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, 2014

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)

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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: 87,884,114

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, 2014 ($1 = NIS 3.861). 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" includes 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 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;
- 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 the intellectual property rights of others;
- estimates of our expenses, future revenues capital requirements and our needs 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, 2013 and 2014 and for the years ended December 31, 2012, 2013 and 2014 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, 2010, 2011 and 2012 and and for the year ended December 31, 2010 and 2011from our audited financial statements not included in this Annual Report. You should read this selected financial data in conjunction with, and it is qualified in its entirety by, our historical financial information and other information provided in this Annual Report including "Item 5. Operating and Financial Review and Prospects" and our financial statements and related notes appearing elsewhere in this Annual Report.

	As of December 31				
	2014	**2013**	**2012**	**2011**	**2010**
Statement of Comprehensive Loss					
Revenues	7,014	12	16	23	-
Cost of Revenue	(1,050)	-	-	-	-
Research and development expenses, net	(12,700)	(8,100)	(6,455)	(5,414)	(736)
General and administrative expenses	(4,011)	(2,684)	(2,601)	(2,482)	(518)
Other income (expenses)	100	-	-	-	(479)
Operating loss	(10,647)	(10,772)	(9,040)	(7,873)	(1,733)
Financial income	319	158	197	570	65
Financial expenses	(383)	(14)	(1,483)	(8,200)	(876)
Financial income (expenses) – net	(64)	144	(1,286)	(7,630)	(811)
Loss and comprehensive loss	(10,711)	(10,628)	(10,326)	(15,503)	(2,544)
Loss per ordinary share (in U.S. dollars)	(0.17)	(0.17)	(0.20)	(0.32)	(0.27)
Basic	(0.12)	(0.17)	(0.20)	(0.32)	(0.27)
Diluted	(0.13)	(0.17)	(0.20)	(0.32)	(0.27)
Weighted average number of ordinary shares used in computing loss per ordinary share	86,610,126	62,379,171	52,595,128	48,087,362	9,600,000
Weighted average number of ordinary shares used in computing diluted loss per share	87,222,188	62,379,171	52,595,128	48,087,362	9,600,000

	2014	2013	2012	2011	2010
Balance Sheet Data:					
Cash and short term investments	22,945	12,113	18,365	18,647	9,152
Working capital	24,299	10,186	17,485	18,223	9,161
Total assets	28,856	14,340	20,096	20,186	10,510
Total liabilities	3,845	2,415	1,078	1,399	12,104
Accumulated deficit	(42,218)	(33,260)	(23,887)	(15,209)	(2,569)
Equity	25,011	11,925	19,018	18,787	(1,594)

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 products. All of our therapeutic candidates are in the clinical development stage, and 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 administrative expenses in support of our operations. We experienced net losses of approximately $10.7 million in 2014, $10.6 million in 2013 and $10.3 million in 2012. As of December 31, 2014, we had an accumulated deficit of approximately $42.2 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 we have out-licensed to Salix Pharmaceuticals, Inc., 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, 2014, we had cash and short term investments of approximately $23 million, and as of December 31, 2013, we had cash and short term investments of approximately $12.1 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 presently generated limited revenues. As we plan to continue expending substantial funds in research and development, including clinical trials, 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, among others:

- 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 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 securing commercialization agreements with third parties and favorable pricing and market share; 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 Salix Pharmaceuticals, Inc.) for bowel preparation; "BEKINDA™" (RHB-102) for acute gastroenteritis and gastritis, and for the prevention of chemotherapy and radiotherapy induced nausea and vomiting; MESUPRON® targeting gastrointestinal and other solid tumor cancers; "RP101" (currently subject to an option-to-acquire by us) targeting pancreatic and other gastrointestinal cancers; "RIZAPORT™" (formerly known as RHB-103) for the treatment of acute migraine headaches; and "RHB-101" for the treatment of hypertension, heart failure and left ventricular dysfunction. Our therapeutic candidates are subject to extensive governmental laws, regulations and guidelines relating to development, clinical trials, manufacturing and commercialization of drugs. 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 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 the clinical trial, or 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 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 the 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 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 some or all jurisdictions. 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, 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 establish 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 collaboration 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 products, RHB-106 and related rights to Salix Pharmaceuticals, Inc., or Salix. We do not control Salix, but we rely on Salix 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 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 adverse effect on our business, financial condition or results of operations.

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 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 this function. 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 Salix, 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. 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 delayed in obtaining regulatory approvals for our therapeutic candidates and may be 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 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.

In October 2012, we and our clinical manufacturer for RHB-104 mutually terminated our relationship after we concluded that another manufacturer would be better suited to conduct the scale up required to produce our clinical trial material in sufficient quantities and fulfill our timeline. It is possible that in the future we may be required to terminate other third party manufacturers, which may cause us to incur additional costs or delays.

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 regards to compliance issues at its manufacturing facility and subsequently invited 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 raw materials.

While there may be several alternative suppliers of API in 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 adversely affect our business, financial condition or results of operation.

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 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, 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. 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 would 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. 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;
- adverse publicity; or
- 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 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 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 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 development and/or commercialization partners previously received marketing approval, we or our 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 development and/or commercialization partners to redesign the therapeutic candidate and 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.

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. 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 products. We may compete for in-license and acquisition opportunities with other, established and well-capitalized pharmaceutical companies. As result, we may be unable to in-license or acquire additional therapeutic products at all or upon favorable terms. Our failure to further in-license or acquire therapeutic products in the future may hinder our ability to grow and could 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 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-104, RHB-105 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, RHB-101, BEKINDA™, RIZAPORT™ and MESUPRON® 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 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 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 contract 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 of RIZAPORT™. Moreover, if we elect not to exercise the option-to-acquire RP101 and/or to extend the option term under the option agreement, 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.

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, 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, 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 technical 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 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 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 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.

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 products;
- other potential advantages of alternative treatment methods and competitive forces that may make it more difficult for us to penetrate a particular market segment;
- 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 products on our own; or
- timing of market introduction of competitive products.

Physicians, various other health care providers, patients, payers 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 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 medication 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 United States.

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 Health 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 rule making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the United States, 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 United States in the healthcare industry and is expected to have meaningful ramifications on tens of millions of citizens in the United States. This legislation is expected to impact the scope of healthcare insurance, the insurance refunds from the insurance companies and possibly also 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 United States 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 products are at some point reimbursable by U.S federal government programs, this attention may result in our products 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 United States 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 United States federal government, which may force significant additional changes to the healthcare system in the United States. 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 pharmaceuticals 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 mounted legal challenges to the healthcare reform legislation. That litigation culminated in a decision from the United States Supreme Court on July 26, 2012 that 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 already indicated 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.

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 United States. 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 United States, 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 United States 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.

Further, 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 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, manufacture, 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 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 wastes. 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 United States. 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 products. Any failure by our licensors or development partners to properly conduct patent prosecution, patent maintenance or patent defense could harm our ability to obtain approval or commercialization of the products, thereby 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, offer 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 United States 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 it 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 decision;
- 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 25, 2015, 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 18,325,016 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 26, 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 United States 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 develop for our ADSs on The NASDAQ, and this may limit the ability of our investors to sell our ADSs in the United States.

There has been limited trading in our ADSs, and an active trading market in our ADSs may never develop or may not be sustained if one develops. Due to the illiquidity of our ADSs, the market price may not accurately reflect our relative value. There can be no assurance that an active market for our ADSs will develop in the future. Because our ADSs are so thinly traded, even limited trading in our ADSs has in the past, and might in the future, lead to dramatic fluctuations in market price and investors may not be able to liquidate their investment in us 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 United States, 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 United States 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, 2014, 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 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.

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

The depositary for the ADSs has agreed to pay to you 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. You will receive these distributions in proportion to the number of Ordinary Shares your 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 you may not receive the same distributions or dividends as those we make to the holders of our Ordinary Shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. 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 its 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. The tension between Israel and Iran and/or these groups may escalate in the future and turn violent, which could affect the Israeli economy generally 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.

