

Dear Patrick :

Thank you for the opportunity to submit a revised budget for your study. This budget includes the following changes.

version16:
- add [****] ([****] sites/[****] screen/[****] randomized)
- remove [****] patients from US to move to [****]
- update visit names
- study amendment fee: update to [****], Initial [****] receiving reported as [****]. Remaining [****] to be [****], add [****], AUS/NZ MAP to be sent to [****],[****], New kit for [****] collection
- costs added for [****]
- extend DNA storage length to 10 years

Q^2 Solutions, a Quintiles Quest Joint Venture has a commitment to peak performance, superior value for our customers, teamwork, innovation and integrity. We look forward to the opportunity to work with you to demonstrate our dedication to these values.

If you have any questions or require further assistance, please feel free to call me.

Yours sincerely,

[****]
Senior Strategic Account Executive
Q^2 Solutions, a Quintiles Quest Joint Venture

RedHill Biopharma Limited **Quote for Services**

Assumptions
Protocol: RHB-104-01 (CR)

Assumptions:

Global Phase III trial
[****] countries, [****] sites: Israel: [****] sites, US/Canada: [****] sites, AUS: [****], NZ: [****], respectively, [****]: [****] sites, [****]: [****] sites
[****] screened , [****] baseline to visit [****], and decreasing number of patients from visit [****] to visit [****]
Recommended couriers:
Israel- sites to [****], sites to Quest ([****],[****] and [****]and [****]),
[****]- sites to [****] ([****],[****]), sites to Quest [****] ([****], [****] and [****] and [****]),
[****]- sites to [****] ([****], [****]), sites to Quest [****] ([****], [****]and [****] and [****]),
Canada - sites to [****] ([****] and [****]), sites to Quest [****] ([****] and [****]),
US- sites to [****] ([****]), sites to Quest [****] ([****]),
Quest [****]
[****] to Quest US- [****] ([****])
Courier mapping- [****],[****],[****]:
Sites to Quest [****],
Sites to Quest [****], [****], [****].
Sites to Quest [****], [****].
Sites to [****]
Quest UK to [****], [****]
Courier mapping- [****] /Australia/New Zealand
Sites to Quest [****]
Sites to Quest [****], [****], [****].
Sites to [****]
Sites to [****], [****].
[****] to Quest [****]
Inbound budget (shipments from sites to Quest Diagnostics): [****], [****]
[****], [****].
PK [****]
PK [****], [****].
Worst case scenario: we assume [****] to be revised in accordance to validation data.
PK [****]
HIV Western Blot- we assume [****]
[****]:
1- [****],
2- [****],
3- [****],
4- [****],
5- [****].
[****]
Stored specimen:
For bidding purpose, we assume average storage of [****]. [****].
DNA extraction samples are due to be stored for 10 years.
Note: RedHill Biopharma is charged for rendered services only.
[****]-
[****] ([****], [****]) [****].
[****].
[****]
[****]
[****]
[****]

Week-end shipments from sites - [****]
EWP(extreme weather packaging)- [****].
Australia and New Zealand supplies are sourced from the US, these quantities are reflected in US region.

- [****]:
- [****] sites ([****] Aust, [****] NZ)
- [****] total visits plus ET
- [****] Enrolled ([****] total patient visits)
- supplies are sourced locally

Forceps can only be shipped in US; remaining countries will be sourced locally by RHB.

RedHill Biopharma Limited **Quote for Services**

Change In Scope History
Protocol: RHB-104-01 (CR)

Category	Updated Study Value	Previous Study Value *	Difference	Comments
Laboratory Testing	$[****]	$[****]	$[****]	Addition of [****] patients ([****] screened/[****] randomized/[****] completed): total of [****] additional patient visits
Supplies	$[****]	$[****]	$[****]	EU supplies increase of [****]% to account for [****] patients.
Additional Pass-Through Services	$[****]	$[****]	$[****]	Reduction in US weekend shipments for patients that moved under [****]:-$[****] [****]budget: $[****] [****] outbound sample shipping: $[****] [****] weekend shipments: $[****]
Study Management	$[****]	$[****]	$[****]	Capture all amendment charges: - update to [****] - add [****] - change to AUS/NZ [****] to [****] - change to [****] - New kit for [****] Per visit quantities updated to capture [****] patients
Storage & Services	$[****]	$[****]	$[****]	[****]
Inbound Transportation	$[****]	$[****]	$[****]	Adjustment to account for [****] shipping
Batched Inbound	$[****]	$[****]	$[****]	Adjustment to account for [****] shipping
Outbound Transportation	$[****]	$[****]	$[****]	Adjustment to account for [****] shipping
Outbound Transportation - Shipping Containers	$[****]	$[****]	$[****]	Adjustment to account for [****] shipping
Estimated Central Laboratory Budget:	**$[****]**	**$[****]**	**$[****]**	