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 United States, 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 United States, and all of our assets and most of the assets of our executive officers and directors are located outside of the United States. Therefore, a judgment obtained against us or most of our executive officers and our directors in the United States, including one based on the civil liability provisions of the U.S. federal securities laws, may not be collectible in the United States 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 United States or to assert U.S. securities law claims in original actions instituted in Israel.

Your obligations and responsibilities as a shareholder 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 United States.

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, 2014, 2013 and 2012 were $70,000, $14,000 and $5,000, respectively. Our current capital expenditures involve equipment and leasehold improvements.

B. Business Overview

We are an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers. From inception, to the end of the period covered by the annual report, we have invested a total of $2.7 million on in-licensing and acquisitions of therapeutic candidates and related technologies.

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 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) 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. Our therapeutic candidates have not yet been approved for marketing and, to date, there have been no 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 may also evaluate, on a case by case basis, co-development and similar arrangements and the commercialization of our therapeutic candidates independently.

Our Strategy

Our goal is to become a significant player in the development of pharmaceuticals for the treatment of inflammatory and gastrointestinal (GI) diseases, including gastrointestinal cancers, with a particular focus on improvements, enhancements and/or innovative uses of existing drugs.

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 protection, 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.

- 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", "MESUPRON®", "RP101" (subject to an option to acquire), "RIZAPORT™" and "RHB-101" and related research and development programs, the most advanced of which are described below.

Our Therapeutic Candidates

Summary

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

Name of Product	Relevant Indication	Potential Advantages Over Most Existing Treatments	Development Stage	Rights in 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. ongoing	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 and Israel ongoing	Acquired all rights to the product, worldwide and exclusive
RHB-104	Multiple Sclerosis (MS)	Oral formulation targeting suspected underlying cause of MS	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 SLE	Pre-clinical studies	Acquired all rights to the product, worldwide and exclusive
BEKINDA™	Oncology support anti-emetic	Reduced number of drug administrations, improved compliance and adherence	Oncology support otential NDA under review; MAA filed in Europe	Worldwide, exclusive license
BEKINDA™	Gastroenteritis/gastritis and potentially another undisclosed indication	No other approved 5HT-3 antagonist for this indication Improved compliance and adherence	Phase III ongoing in gastroenteritis and gastritis	Worldwide, exclusive license
RHB-106	Bowel preparation	Oral pill; avoid severe bad taste of chemical solutions; No known nephrotoxicity issues	Licensed to Salix Pharmaceuticals	Licensed to Salix Pharmaceuticals
MESUPRON®	Gastrointestinal and other solid tumor cancers	Oral administration; new non-cytotoxic approach to cancer therapy inhibiting both tumor metastasis and growth	Under review; Pre-clinical studies planned, to be followed by clinical trials	Worldwide exclusive license; excludes China, Hong Kong, Taiwan and Macao
RP101	Pancreatic cancer and other gastrointestinal cancers	Oral administration; may prevent chemoresistance, thus maintaining sensitivity of the tumor to chemotherapy and potentially enhancing patient survival	Under review; Pre-clinical studies planned, to be followed by clinical trials	One year 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	Avoids exacerbation of nausea; administared 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 filed	Worldwide, exclusive license and co-development
RHB-101	Heartfailure and hypertention	Once-daily oral administration, reduced food effect, reduced dose (less API)	Under review; additional CMC requiredprior to European and U.S. marketing applications; PK study required before filing U.S. NDA	Worldwide, exclusive license

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 digeston 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 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. *H. pylori* was added by the FDA to the list of qualifying pathogens 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.

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 more than 20% of the patients due to the development of antibiotic resistance, as reported by Dr. Lennita Wannmacher in a 2011 report submitted to the World Health Organization. The potential advantage of RHB-105 over these drugs (such as PrevPac® of Takeda Pharmaceuticals NA and Pylera® of Aptalis Pharma) was shown in a Phase II study comprising 130 subjects, in which RHB-105 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. TJ. Borody, et. al. in Alimentary Pharmacology & Therapeutics.

We estimate that 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 price of current branded treatments, we estimate the potential U.S. market for RHB-105 to be between $1 billion and $1.5 billion.

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 Phase III trial in the United States is currently underway, and we expect top-line data during the second quarter of 2015. We intend to seek marketing approval for RHB-105 from the FDA through the 505(b)(2) regulatory path.

We entered into an agreement with Professor David Y. Graham, MD, from Baylor College of Medicine, Houston, Texas, U.S. to serve 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	Planned 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
TBD	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 December 2013
ERADICATE Hp	Phase III	Examining the effectiveness, safety and pharmacokinetics of the final formulation	12 sites in the US	Up to 120	Actively enrolling patients	Top-line data expected Q2 2015

An additional Phase III study comparing RHB-105 to standard of care therapy is planned to be underataken following completion of the ongoing 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 Crohn's disease and are suspected of decreased recognition of MAP in the body.

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."

In recent years, 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 Quest Diagnostics Ltd. 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 Quest Diagnostics, 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, and that we intend to initiate a study of approximately 40 Crohn's disease patients to assess the clinical utility of the companion diagnostic test during the second or third quarter of 2015.

Market

According to GlobalData, a provider of market intelligence for the pharmaceutical sector, approximately 1.3 million patients worldwide suffered from Crohn's disease in 2014, of which over 900,000 patients were treated with drug therapy.

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 Professor 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 $4.8 billion worldwide in 2014. The report also estimates that the worldwide market for drug treatment of Crohn's disease will exceed $5.7 billion in 2015.

Competition

Unlike other drugs on the market for the treatment of Crohn's disease, which are immunosuppressive agents, RHB-104 is intended to directly 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 report of these side effects is shown in the following chart published by Dr. Carol Nacy *et. al.* in a report from the American Academy of Microbiology that was published in June 2007.

Drug Family	Example of Drug from the Family	Effect	Common Side Effects
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	High effectiveness, but only for a certain 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 andtibody drugs. The 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 Sequella's CM Analog, an innovative cellular therapy with stem cells by Hospital Clinic in Barcelona, Spain, which is in early stage of development, and new anti-TNFα and other biological therapies which are under development to treat Crohn's disease. A clinical trial was recently initiated by Salix 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 and Israel 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 in the United States, Canada and Israel, from 100 to 120, and expect to include new sites in Australia, New Zealand and Europe.

The trial of RHB-104 in North America and Israel is being led by Professor David Y. Graham, MD, from 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 agreement directly with the Canadian manufacturer See " – Manufacturing Agreement Related to RHB-104."

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 inVentive Health and our agreements were transferred to inVentive. 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 theFDA 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. 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) may be submitted in Europe in the coming months.

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	Examining the product's effectiveness in alleviating symptoms of Crohn's disease in patients	US, Canada. Israel. Australia, New Zieland and Europe	270	Phase III trial in North America and Israel has commenced	First patient entered study in Q3 2013
To be determined	Phase III (Europe – "MAP Europe")	Examining the product's effectiveness in alleviating symptoms of Crohn's disease in patients	To be determined	To be determined	Under examination	
Food Effect Study	PK Study	Determine the effect of food on the Bioavailability of RHB-104 in healthy volunteers	Canada	84	Completed	Completed 2014
Drug-Drug Interaction Study	PK Study	The main objective of this study was to assess the net pharmacokinetic effect of multiple doses of RHB 104 on metabolizing enzymes	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 Multiple Sclerosis (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 results expected during the second half of 2015.

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	Exploratory	Israel	16-18	In process	Interim results expected in H2 2015

Additional trials will be required as part of the RHB-104 Multiple Sclerosis 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. It is being developed for use in the following indications:

1) Prevention of chemotherapy and radiotherapy induced nausea and vomiting (oncology support).

2) Gastroenteritis and gastritis

3) A third, yet undisclosed, indication

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™".

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 2014 report from EvaluatePharma, a provider of market intelligence for the pharmaceutical sector, the worldwide sales of 5-HT3 serotonin receptor inhibitors were estimated to have exceeded $940 million in 2014.

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®, 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.

Zofran® is one of the leading branded 5-HT3 serotonin receptor inhibitor drug, reaching worldwide sales of approximately $111 million in 2014 according to a 2014 report from EvaluatePharma. Ondansetron became generic in the U.S. in December 2006. The drug is available in the U.S. in the form of oral tablet, 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.

Aloxi® is a second-generation drug from the same family of inhibitors. To the best of our knowledge, it is currently administered only intravenously (IV) 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 $400 per treatment with Aloxi® IV and $500 per capsule of Akynzeo®, according to www.goodrx.com, a website providing pricing data for prescription drugs at local and mail-order pharmacies in the U.S. 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.

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® 8mg, 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 United States is delivered intravenously (IV) and costs approximately $400 per dose according to www.goodrx.com. BEKINDA™ is planned to be delivered orally, in tablet form. Oral administration is expected to allow independent 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 $500 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 Actavis 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, it is currently inactive.

Clinical Development

We completed two comparative bioavailability studies of BEKINDA™ given once daily as compared to approved regimens of Zofran 8mg 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 16mg suppository, which is approved in major territories in the EU.

In order to carry out pharmacokinetic l 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	Planned 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. In addition, we are currently in discussions with the FDA regarding the potential U.S. marketing approval pathway for BEKINDA™ in oncology support.

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."

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 prevent 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 intravenous 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 (the GUARD study) that is conducted in up to 12 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 from 30 minutes after the first dose through discharge from the emergency department. 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 2015.

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 2015

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."

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") 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 $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 Salix Pharmaceuticals, Ltd."

Competition and Market

According to a 2014 report by EvaluatePharma, the worldwide market of laxative products intended for cleansing the gastrointestinal system was estimated at approximately $1.4 billion in 2014.

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 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 has an advantage compared to currently available tableted 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 also 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 Salix Pharmaceuticals Inc.) and Fleet (produced by C.B. Fleet Company, Inc., or C.B. Fleet), 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 over-the-counter products of C.B. Fleet were recalled from the market, while the prescription products must carry a severe warning (black box label). As announced by Salix Pharmaceuticals Inc., 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 Salix Pharmaceuticals, Inc. in the U.S. and by Norgine in Europe. Its price in the U.S. is approximately $89 per kit. It requires drinking of about 2 liters of solution, and some users report it has an unpleasant taste. Salix Pharmaceuticals estimated in their quarterly report for the period ended September 30, 2014 that 2014 sales of Moviprep® would be approximately $86 million. 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, eliminates the need to drink several liters of solution, 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 capsule preparations which are based on sodium phosphate.

Salix Pharmaceuticals, Inc., 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

Salix Pharmaceuticals has announced its intent to conduct a clinical investigation in this program during the second half of 2015.

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical site	Planned 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

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 drug. Under this agreement, we are responsible for all development, regulatory and commercialization of MESUPRON®.

Competition and Market

MESUPRON® orally-administered first-in-class 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 12th 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 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 classed 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.

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 drug's safety and tolerability profile. The Phase II trials with MESUPRON® in both indications suggested activity as measured by both tumor response rate and overall survival of patients when administered in combination with first-line chemotherapeutic agents. 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.

Additional studies, including preclinical studies, are anticipated as part of the MESUPRON® global development program and regulatory strategy. On January 5, 2015, we announced that we expect in the second half of 2015 to have initial data from non-clinical studies which we plan to conduct to further evaluate the mechanisms of action and define the patient populations for MESUPRON®.

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 RP 101", on August 13, 2014, we entered into a binding exclusive option agreement for the acquisition of the oncology drug 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, excepting indications for pancreatic cancer in South Korea. During the option period we may, at our discretion, conduct development activities with RP101. The one year option may be extended by us under certain agreed terms.

Competition and Market

RP101 has been studied as an adjunct treatment of pancreatic cancer with potential applicability to other gastrointestinal cancers.

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 12th most common cancer in the world. According to a report by GlobalData, 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 wordwide sales of pancreatic cancer therapies are estimated to reach approximately $1.6 billion by 2017, according to GlobalData.

According to the 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 classed 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.

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.

Additional studies, including preclinical studies, are anticipated as part of the RP101 global development program and regulatory strategy. On January 5, 2015, we announced that we expect in the second half of 2015 to have initial data from non-clinical studies which we plan to conduct to further evaluate the mechanisms of action and define the patient populations for RP101.

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™ (formerly known as RHB-103)

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 "– License Agreement for RIZAPORT™" for more information regarding this agreement.

Competition and Market

To the best of our knowledge, the main marketing competitors of RIZAPORT™ are oral drugs from the triptan family, 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. The target market for RIZAPORT™ is the triptan market, which was estimated at approximately $870 million worldwide in 2014 according to a 2013 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. According to the 2013 annual report of Merck and Co. Inc., the worldwide direct sales of Merck and Co.'s rizatriptan-based drugs in 2013 were $149 million.

We believe that RIZAPORT™ will 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 appealing to migraine 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 pediatric and geriatric populations 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 certain matters that 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™ is having compliance discussions with FDA that are not specific to RIZAPORT™.

In April 2014, together with IntelGenx Corp., we initiated a comparative bioavailability study of 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. BfArM subsequently informed us that the MMA had been validated and the formal review began on November 25, 2014.

We and IntelGenx are continuing negotiations with potential commercialization partners and, to the extent feasible, plan to conclude discussions with a U.S. commercialization partner in the first half of 2015.

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	Planned 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 product and the profile of the reference product	Ended 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 FDA	Ended 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 Medicine Agency	Ended 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."

RHB–101

RHB-101 is intended for the treatment of hypertension, heart failure and left ventricular dysfunction (following myocardial infarction) by means of controlled release of an active ingredient known as carvedilol, which is designed to be administered to patients on a once-daily basis. We believe that our once-daily RHB-101 is an improvement over existing generic carvedilol-containing drugs, which are administered several times per day.

RHB-101 is based on a patented technology for the controlled release of drugs administered orally. The technology is based on a drug-release polymer system built of an external envelope that is consumed at a slow rate, and an internal matrix that breaks down on contact with the fluids of the gastrointestinal system, releasing the drug at a constant rate according to the drug's exposed geometric surface.

We acquired the rights to RHB-101 under a November 18, 2009 agreement with Egalet a/s, pursuant to which we received a worldwide, exclusive and perpetual license to certain patent rights related to RHB-101.

We have executed a non-binding letter of intent for the out-licensing of RHB-101 with a potential European partner for the manufacturing and commercialization of RHB-101 in a specified EU territory, as well as the supply of finished product to us or our sublicensees for the rest of the EU. We plan, to the extent feasible, to complete the above-mentioned transaction during the first half of 2015. See "– Acquisition and License Agreements – License Agreement for RHB-101."

Competition and Market

At present, the market may be divided into two main parts: The first part of the market includes generic drugs based on the immediate release of the generic active ingredient known as carvedilol (such as Coreg® produced by GlaxoSmithKline). According to EvaluaPharma, a provider of market intelligence for the pharmaceutical sector, the U.S. patent for Coreg® expired in 2007. These generic drugs are administered to patients twice a day, due to their relatively short active span, as opposed to the proposed once daily administration of RHB-101. Administration once per day instead of several times per day has the potential to be a significant advantage, including improved compliance, especially for the elderly who commonly take a relatively large number of drugs over long periods of time.

The second part of the market is based on a patented drug known under the trade name of Coreg CR® (produced by GlaxoSmithKline). This drug is an improvement over the generic Coreg® drug, having a longer duration of action and being administered once per day. One of the potential advantages of RHB-101 over Coreg CR® is that RHB-101 is expected to be priced below the current price of Coreg CR®. Further potential advantages indicated by studies conducted to date consist of: (i) a reduced food effect on bioavailability, expected to allow patients to take RHB-101 with or without food while Coreg CR® is indicated to be taken with food and (ii) a markedly reduced dose (approximately 27% less API in mol units).