* Budget taken from RedHill Biopharma Limited: RHB-104-01 (CR).v15

Date	Reason	Total Value	Difference
31-Oct-11	Original	$[****]	$[****]
14-Nov-11	Version2 reflects the amended protocol (28October 2011)- MAP testing and Chemistry/Hematology/Inflammatory markers/Urinalysis/Other AP markers	$[****]	$[****]
24-Nov-11	version3: updated MAP testing processes/pricing, increasing number of MAP tests, expanded stool culture COP panel (addition of [****] agents: [****])	$[****]	$[****]
21-Dec-11	version4: MAP validations/testing and other analysis [****]: revised countries:patients distribution for USA, Canada versus Israel resulting in a grand total of [****] screned/ week26-week[****] patients in North America and [****] patients in Europe Combined shipments(ambient/frozen) at screening, [****] and [****] Updated selection of couriers in Canada and US for ambient shipments with [****] and Quest courier respectively	$[****]	$[****]
11-Jan-12	Version 5: Updated discounting in testing and study management section.	$[****]	$[****]

29-Aug-12	version6 reflects Protocol dated 22-Aug-2012 Updated country:site:visit:patient distribution. 3 countries, [****] sites, [****] screened/other visits patients Routine clinical laboratory tests (hematology, biochemistry, inflammatory markers and stool tests performed at Quest Diagnostics. Viral serology performed at screening visit. Urine pregnancy kits and urinalysis dipsticks to be supplies by Quest to sites [****]assay performed at Quest Diagnostics (frozen whole blood), Additional samples of [****]blood([****]) collected and frozen at weeks [****]. These samples will be retained at Quest Diagnostics during the course of the study for future MAP assessment. PK specimens management Courier model as follow: (1) Combined shipments (ambient and frozen) at screening, [****] only.	$[****]	$[****]
7-Mar-13	version 7 reflects FINAL protocol dated 20Feb2013 All testing managed by Quest Diagnostics: safety, MAP testing and PK analysis.	$[****]	$[****]
20-Mar-13	version8 captures study specs discussed on 20-March with RHB.	$[****]	$[****]
15-Apr-13	version9: PK analysis ([****]) done by a 3rd party located in Canada (confirmed by RHB 5-April); PK analysis ([****]) to be confirmed soon by RHB: testing AND validation fees as line items into this budget (zero quantity) - budget to be updated if QDCT eventually perform PK tissue analysis; validation fees(removed and to be included into the existing fully separate contract relating to MAP validations; no changes into the transportation budget ([****]s collected at the same time than other [****]samples).	$[****]	$[****]
2-Sep-13	version10 captures the most recent decisions/information including notably the protocol amendment, approved [****], [****]for v, updated samples processes for Israel, US/Canada, special supplies.	$[****]	$[****]
25-Sep-13	version11- adjusted testing/aliquoting/storage mapping.	$[****]	$[****]
8-Oct-13	version 12: Updated patients:visits distribution based on info dated 9-October (decreasing grand total number of patient-visits)	$[****]	$[****]
5-Jun-14	version13: add Australia and New Zealand; add estimate for optional [****]use in US only.	$[****]	$[****]

14-Nov-14	version14: add [****]; update site numbers; [****]kits, starter packs and resupplies have been updated based on study amendments; Israel and [****] shipping costs from sites direct [****]have been line itemed until Quest is notified to begin shipping directly- budget to be updated with these costs at that time; outbound shipping of cooled [****] has also been included- estimate [****] shipments per site; [****]charge included as line item; add [****]	$[****]	$[****]
15-Jan-15	version15: - update site/visit/patient numbers per Patrick 19 Jan 2015, - addition of [****], - revised [****]volume of samples	$[****]	$[****]
18-Jun-15	version16: [****] ([****] sites/[****] screen/[****] randomized) - remove [****] patients from US to move to [****] - update visit names - study amendment fee: update to [****]results, [****]reported as[****]. [****]Remaining [****] related results to be [****], add [****], AUS/NZ MAP to be sent to [****], change to PK, New kit for calprotectin collection - costs added for [****] - extend DNA storage length to 10 years	$[****]	$[****]

RedHill Biopharma Limited **Quote for Services**

Budget Summary
Protocol: RHB-104-01 (CR)

Study Duration:	[****]	Total Investigators:	[****]
Quote Date:	[****]	Total Countries:	[****]
Quote Expiration Date:	[****]	Total Visits:	[****]
		Total Patient-Visits:	[****]

Estimated Grand Total Amount **$[****]**
Average Cost Per Patient-Visit **$[****]**
Average Cost Per Patient **$[****]**

Budget Summary [1]

Sub-Totals	Region	Billing Amount	Conversion Rate	Estimated Total Amount
	USA, Canada	$[****]	1.0000	$[****]
* See Budget Summary_EU	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
	Study Set-up Fees	$[****]	1.0000	$[****]
				$[****]

Average Cost Per Patient-Visit	Region	Estimated Total Amount	Patient Visits	Average Cost
	USA, Canada	$[****]	[****]	$[****]
	Israel, [****], [****]	$[****]	[****]	$[****]
	Australia, New Zealand	$[****]	[****]	$[****]
	Study Set-up Fees	$[****]		
		$[****]	**[****]**	**$[****]**

Average Cost Per Patient	Region	Estimated Total Amount	Patients	Average Cost
	USA, Canada	$[****]	[****]	$[****]
	Israel, [****], [****]	$[****]	[****]	$[****]
	Australia, New Zealand	$[****]	[****]	$[****]
	Study Set-up Fees	$[****]		
		$[****]	**270**	**$[****]**

Detailed Budget Summary

Laboratory Testing	Region	Billing Amount	Conversion Rate	Estimated Total Amount
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
Laboratory Testing Total 1LT,3LT,5LT,6LT,7LT,8LT,9LT				**$[****]**

Supplies	Region	Billing Amount	Conversion Rate	Estimated Total Amount
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
Supplies Total *SL				**$[****]**

Additional Pass-Through Services	Region	Billing Amount	Conversion Rate	Estimated Total Amount
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
Additional Pass-Through Services Total				**$[****]**

Storage	Region	Billing Amount	Conversion Rate	Estimated Total Amount
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
Storage Total 1ST,2ST,3ST				**$[****]**

Study Management	Region	Billing Amount	Conversion Rate	Estimated Total Amount
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]

	Study Set-up Fees	$[****]	1.0000	$[****]
Study Management Total [1SM,2SM,3SM,4SM,5SM,6SM,7SM,8SM]				**$[****]**
Inbound Transportation	**Region**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
Inbound Transportation Total [1IT,2IT,3IT,**]				**$[****]**
Inbound Batched Shipments	**Region**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
Inbound Batched Shipments Total [1IT,2IT,3IT,***]				**$[****]**
Outbound Transportation	**Region**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**
	USA, Canada	$[****]	1.0000	$[****]
	Israel,[****], [****]	$[****]	1.0000	$[****]
	Australia, New Zealand	$[****]	1.0000	$[****]
Outbound Transportation Total [1OT,2OT,3OT,4OT,5OT,6OT,7OT]				**$[****]**
Shipping Container Transportation	**Region**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**
	USA, Canada	$[****]	1.0000	$[****]
	Israel, [****], [****]	$[****]	1.0000	$[****]
Shipping Container Transportation Total [5OT,6OT,7OT]				**$[****]**

Fee Type	Israel	[****]	[****]	Total EU
Laboratory Testing	$[****]	$[****]	$[****]	$[****]
Supplies	$[****]	$[****]	$[****]	$[****]
Special Services	$[****]	$[****]	$[****]	$[****]
Study Management	$[****]	$[****]	$[****]	$[****]
Storage & Services	$[****]	$[****]	$[****]	$[****]
Inbound Transportation	$[****]	$[****]	$[****]	$[****]
Batched Inbound	$[****]	$[****]	$[****]	$[****]
Outbound Transportation	$[****]	$[****]	$[****]	$[****]
Outbound Transportation - Shipping Containers	$[****]	$[****]	$[****]	$[****]
Estimated Central Laboratory Budget:	$[****]	$[****]	$[****]	**$[****]**