The 2013 sales of Coreg CR® in the U.S. were estimated at approximately $185 million according to the EvaluatePharma 2014 annual U.S. product sales report. Coreg CR® is not marketed in Europe. The European market of immediate release carvedilol in 2013 was in excess of $200 million according to IMS Health. In 2013, the sale of generic immediate release of carvedilol reached approximately $100 million in the U.S. according to data published by IMS Health. Consolidating sales data for both segments of the market indicate that the worldwide target market of RHB-101 was estimated at approximately $485 million in 2013.

According the EvaluatePharma, a leading market intelligence and information resource, GlaxoSmithKline's U.S. patent on Coreg CR® is expected to expire in 2023. To the best of our knowledge, generic competitors of Coreg CR® may reach the market immediately. In particular, in 2008 Mutual Pharmaceutical Company Inc. submitted an application in the U.S. for approval of a generic version of this drug and reached an agreement with GlaxoSmithKline, pursuant to which GlaxoSmithKline agreed, after several rounds of court hearings, not to sue Mutual Pharmaceutical Company Inc. Entry of generic drugs competing with Coreg CR® may cause a significant decrease in the price of Coreg CR®, thereby reducing the current price differential between this drug and the segment of generic carvedilol-containing drugs.

Clinical Development

The following chart summarizes the clinical trial history and status of RHB-101:

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**
5 PK studies	Comparative Bioavailability	Comparative biovailabitiy of the three doses of RHB-101 being developed (12,5 mg, 25 mg, and 50 mg)		Total of 122 healthy volunteers		Completed by 2012

Supplemental studies may be required as part of the RHB-101 global development program and regulatory strategy.

In March 2013, we held a Scientific Advice meeting regarding RHB-101 with the Danish Health and Medicines Authority (DKMA), Based on the feedback from DKMA, we believe that no further clinical studies will be required prior to submission of the MAA. Based on the feedback received from DKMA, we are required to focus on certain chemistry, manufacturing and control modules, the completion of which is expected to allow the submission of an MAA.

In May 2013, we held a Type B meeting with the FDA regarding RHB-101. Based on the feedback received from FDA, prior to the NDA submission, we will be required to conduct a comparative bioavailability study and a dose linearity study.

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 from the transfer 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 under 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 Pharmaceuticals, Ltd. ("Salix"), 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 affiliates products, technology and related activities in the purgative field and by excluding 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 secure directly 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 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 that becomes relevant.

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 drug candidate RP101 and next generation compounds, with RESprotect GmbH, a German privately-held biopharmaceitucal company ("RESprotect"). 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 pancreatic cancer indication in South Korea.

In consideration for the option, we paid RESprotect for a one year option, which may be extended by us under certain agreed terms. During the option period, we are entitled, at our discretion, to conduct development activities on 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-digit 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 initial 12 months option period or if the term of the option is extended, the extended ption period, and (iii) by written notice of termination by 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 $1.3 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 RHB-101

On November 18, 2009, we entered into an agreement with Egalet a/s, a private Danish pharmaceutical company, pursuant to which Egalet a/s granted us a worldwide, exclusive and perpetual license to use its rights in patents and know how relating to a therapeutic candidate containing the active ingredient “Carvedilol” and which is referred to by Egalet a/s as “Egalet Carvedilol.” The name given to this product by us is RHB-101.

The license granted to us includes the right to grant sublicenses. The license covers the development, manufacture, commercialization, use, sale, offer for sale and import of the product for all uses, including medical uses, diagnostics, and other uses in human beings and/or animals.

The granted license is exclusive with regard to Egalet Carvedilol. We also received a non-exclusive license in additional patents for which Egalet a/s retained a right to use such patents in connection with other products.

In consideration for the license, we paid Egalet a/s $100,000. Furthermore, we are obligated under the license to pay Egalet a/s the following additional amounts:

- $200,000 on the date of our filing of an application for marketing of the product with the FDA and acceptance by theFDA of such filing for review;
- $500,000 on the date of receipt of the marketing approval from the FDA; and
- royalties at a rate of 30% of the amounts received by us from our own sales or from sublicenses payments, for a fixed period up to the expiration of the patents exclusively granted to us or 12 years from the date of the first sale of the product, whichever is earlier, in any country where a patent forming the subject of the license is registered.

Egalet a/s had the right to terminate the license if we fail to initiate clinical trials within 24 months, except if the failure to do so was due to the decision of regulatory authorities, is related to technical problems or other reasons beyond our control or influence. We believe that we satisfied this requirement.

We have the right to terminate the agreement if Egalet a/s is in material breach and does not cure the breach within ninety (90) days, and we may voluntarily terminate the agreement upon providing thirty (30) days written notice to Egalet a/s.

The license also included various intellectual property representations of Egalet a/s, including that the intellectual property licensed to us did not infringe upon third party patents or other intellectual property rights, except for one patent in Europe and one patent in the U.S. We subsequently filed an objection to the validity of the relevant European patent and on May 27, 2011, the European Patent Office annulled that patent. With respect to the patent in the U.S., we believe that RHB-101 does not infringe that patent to the extent that RHB-101 contains a “carvedilol free base” and does not contain carvedilol phosphate. RHB-101 does not contain carvedilol phosphate at present and only contains carvedilol free base.

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., which consent may not be unreasonably withheld.

In consideration for the license, we made a one-time payment and another annual payment on account of the minimum royalty payment in year two of the agreement, in the aggregate amount of $55,000. In addition, we are required to make additional annual minimum royalty payments of $15,000 in year three, $20,000 in year four and $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

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 will pay the University of Minnesota a one-time upfront payment and an additional milestone payment. We are developing a diagnostic test for MAP in conjunction with Quest Diagnostics.

Exclusive License Agreement with Salix Pharmaceuticals, Ltd.

On February 27, 2014 we entered into a worldwide exclusive license agreement with Salix Pharmaceuticals, Ltd. ("Salix") 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, Salix has 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 our agreement with Salix, we received upfront payments 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.

Our agreement with Salix 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 to Salix shall become fully-paid, perpetual, royalty-free and irrevocable. We have the right, following notice to Salix, to terminate the agreement in the event that Salix 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.

On February 22, 2015, Salix announced that it had entered into a definitive agreement with Valeant Pharmaceuticals International, Inc., or Valeant, a public company traded on The New York Stock Exchange and Toronto Stock Exchange, under which Valeant will acquire all of the outstanding common stock of Salix. The announcement stated that the transaction is expected to close in the second quarter of 2015, subject to customary closing conditions and regulatory approval.

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. According to the agreement, as amended, we agreed to pay our Canadian service provider a monthly fee of $7,500. 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 with respect to BEKINDA™, RHB-104 and RHB-105.

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, 2014, the estimatedtotal cumulative discount we will receive from our Canadian service provider is approximately $1.6 million.

Manufacturing Agreements

Manufacturing Agreements Related to RHB-104

On October 21, 2012, we entered into an agreement with our Canadian service provider which, in turn, entered into a back-to-back agreement with a Canadian drug manufacturer to complete the manufacturing and supply of RHB-104 for our clinical trials. In addition, we entered into additional manufacturing agreements directly with the Canadian manufacturer.

The agreements provide for the Canadian manufacturer to manufacture sufficient amounts of RHB-104 for our clinical trials and other planned tests, pursuant to our specifications and in accordance with regulatory requirements.

All manufacturing will be done under GMP. Milestone payments will be triggered upon the performance by the manufacturer of various services, such as manufacturing process, project management support and regulatory support, analytical work and stability work. Actual payment amounts may deviate significantly due to changes in the manufacturing processes, the cost of raw materials, laboratory tests and other expenses, subject to the consent of the parties. Milestones are currently expected to be achieved over the next two years. The total costs of the manufacturing agreements with the Canadian service provider and the Canadian manufacturer are expected to be approximately $0.9 million.

The agreements will remain and can be terminated with thirty days' advance notice.

See "– Master Service Agreement with 7810962 Canada Inc." for a description of our agreement with our Canadian service provider.