RedHill Biopharma Limited **Quote for Services**

Detail Summary
Protocol: RHB-104-01 (CR)

Laboratory Testing	Region	Time Points	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	TBD	TBD	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	1	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Laboratory Testing Total							**$[****]**			**$[****]**	**$[****]**

Supplies	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
[****]	USA, Canada	CASE	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	CASE	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	BOX	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	CASE	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	PACK	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	Israel, [****], [****]	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	EACH	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Supplies Total							**$[****]**			**$[****]**	**$[****]**

Additional Pass-Through Services	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

Additional Pass-Through Services	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
[****]			[****]								
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Additional Pass-Through Services Total							**$[****]**			**$[****]**	**$[****]**

Storage	Region	Aliquots	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

Storage	Region	Aliquots	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
	Israel, [****],		413	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		9,499	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		413	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		922	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		Line	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]	Item								
	Israel, [****],		922	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		121	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		Line	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]	Item								
	Israel, [****],		121	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		Line	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]	Item								
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		1,219	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		6,307	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		6,307	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		669	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		15,387	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		669	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		669	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		79,611	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		669	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		669	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		79,611	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		669	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		262	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		31,178	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									
	Israel, [****],		262	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	[****]	[****]									

[****]	Israel, [****], [****]	[****]	262	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	31,178	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	262	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	931	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	931	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	931	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	53	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	262	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	262	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	922	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	922	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	922	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	121	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	121	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]	[****]	121	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

Storage	Region	Aliquots	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand	[****]	[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Storage Total							**$[****]**			**$[****]**	**$[****]**

Study Management	**Region**	**Unit**	**Quantity**	**Billing Currency Unit Price**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**	**Previous Quantity**	**Previous Billing Currency Unit Price**	**Previous Estimated Total Amount**	**Estimated Total Variance**
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Study Set-up Fees		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Study Set-up Fees		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Study Set-up Fees		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Study Set-up Fees		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Study Management Total							**$[****]**			**$[****]**	**$[****]**

Inbound Transportation	**Region**	**Unit**	**Quantity**	**Billing Currency Unit Price**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**	**Previous Quantity**	**Previous Billing Currency Unit Price**	**Previous Estimated Total Amount**	**Estimated Total Variance**
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]

[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Inbound Transportation Total							**$[****]**			**$[****]**	**$[****]**

Inbound Batched Shipments	**Region**	**Unit**	**Quantity**	**Billing Currency Unit Price**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**	**Previous Quantity**	**Previous Billing Currency Unit Price**	**Previous Estimated Total Amount**	**Estimated Total Variance**
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Inbound Batched Shipments Total							**$[****]**			**$[****]**	**$[****]**

Outbound Transportation	**Region**	**Unit**	**Quantity**	**Billing Currency Unit Price**	**Billing Amount**	**Conversion Rate**	**Estimated Total Amount**	**Previous Quantity**	**Previous Billing Currency Unit Price**	**Previous Estimated Total Amount**	**Estimated Total Variance**
[****]	USA, Canada		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	[****]	$[****]	[****]	$[****]	$[****]	$[****]

[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Australia, New Zealand		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Outbound Transportation Total							**$[****]**			**$[****]**	**$[****]**

Shipping Container Transportation	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount	Previous Quantity	Previous Billing Currency Unit Price	Previous Estimated Total Amount	Estimated Total Variance
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	USA, Canada		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
[****]	Israel, [****], [****]		[****]	$[****]	$[****]	1.0000	$[****]	[****]	$[****]	$[****]	$[****]
Shipping Container Transportation Total							**$[****]**			**$[****]**	**$[****]**

RedHill Biopharma Limited **Quote for Services**

Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR)

[****]

RedHill Biopharma Limited **Quote for Services**

Patient Visit Schedule
All Locations
Protocol: RHB-104-01 (CR)

Country	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
Calculated Totals:	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
Canada (Toronto)	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
United States (New York)	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
Israel (Tel Aviv)	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
Israel (Tel Aviv) - sites direct to [****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
Canada (Toronto) - sites direct to [****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
United States (New York) - sites direct to [****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
Australia ([****])	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
Australia ([****]) - sites direct to [****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
New Zealand ([****])	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
New Zealand ([****]) - [****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
[****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
[****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
[****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]
[****]	[****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****][****]

RedHill Biopharma Limited **Quote for Services**

End Notes
Protocol: RHB-104-01 (CR)

Global Summary

[1] See Study Specific Assumptions and Pricing Model, herein. Budget excludes any "TBD" (To Be Determined) items.