Manufacturing Agreements Related to RHB-105

On July 5, 2011, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with a Canadian drug manufacturer to formulate, manufacture and supply a clinical trial batch of RHB-105. In addition, we entered into additional manufacturing agreements directly with the Canadian manufacturer.

The agreements provide for the Canadian manufacturer to manufacture sufficient amounts of RHB-105 for our clinical trials and other planned tests pursuant to our specifications and in accordance with regulatory requirements.

All manufacturing will be done under GMP. Milestone payments will be triggered upon the performance by the manufacturer of various services, such as manufacturing process, project management support and regulatory support, analytical work and stability work. Actual payment amounts may deviate significantly due to changes in the manufacturing processes, the cost of raw materials, laboratory tests and other expenses, subject to the consent of the parties. Milestones are currently expected to be achieved over the next two years. The total costs of the manufacturing agreements with the Canadian service provider and the Canadian manufacturer are expected to be approximately $0.5 million.

The agreement will remain in force until terminated. This agreement provides that 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.

See "– Master Service Agreement with 7810962 Canada Inc." above for a description of our agreement with our Canadian service provider.

Manufacturing Agreement Related to RHB-106

On June 27, 2011, we entered into an agreement, which was subsequently amended, with Pharmaceutics International Inc., a U.S. drug manufacturer, for the manufacture of RHB-106.

Pursuant to this agreement, as amended, the manufacturer is entitled to receive approximately $462,000, payable uponcompletion of milestones during the production periods and reimbursement of certain expenses over a period of approximately three years. Other than minor material storage services, no services are currently being performed by this manufacturer following our entering into an Exclusive License Agreement with Salix Pharmaceuticals, Ltd. See"– Exclusive License Agreement with Salix Pharmaceuticals, Ltd."

We may terminate the agreement at any time and for any reason upon providing thirty (30) days' written notice to Pharmaceutics International Inc.

Manufacturing Agreement Related to BEKINDA™

On March 21, 2011, we entered into an agreement with a U.S. drug manufacturer, Pharmaceutics International, Inc., for the manufacture and supply of BEKINDA™ for our clinical trial. In addition, we entered into further agreements with Pharmaceutics International, Inc. to manufacture, test and supply registration batches of BEKINDA™.

The agreements, as amended, provide for Pharmaceutics International, Inc. to manufacture sufficient amounts of BEKINDA™ for our clinical trials and other planned tests pursuant to our specifications and in accordance with regulatory requirements.

Pursuant to the agreement, as amended, the manufacturer is entitled to receive up to approximately $1.3 million payable upon the completion of various milestones during the production periods and reimbursement of certain expenses. The majority of the milestones were completed by the end of the year 2014 with few activities continuing in support of regulatory requirements.

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 inVentive 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. InVentive 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, inVentive Health is entitled to receive $7.1 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 milestones 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.

Clinical Services Agreement related to RHB-105

On October 29, 2012 we entered into an agreement with Clinipace World Wide, Inc. (CPWW) an international CRO company, for the purpose of performing the clinical trial for RHB-105. CPWW specializes in the performance of clinical trials 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, CPWW is entitled to receive $1.6 million in connection with the Phase III clinical trial in North America. The fee includes payment of $0.8 million in connection with professional services to be provided by CPWW, as well as reimbursement of investigator grant costs and pass-through costs to be paid during the trial. The payments will be spread over the period of the clinical trial.

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 if the other party is in material breach and does not cure within thirty (30) days. This agreement also provides that we may terminate the agreement at any time without cause upon providing sixty (60) days written notice to CPWW.

Intellectual Property

Our success depends in part on our ability to obtain and maintain proprietary protection for our technology, 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 240 issued patents and 70 patent applications. The patents and patent applications are registered in various 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

Patent Family 13, owned by us, is comprised of twenty issued patents in the U.S., Australia, Canada, Austria, Belgium, Switzerland/Liechtenstein, Cyprus, Germany, Denmark, Spain, France, the United Kingdom, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal and Sweden. This family is entitled "Improved Method of Eradication of *H.pylori*". The patent family has priority rights dating to April 30, 1998 and the patents in this family will expire April 30, 2019. This patent family was acquired as part of our asset purchase agreement with Giaconda Limited.

The family relates to methods for the treatment and/or prevention of recurrence of a gastrointestinal disorder associated with *H. Pylori*, which entails administering to the patient a therapeutically effective amount of a first antibiotic, which is an ansamycin and a therapeutically effective amount of at least a second antibiotic or antimicrobial agent. The invention also provides pharmaceutical compositions for use in the methods of the invention.

Patent Family 14, also owned by us, is comprised of two pending U.S. non-provisional patent applications and one pending PCT International patent application that we filed in 2014. This family relates to pharmaceutical compositions and methods for the treatment of disorders associated with infection by *H. pylori* or the prevention of recurrence of disorders associated with infection by *H. pylori*.

RHB-104 – Inflammatory Bowel Disease

Patent Family 8, owned by us, is comprised of thirty six issued patents in the U.S., Australia, Canada, Israel, New Zealand, Norway, Philippines, South Africa, Austria, Belgium, Switzerland, Lichtenstein, Cyprus, Germany, Denmark, Spain, Finland, France, the United Kingdom, Greece, Ireland, Italy, Luxembourg, Monaco, the Netherlands, Portugal and Sweden. This patent family was acquired from Giaconda Limited as part of our asset purchase agreement with them.

This family is entitled "Method and Composition for Treating Inflammatory Bowel Disease". The patent family has priority rights dating to April 1, 1997 and the patents in this family will expire April 1, 2018. The patents described a method and composition of medications used to treat inflammatory bowel disease, which includes Crohn's disease. It further provides combinations of anti-atypical mycobacterial agents effective against the atypical mycobacterial strains. It also provides a method of potentially immunizing patients with extracts of non-pathogenic mycobacteria.

Patent Family 9, also owned by us, is comprised of four issued patents in the U.S., Australia, Japan and New Zealand, and eight pending patent applications in the US, Canada, Europe, Israel, Philippines, and South Africa. This patent family was acquired from Giaconda Limited as part of our asset purchase agreement.

This family is entitled "Method and Composition for Treating Inflammatory Bowel Disease" and covers improved compositions comprising rifabutin, clarithromycin, and clofazimine for use in the treatment of Inflammatory Bowel Diseases. In one instance, the compositions may comprise a formulation of rifabutin, clarithromycin, and clofazimine in a single dosage form, such as a capsule or tablet, with one or more specific excipients. This family also covers a method for formulating the compositions to provide a solid oral dosage form of the composition which has improved efficacy and a reduced likelihood of side effects.

Patent Family 10, in-licensed by us from the University of Central Florida Research Foundation Inc. (UCF), is comprised of one issued U.S. Patent, US Patent No. 7,488,580 entitled "Protocol for Detection of the Intracellular Infection *Myobacterium Avium Paratuberculosis* in Blood", which will expire in 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.

Patent Family 11, in-licensed by us from The University of Minnesota, is comprised of two issued U.S. patents, both entitled "Mycobacterial Diagnostics". One U.S. patent will expire on October 26, 2022, and the other U.S. patent will expire on August 8, 2026. The acquired diagnostic technology is intended for the detection of *Mycobacterium avium subspecies paratuberculosis* (MAP) bacterium.

RHB-104 – New Indications

Patent Family 12, owned by us, is comprised of sixteen patent applications pending in the U.S., Australia, Brazil, Canada, Chili, China, Europe, India, Israel, Japan, Korea, Mexico, Russia, Singapore, Ukraine, and South Africa. The family is entitled "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 has priority rights dating to September 2011.