Global Summary - Laboratory Testing (LT)

[1LT] Quoted fees reflect Q² Solutions', a Quintiles Quest Joint Venture, Year 2011 Fee Schedule.

[2LT] Referral test to be performed by UFC. Fee includes the referral laboratory charge plus a referral fee for sample handling, data entry and result reporting. Any fee increase imposed by the Referral laboratory will be passed on to Client.

[3LT] Fees quoted for testing services performed are exclusive of any applicable added Taxes (including Value Added Tax (VAT)).

[4LT] Test to be performed by our alliance partner laboratory, Tan Tock Seng, in Singapore.

[5LT] The sample testing fees include the receipt of samples into a Q^2 Solutions, a Quintiles Quest Joint Venture, -owned, affiliate or alliance partner laboratory, the direct costs associated with the laboratory testing of the samples, retention of the unused samples for a maximum of fourteen (14) days, laboratory quality control and global standardisation of equipment, processes, controls and calibrators.

[6LT] The sample testing fees also include the distribution of interim result reports (per patient visit) and final result reports to Investigator(s) and/or Clients/CROs as applicable and agreed in the Central Laboratory Worksheet. Any final result reports issued in hard copy will be sent via standard postal service or (within the continental United States only) Q^2 Solutions, a Quintiles Quest Joint Venture, -US proprietary courier.

[7LT] It is Q^2 Solutions', a Quintiles Quest Joint Venture, experience that investigator sites experience significant challenges producing a peripheral blood smear (PBS) of sufficient quality for an appropriate hematology laboratory PBS review. Therefore, it is standard Q^2 Solutions', a Quintiles Quest Joint Venture, practice to not provide glass slides and to not require the sites to make PBS slides . The performance by Q^2 Solutions, a Quintiles Quest Joint Venture, of a routine safety CBC analysis (hematology) does involve the occasional review of PBS slides for the white blood cell morphology and differential, red blood cell morphology and platelet evaluation if the instrument or the SOP flags the specimen for a PBS slide review. The PBS slide can be appropriately created and reviewed in the majority of cases by the laboratory from the submitted CBC sample if a review is required.

[8LT] If the protocol requires a PBS slide review then glass microscope slides will be provided to the site(s) for each appropriate visit so that the site can create and provide a PBS to the central laboratory. Protocols where in our experience peripheral blood smears are recommended include significant hematological/bone marrow abnormalities (white or red cell, platelet abnormalities), leukaemia's, HIV clinical trials, sepsis, or other severe illnesses that would be impacting the hematological system. Our scientific affairs and medical affairs teams are available to further discuss the needs of your protocol regarding any requirements for PBS creation by the site or by the laboratory and PBS slide review by the Quest laboratory. Please could you confirm if this protocol requires a peripheral blood smear review or if subjects in this study are expected to have hematological abnormalities where we would recommend the preparation of peripheral blood smears at the investigator site.

[9LT] CBC and Peripheral blood smear pricing are based on assumptions received at the point of preparing this quotation. Q^2 Solutions, a Quintiles Quest Joint Venture, reserves the right to adjust these pertinent to further discussion with the customer.

Global Summary - Supplies (SL)

[*] The Supplies total for shipping containers is based on one separate shipment for each patient visit and reflects a "worst case scenario." Shipper container costs may be dramatically reduced when sites batch specimens prior to shipment to the laboratory.

Global Summary - Storage (ST)

[1ST] The "In" fee includes receipt, preparation, storage and entry of specimens into Q^2 Solutions, a Quintiles Quest Joint Venture storage facility and computer system.

[2ST] The "Monthly Maintenance" fee includes inventory, storage, temperature monitoring and continuous security coverage at Q^2 Solutions, a Quintiles Quest Joint Venture storage facility.

[3ST] The "Pull" fee includes the removal of requested specimens from storage, sorting of specimens prior to shipment (in a manner requested by client, e.g. - by patient, by visit) and the generation of a manifest.