BEKINDA™ (RHB-102) - Oncology Support

Patent Family 3, in-licensed by us from Temple University, is comprised of twenty-two issued patents in the U.S., Canada, Australia and Europe and two pending patent applications in Japan. The European patent was validated in seventeen European countries, including Austria, Cyprus, Switzerland, Germany, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Luxembourg, Netherlands, Monaco, Portugal, Sweden and Turkey. This family is entitled "Amino Acid Modulated extended Release Dosage Form" and has a priority date of December 20, 1999 for the U.S. patents, and the earliest U.S/ patent will expire December 20, 2019. The non-U.S. patents will expire February 20, 2022. This family covers an extended release tablet comprising a plurality of granules of an effective amount of a pharmaceutically active compound, at least one amino acid, and an intragranular polymer in which the granule is dispersed within a hydrophilic extragranular polymer matrix which is more rapidly hydrating than the intragranular polymer.

Patent Family 4, in-licensed by us from Temple University, is comprised of nineteen issued patents in the U.S., Canada, Mexico and Europe, and one pending patent application in Hong Kong. The European patent was validated in fifteen European countries, including Austria, Belgium, Switzerland, Germany, Denmark, Spain, Finland, France, United Kingdom, Greece, Ireland, Italy, Netherlands, Portugal and Sweden. This family is entitled "Monolithic tablet for controlled drug release" and has priority date of March 9, 1998. The non-U.S. patents in this family will expire March 2, 2019 and the U.S. patent will expire on March 9, 2018. This family relates to a swellable hydrophilic matrix tablet that delivers drugs in a controlled manner over a long period of time. The drug is disposed in a matrix composed of HPMC or polyethylene oxide, in the presence of a salt, which may be a combination of salts.

Patent Family 5, owned by us, is comprised of two pending U.S. non-provisional patent applications and two pending PCT international patent applications. This family is entitled "Antiemetic Extended Release Solid Dosage Forms" and has a priority date of March 14, 2013. The family covers once daily solid oral dosage forms with a core comprising an antiemetic drug, a seal coat surrounding the core, and an immediate release drug layer comprising an antiemetic drug surrounding the first seal coat.

BEKINDA™ (RHB-102) - Gastroenteritis and Other Conditions

Patent Family 6, owned by us, is comprised of four U.S. provisional patent applications and relates to an oral, extended-release, once-daily formulation of an antiemetic drug for treating gastroenteritis and other conditions. We filed this application in 2014.

RHB-106 - Colonic Evacuation

Patent Family 15, owned by us, is comprised of seven issued patents in the U.S., Australia, Canada and New Zealand, and one pending application in Europe. This family is entitled "Improved Preparation for Colonic Evacuation". The patent family has priority rights dating to November 3, 1995 and the non-U.S. patents in this family will expire November 1, 2016 and the U.S. patents expire October 31, 2016. This patent family was acquired from Giaconda Limited as part of our asset purchase transaction.

This family relates to an osmotic colonic evacuant in solid oral dosage form comprising an orthostatic lavage in powder form and a pharmaceutically acceptable excipient, diluent and/or adjuvant. It also relates to a method of evacuating a patient's colon, a method of treating small bowel bacterial overgrowth or irritable bowel syndrome and a method of treating acute or chronic bacterial bowel infection. It further relates to a sequential pack for the oral administration of at least two treatment regimens, including a first treatment regimen comprising of an osmotic colonic evacuant in solid oral dosage form, in unit dosage form adapted and presented for a first administration period, together with a second treatment regimen comprising of an osmotic colonic evacuant in solid oral dosage form, in unit dosage form adapted and presented for a second administration period.

Patent Family 16, also owned by us, includes one PCT International patent application. The national stage deadline to file various country specific patent applications was January 27, 2015.

In February 2014, we entered into an exclusive agreement by which Salix Pharmaceuticals licensed the worldwide exclusive rights to the RHB-106 patent estate. As part of the agreement, Salix is responsible for the patent families related to RHB 106.

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.

Patent Family 17 is comprised of nine issued patents in the U.S., Australia, Canada, Japan, Korea, Mexico, Russia, and Singapore, and four pending patent applications in Brazil, Europe, India and Korea. This 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.

Patent Family 18 is comprised of seven issued patents in the U.S., Australia, Canada, India, Japan, and Mexico, and one pending patent application in Brazil. This family relates to Urokinase inhibitor compounds. The patents in this family will expire in 2024.

Patent Family 19, is comprised of one European patent validated in twenty European countries, seven patents in the U.S., China, India, and Japan, and two pending patent applications in the U.S. and Japan. This family related to methods for the production of phenylalanine derivatives. The patents in this family will expire in 2023.

Patent Family 20 is comprised of one European patent validated in five European countries, eleven issued patents in the U.S., Australia, Canada, China, India, Japan, Korea, Mexico, Russia and Singapore, and one pending patent application in Brazil. This family relates to methods for producing phenylalanine derivatives. The patents in this family will expire in 2025.

Patent Family 21 is comprised of one U.S. patent, which relates to a method for producing phenylalanine derivatives. The U.S. patent will expire October 24, 2025.

Patent Family 22 is comprised of two European patents, each validated in fourteen European countries, and seven pending patent applications in the U.S., Brazil, Canada, China, Japan and Mexico. This family relates to Urokinase Inhibitors. The patents in this family will expire in 2019.

Patent Family 23 is comprised of one U.S. patent, which relates to a method of preparing methylhydroxyalkylcellulose. The U.S. patent will expire September 15, 2026.

Patent Family 24 is comprised of one European patent validated in five European countries, seven issued patents in Australia, Canada, Japan, Korea, Mexico, Russia and Singapore, and two pending patent applications in Brazil and the U.S. This family relates to formulations for phenylalanine derivatives. The patents in this family will expire in 2025.

Patent Family 25 is comprised of one European patent validated in five European countries, one German patent, and two issued U.S. patents. This 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. 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.

Patent Family 26 is comprised of three issued patents in the U.S., Mexico, and Korea. This family relates to 5' substituted nucleosides and the patents in this family will expire in January 2016.

Patent Family 27 is comprised of four issued patents in the U.S., Australia, China, and Japan, and six pending patent applications in Brazil, Canada, Germany, Europe, India, and Mexico. This family relates to nucleosides and patents issuing from this family will expire in 2027.

Patent Family 28 is comprised of one issued patent in Germany and two pending patent applications in the U.S. and Europe. This family relates to uracil derivatives, and patents issuing from in this family will expire in 2029.

RIZAPORT™ - Migrane

Patent Family 7, in-licensed by us from IntelGenx Corp., is comprised of three issued U.S. patents, one pending U.S. non-provisional patent application, and one pending PCT international patent application. These patents and applications cover various aspects of the VersaFilm™ technology. The central U.S. patent for a multi-layer film formulation comprising the combination of a hydroxypropyl cellulose and a modified starch was issued November 7, 2006 and expires in 2022. IntelGenx Corp. may be pursuing additional patent protection on this product.

RHB-101 - Cardio

Patent Family 1, in-licensed by us from Egalet a/s, is comprised of ten issued patents granted in Austria, Belgium, Switzerland, Germany, Denmark, Spain, France, the United Kingdom, Ireland and Italy. This family is entitled "Controlled Release Solid Dispersion of Carvedilol". The patent family has a priority date of September 21, 2001 and, assuming no extension or adjustment of term, the patents in this family will expire September 23, 2022.

Patent Family 2, also in-licensed by us from Egalet a/s, is comprised of one U.S. patent, entitled "Controlled Release Carvedilol Compositions". The U.S. patent has a priority date of November 8, 2002 and an expiration date of June 13, 2024.

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 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 from one country to another, so that securing the applicable regulatory approvals of one country does not imply the approval of 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 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 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 1 clinical studies, the product 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 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 1 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 and/or its API will be produced, it will either approve commercial marketing of the drug product 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.

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 drugs 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 drugs 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

On December 24 2013, we entered into amendment to the lease agreement for the lease of offices in the "Platinum" building at 21 Ha'arba'a Street, Tel Aviv, Israel. Pursuant to the lease agreement, as amended, we lease approximately 394 square meters of office space, a 27 square meter warehouse and six parking spaces. The monthly rent is NIS 63,000 (approximately $16,000), linked to the Israeli Consumer Price Index of January 2011. The lease term under the amendment will expire on January 31, 2017, and we have an option to extend the lease term by three additional years. As security for its obligations under the Lease Agreement, we provided a bank guarantee in the amount of NIS 280,000 (approximately $73,000). Since April 2011, these offices have served as our corporate headquarters.

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 an emerging Israeli biopharmaceutical company focused on the development and acquisition of late clinical-stage, proprietary, orally-administered drugs for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers.

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 in the gastrointestinal tract. 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, 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 by which Salix licensed the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation, and rights to other purgative developments.

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 may be 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, it 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™ (formerly known as 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™."

RHB-101 is a patented formulation once-daily controlled release formulation of carvedilol intended for the treatment of hypertension, heart failure and left ventricular dysfunction (following myocardial infarction). We acquired the rights to RHB-101 pursuant to a November 18, 2009 agreement with Egalet a/s. Pursuant to this agreement, we received a worldwide, exclusive and perpetual license to certain patent rights related to RHB-101. We paid Egalet a/s $100,000 and are required to make milestone payments of up to $700,000 and pay future royalties, for a fixed period of time as determined under the agreement, at a rate of 30% of the amounts received by us from sales of the product by us or from sublicenses payments. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements - License Agreement for RHB-101."

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 2014 we had for the first time meaningful revenues as a result of the Salix transaction. 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. 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. In 2014 and 2013, the majority of the financial income and expense was from changes in the exchange rates on our cash, cash equivalents and bank deposits held in currencies other than the U.S. dollar.

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 our inception, we have not recognized impairment to our intangible assets. 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, 2014, we had an accumulated deficit of approximately $42.2 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, 2014, we had approximately $22.9 million of cash, cash equivalents and short term investments, and as of February 25, 2015, following the closing of the underwritten public offering, we had cash and short term investments of approximately $34.6 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
	2012				2013				2014			
Revenues	4	5	3	4	4	4	3	1	7,005	4	4	1
Cost of revenue	-	-	-	-	-	-	-	-	1,050	-	-	-
Research and development expenses, net	2,330	1,498	1,379	1,248	1,346	1,982	2,207	2,565	1,736	3,157	4,103	3,704
General and administrative expenses	607	573	550	871	675	548	545	916	1,027	961	912	1,111
Other income	-	-	-	-	-	-	-	-	100	-	-	-
Operating loss (income)	2,933	2,066	1,926	2,115	2,017	2,526	2,749	3,480	(3,292)	4,114	5,011	4,814
Financial income	258	40	57	(158)	43	17	53	45	89	133	415	(318)
Financial expenses	59	247	98	1.079	3	3	3	5	4	543	(360)	196
Net loss (income)	2,734	2,273	1,967	2,352	1,977	2,512	2,699	3,440	(3,377)	4,524	4,236	5,328

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, 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 partialy offset by an increase in research and development expenses.

Financing Income and Expenses

We recognized net financial expense, 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 financing income and expenses for the years of 2014 and 2013 derived mainly from changes in exchange rates.

Comparison of the Year Ended December 31, 2013 to the Year Ended December 31, 2012

Research and development expenses for the year ended December 31, 2013 were $8.1 million, an increase of $1.6 million, or 25%, compared to $6.5 million for the year ended December 31, 2012. The increase resulted primarily from approximately $2.4 million in clinical trial costs related mainly to BEKINDA™, RIZAPORT™ and RHB-104 and RHB-105 which were partially offset mainly by a $1 million discount from the Canadian service provider mainly related to RHB-104 development expenses.

General and Administrative Expenses

General and administrative expenses for the year ended December 31, 2013 were $2.7 million, an increase of $0.1 million, or 4%, compared to $2.6 million for the year ended December 31, 2012. The increase resulted primarily from an increase in payroll and related expenses as result of recruitments of new employees, partially offset by a decrease in share-based payments.

Operating Loss

During the year ended December 31, 2013 our operating loss was approximately $10.8 million, an increase of $1.8 million, or 20%, compared to $9 million for the year ended December 31, 2012. The increase in operating loss was mainly due to an increase in our research and development activities mentioned above.

Financing Income and Expenses

We recognized net financial income of $0.1 million for the year ended December 31, 2013, compared to net financial expenses of $1.3 million for the year ended December 31, 2012. The income for the year of 2013 derived from fair value gain on financial assets and changes in exchange rates while the expenses for the year of 2012 represented primarily a non-cash financing expense of $1.5 million due to the accretion and settlement of royalty obligations to investors.

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 Salix Pharmaceuticals, Ltd. As of December 31, 2014, we had approximately $22.9 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 approximaly $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 Worlwide Exclusive License Agreement with Salix Pharmaceuticals, Ltd. ("Salix") 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 Salix Pharmaceuticals, Ltd.*"

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.

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 its 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, 2014, net cash flow used in operating activities was approximately $12.2 million, compared to approximately $8.4 million for the year ended December 31, 2013 and $6.8 million for the year ended December 31, 2012. The increase in net cash flow used in operating activities was a direct result of the increase in our operations, reflected by increased payments for research and development activities which were partially offset by the revenues from the Salix transaction.

Investment activities

Net cash flow used in investing activities for the year ended December 31, 2014 was approximately $17.9 million, compared to approximately net cash flow provided by investing activities of $1.1 million in the year ended December 31, 2013 and net cash flow provided by investing activities of $3.0 million in the year ended December 31, 2012. For the year ended December 31, 2014, we invested a total of $17.0 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 sale financial assets at fair value and $0.5 million from withdrawal from bank deposits to cash and cash equivalents. For the year ended December 31, 2012, we invested a total of $1 million in the purchasing of marketable securities and we received proceeds of $1.6 million from sale of marketable securities and $2.5 million from withdrawal from bank deposits to cash and cash equivalents.

Financing activities

Net cash flow resulting from financing activities for the year ended December 31, 2014 amounted to approximately $24.4 million, compared with approximately $2.3 million for the year ended December 31, 2013 and $6.6 million for the year ended December 31, 2012. 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. In 2013, most of the cash flows from financing activities resulted from the exercise of warrants from the August and November 2010 mandatory convertible loans in a total amount of $2.2 million, while in 2012 most of the cash flow was from investment agreements for the issuance ordinary shares and warrants in consideration of an aggregate investment amount of approximately $6.2 million.

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.

	R&D Expenses (U.S. dollars in millions)		
	2014	**2013**	**2012**
Payroll and related expenses	0.6	0.5	0.5
Professional services	1.7	1.3	0.9
Share-based payments	0.9	0.8	0.9
Clinical trials, net	8.5	5.0	3.6
Intellectual property development	0.6	0.2	0.3
Other	0.4	0.3	0.3
Total	12.7	8.1	6.5

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 Israeli 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, 2014:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
		(U.S. dollars in thousands) (Unaudited)			
Office lease obligations	1,186	195	390	390	211
Accounts payable and accrued expenses	1,720	1,720	-	-	-
Total	2,906	1,915	390	390	211

The foregoing table does not include our in-license agreements with Egalet a/s, Temple University, IntelGenx Corp., Wilex AG, the option agreement with RESprotect GmbH, our asset sale agreement with Giaconda Limited aad 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 royalties on our net income, an aggregate amount of approximately $1.6 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 also does not include payments payable under our manufacturing agreements or payments under our clinical services agreements, all of which are contingent upon the completion of milestones. See "Item 4. Information on the Company - Business Overview - Manufacturing Agreements" and "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	49	Chief Executive Officer and Chairman of the board of directors
Ori Shilo	48	Deputy Chief Executive Officer Finance and Operations, and Director
Reza Fathi, Ph.D.	60	Senior Vice President Research and Development
Gilead Raday	40	Senior Vice President Corporate and Product Development
Adi Frish	45	Senior Vice President Business Development and Licensing
Guy Goldberg	39	Chief Business Officer
Uri Hananel Aharon	34	Chief Accounting Officer
Directors		
Dr. Shmuel Cabilly (2)	65	Director
Eric Swenden	71	Director
Dr. Kenneth Reed	61	Director
Dan Suesskind (1)	71	Director
Ofer Tsimchi (1), (2)	55	External Director
Aliza Rotbard (1), (2)	69	External Director

(1) Member of our audit committee that also serves as our financial statements committee.
(2) 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 since August 3, 2009. 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. The board of directors has determined that Mr. Shilo is a financial and accounting expert under Israeli law.