Global Summary - Study Management (SM)

[1SM] The Study Management set-up fees quoted include provision for our standard toxicity and exclusions flagging; and cumulative data transmissions sent weekly via email zip file or SFTP or portals in our standard data file format. The fees do not include any set-up related to storage samples, new testing method set-up's, algorithms, microbiology testing or referral lab data entry. If client requires Q^2 Solutions, a Quintiles Quest Joint Venture, to add any of these elements or set up additional flagging options and use data files which differ to our standard format, we reserve the right to adjust our set-up fees accordingly.

[2SM] The Project Management Study Set-Up fee includes an internal review of the protocol in conjunction with the client's study team and formulation of an agreed Central Laboratory Worksheet signed off by Client and Q2 Solutions, a Quintiles Quest Joint Venture, which lays out detailed specifications for the set-up and management of the study. Q^2 Solutions, a Quintiles Quest Joint Venture, will design study documents, which include Investigator Manuals in the languages specified in the budget, a Lab Requirement Summary and pictogram, and study specific test Requistion forms in accordance with these specifications, as part of this fee. The design of visit specific specimen collection kits and set-up of Investigator site information is included as part of Project Management set-up.

[3SM] The fee Per Visit for Project Management covers ongoing Project Management support, 24/7 investigator assistance/support by Q^2 Solutions, a Quintiles Quest Joint Venture, CRC Support Team, including the use of toll-free phone lines. Auto faxing of supply expiry details and inclusion of alerts and delta flagging are also covered by this fee.

4SM The fee Per Visit for Data Management covers ongoing Data Management support, maintenance of the results database and the actioning and documentation of all necessary data revisions and data transfers up to once per week.

5SM The fee Per Visit for Logistics covers the expertise and management of the ongoing study logistics, shipment tracking, processing and auditing of courier invoices and the performance management of the courier companies.

6SM Q^2 Solutions, a Quintiles Quest Joint Venture, proprietary software Result/ViewTM – web-based version shall be included for the two users per study at no additional charge, more than two users will be charged. This includes training and support by telephone.

7SM Q^2 Solutions, a Quintiles Quest Joint Venture will charge a per work order fee associated with each pull order. The purpose of this is to maximize the batching of samples whenever they are pulled for regular or ad hoc shipments from sample storage in order to create operational efficiency.

8SM Q^2 Solutions, a Quintiles Quest Joint Venture will charge a STAT per work order fee associated with each STAT pull order request. The purpose of this charge is for STAT pull order requests needed in 5 business days or less.

Global Summary - Inbound Transportation (IT)

** The Inbound Transportation total is representative of individual patient specimen shipments and reflects a "worst case scenario". Transportation totals may be dramatically reduced when sites batch specimens prior to shipment to the laboratory. Please note if India, Russia and the Ukraine are participating in the study those countries dry ice and packaging fees are included in the inbound charges.

*** The Total Batched Inbound Transportation is representative of 24 batched shipments per site for frozen samples. Please note if India, Russia and the Ukraine are participating in the study those countries dry ice and packaging fees are included in the inbound charges.

1IT The inbound specimen transportation fees are based on typical volumetric weight, and vary by city. Q^2 Solutions, a Quintiles Quest Joint Venture will bill client actual transport costs, per the invoice of the transport company. Any change to the fee imposed by the courier will be passed on to client. Additional charges for secondary cities, holidays and weekend service may apply.

2IT The USD ($) Inbound Diagnostic Transportation fees quoted are based on an estimated exchange rate of £1 GBP = $ 1.6022. However, all Inbound Diagnostic Transportation will be billed at the actual £GBP to USD ($) rate ruling in the applicable month as published by UK Customs and Excise. Thus the Inbound Transportation fees may vary from those quoted in this budget in any given month depending on what the actual exchange rate is.

3IT The Logistics estimates included represent our best recommendations based on recent experience. We welcome the opportunity to discuss carrier performance and recommendations since the decision on courier selection ultimately resides with the sponsor.

Global Summary - Outbound Transportation (OT)

1OT Initial Supply Shipments: Initial shipments will be distributed within ten (10) working days from Client's approval of the (a) requisition form, (b) Investigator Manual, and (c) receipt of Client's final Investigator list. Q^2 Solutions, a Quintiles Quest Joint Venture, must also receive Client's approval of Q^2 Solutions', a Quintiles Quest Joint Venture, verification report (without changes) at least 2 days prior to shipment.

2OT Please note that Q^2 Solutions, a Quintiles Quest Joint Venture does charge an additional fee for expedited/priority starter pack shipments.

3OT Shipment of Re-supplies: Re-supply orders will be distributed within five (5) working days of Q^2 Solutions', a Quintiles Quest Joint Venture, receipt of the Request for Supplies form from the Investigator or Client. Any re-supply orders containing special supplies shall be shipped upon supply availability and may require more than a five (5) working day turnaround.

4OT Q^2 Solutions, a Quintiles Quest Joint Venture, will use commercially-reasonable efforts to provide re-supply orders with less than five (5) working-days prior notification from Client or the Investigator ("STAT re-orders"). However, Client will be responsible for all additional labor and transportation charges associated with STAT re-orders.

5OT The Outbound transportation fees are based on typical volumetric weight. Q^2 Solutions, a Quintiles Quest Joint Venture will bill client actual transport costs per the invoice of the transport company. Any change to the fee imposed by the courier will be passed on to client. Priority shipments, e.g. next-day air are additional. Fees for outbound supply shipments do not include any imposed tariffs.

6OT The USD ($) Outbound transportation fees quoted are based on an estimated exchange rate of £1 GBP = $ 1.6022. However, all Outbound Transportation will be billed at the actual £GBP to USD ($) rate ruling in the applicable month as published by UK Customs and Excise. Thus the actual Outbound Transportation fees may vary from those quoted in this budget in any given month depending on what the actual exchange rate is.

7OT The Logistics estimates included represent our best recommendations based on recent experience. We welcome the opportunity to discuss carrier performance and recommendations since the decision on courier selection ultimately resides with the sponsor.

Exhibit 4.22

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMIITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION

REDHILL BIOPHARMA LTD

Change Specification Form

(Q²Solutions, a Quintiles Quest Joint Venture)

Protocol:	**Requester:**	
RHB-104-01	Patrick McLean	
Proposed date	**Project Manager(s):**	**Date of Request:** 17-Jun-15
of Implementation:	Fitt,Penny	**Request Reference – Title:** US-9182
6 weeks from approval	KLINGLER, MARIANA	

Original Specifications (if applicable):

N/A

Change in Specifications/New Specifications:

Addition of [****]. [****] sites, [****] patients randomized in one year with the first patient in [****], [****]. We are assuming a [****] screen failure rate. This country is to follow the EU MAP process.

Please see details of changes :

☒ **Database**

- ☒ Addition of investigator site (Per site) [****]

☒ **Investigator Manual**

- ☒ Create/Update contact & transport appendix/SSIs

☒ **Management Fees**

- ☒ Administration fee

☒ **Requisition(s) including Starter/Reorder Forms**

- ☒ Forms (Requisitions/Starter pack/Reorder) : update 1-3

Total Amendment Fee: $ [****] for account 64160601 (US)

This Change Specification Form includes the cost of the amendment fee associated with the above noted change(s). The amendment budget will include any additional supply, testing, or transportation charges incurred as a result of these changes.

Comments

Reviewer's Name:

Signature: /s/ Uri Hananel Aharon, CAO Date: Sep. 17, 2015

Signature: /s/ Ori Shilo, Deputy CEO Date: Sep. 17, 2015

Exhibit 12.1

CERTIFICATION BY CHIEF EXECUTIVE OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dror Ben-Asher, certify that:

1. I have reviewed this annual report on Form 20-F of RedHill Biopharma Ltd.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 25, 2016

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

Exhibit 12.2

CERTIFICATION BY CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Ori Shilo certify that:

1. I have reviewed this annual report on Form 20-F of RedHill Biopharma Ltd..;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting;

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: February 25, 2016

/s/ Ori Shilo
Ori Shilo
Deputy Chief Executive Officer Finance and Operations

Exhibit 13

CERTIFICATION BY CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of RedHill Biopharma Ltd. (the "Company") on Form 20-F for the period ended December 31, 2015 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that to such officer's knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 25, 2016

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

/s/ Ori Shilo
Ori Shilo
Deputy Chief Executive Officer Finance and Operations

Exhibit 15.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form F-3 (file No. 333-193503), the Registration Statement on Form S-8 (file No. 333-207654) and the Registration Statement on Form S-8 (file No. 333-188286) of RedHill Biopharma Ltd. of our report dated February 24, 2016, relating to the financial statements which appears in this Form 20-F.

Tel-Aviv, Israel
February 25, 2016

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

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