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.

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 United States 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.

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.

Aliza Rotbard has served as an external director on our board of directors since May 4, 2011, as the Chairman of our audit committee and a member of our compensation committee since May 5, 2011. Ms. Rotbard served as the Deputy General Manager of the Tel-Aviv Stock Exchange, was the founder and CEO of DOORS Information Systems and currently serves as an external director of Kamada Ltd., ProSeed Venture Capital Fund Ltd., AIG-American Insurance Group, Hadera Paper Ltd., R.V.B. Holdings Ltd. and Queenco Leisure International Ltd. Ms. Rotbard also serves as a director of Israel Discount Bank, MobileMax Technologies Ltd. and Pointer Telocation Ltd. Ms. Rotbard holds a B.Sc. in Mathematics and Physics from the Hebrew University of Jerusalem, Israel. The board of directors has determined that Ms. Rotbard is a financial and accounting expert under Israeli law.

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, 2014 was approximately $3.0 million. Out of that amount $1.5 million was paid as salary and consultants fees, $1.2 million was attributed to the value of the options granted to directors and senior management during 2014, approximately $0.1 million was attributed to retirement plans and $0.2 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 (the "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, 2014. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2014.

Name and Position of director or officer	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 $US dollars are based on representative U.S. dollar – NIS rate of exchange on February 22, 2015						
Dror Ben-Asher, Chief Executive Officer [5]	280,216	9,148	-	307,061	20,040	616,465
Ori Shilo, Deputy CEO, Finance and Operations [6]	237,564	9,148	-	238,825	16,700	493,237
Reza Fathi, Senior VP Research and Development	233,175	-	-	172,323	20,130	425,628
Gilead Raday, Senior VP Corporate & Products Developments	216,000	-	-	137,859	17,286	371,145
Guy Goldberg, Chief Business officer	199,258	9,148	-	137,859	13,360	359,625

(1) "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 2014.

(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 2014 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), comunication 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 $19,000). 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.

(6) Mr. Shilo's employment terms as the Company's Deputy CEO Finance and Operations provide that Mr. Shilo is entitled to a monthly base gross salary of NIS 61,400 (approximately $16,000). Mr. Shilo 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. Shilo is entitled to reimbursement of car-related expenses from the Company. Mr. Shilo's employment terms include an advance notice period of 180 days by the Company and 90 days by Mr. Shilo. During such advance notice period, Mr. Shilo 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. Shilo's employment is terminated in connection with a "hostile takeover", Mr. Shilo 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. In addition, in case of an "hostile takeover", all options granted to Mr. Shilo 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, Mr. Ofer Tsimchi and Ms. Aliza Rotbard, an annual cash fee of NIS 49,410 (approximately $12,800) and a cash fee of NIS 3,300 (approximately $900) per meeting (or a smaller amount in case they do not physically attend the meeting).

Effective as of October 1, 2011, Dr. Reed, Mr. Swenden, Dr. Cabilly and Mr. Suesskind receive the same cash remuneration as was approved for the external directors as described above.

On April 30, 2014, our shareholders approved equity grants of options to purchase 80,000 ordinary shares each to Mr. Swenden, Dr. Reed and Mr. Suesskind an and equity grants of options to purchase 240,000 ordinary shares each to Dr. Cabilly, Ms. Rotbard and Mr. Tsimchi an. The option has term of seven (7) year and exercise price of $1.48 per share. The options vest quarterly over four (4) years in equal parts, which commenced retroactively as of march 19, 2014. The options will become fully vested, in accordance with the terms of the grant, on March 31, 2018.

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 directors of the first class, currently consisting of Dror Ben-Asher and Ori Shilo, 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 2015, 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. 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 service contracts with two of our directors, Dror Ben-Asher and Ori Shilo that provide for benefits upon termination of their employment as directors. 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.

Ms. Aliza Rotbard and Mr. Ofer Tsimchi 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. Aliza Rotbard, 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), Ms. Aliza Rotbard and Dr. Shmuel Cabilly, 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), Mr. Dan Seusskind and Mr. Ori Shilo, 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. Aliza Rotbard, Mr. Ofer Tsimchi and Mr. Dan Suesskind, with Ms. Rotbard 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 member of our audit committee is an audit committee financial expert as defined by the Securities and Exchange Commission rules and has 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 (the "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 permitting 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 $20 million This insurance was renewed in December 2014, for the period commencing on December 16, 2014 and ending on December 15, 2015. 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 25, 2015, we had 10 employees and we also received services from 10 consultants who provide services to us in the U.S., Canada and Belgium.

	As of December 31,					
	2012		2013		2014	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management and administration	6	2	8	2	9	2
Research and development	1	6	0	8	1	8

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 25, 2015 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 99,384,114 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 25, 2015. 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		
Eric Swenden (1)	4,943,746	4.96%
Dr. Kenneth Reed (2)	4,550,172	4.56%
Dr. Shmuel Cabilly (3)	4,209,178	4.22%
Dan Suesskind (4)	1,073,590	1.07%
Ofer Tsimchi (5)	225,000	*
Aliza Rotbard (6)	255,000	*
Executive officers		
Dror Ben-Asher (7)	5,911,655	5.76%
Ori Shilo (8)	5,199,590	5.10%
Reza Fathi, Ph.D. (9)	1,148,125	1.14%
Gilead Raday (10)	1,022,500	1.02%
Adi Frish (11)	717,500	*
Guy Goldberg (12)	254,167	*
Uri Hananel Aharon (13)	239,128	*
All directors and executive officers as a group (13 persons)	29,749,351	29.94%

* Less than 1.0%

(1) Includes options to purchase 315,000 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 315,000 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.

(3) Includes options to purchase 315,000 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.

(4) Includes options to purchase 935,000 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.

(5) Includes options to purchase 225,000 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 225,000 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 2018 and 2021.

(7) Includes options to purchase 3,180,625 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.

(8) Includes options to purchase 2,604,375 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.

(9) Includes options to purchase 1,148,125 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.

(10) Includes options to purchase 1,022,500 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.

(11) Includes options to purchase 717,500 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.

(12) Includes options to purchase 254,167 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.7 and $1.48 per share, and the options expiry date range between 2019 and 2021.

(13) Includes options to purchase 237,500 ordinary shares exercisable within 60 days of February 22, 2015. The exercise price of these options range between $0.69 and $1.48 per share, and the options expiry date range between 2018 and 2021.

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, 2015, there were 18,325,016 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 99,384,114 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 25, 2015. 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
OrbiMed Israel Partners Limited Partnership (1)	9,332,120 (2)	9.16%
Dror Ben-Asher (3)	5,911,655	5.76%
Eric Swenden (4)	4,943,746	4.96%
Ori Shilo (5)	5,199,590	5.10%
Dr. Kenneth Reed (6)	4,550,172	4.56%
Dr. Shmuel Cabilly (7)	4,209,178	4.22%
Migdal Insurance Company (8)	5,363,552	5.32%
Broadfin Capital (9)	5,967,730 (10)	5.94%

(1) 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.

(2) 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.

(3) Consists of options to purchase 3,180,625 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.

(4) Consists of options to purchase 315,000 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) Consists of options to purchase 2,604,375 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.

(6) Consists of options to purchase 315,000 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.

(7) Consists of options to purchase 315,000 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.

(8) Consists of warrants to purchase 1,435,898 ordinary shares exercisable within 60 days of February 24, 2014 with an exercise price of NIS 4.9 ($1.401 based on the exchange rate reported by the Bank of Israel on January 12, 2014), linked to changes in the NIS-US dollar exchange rate and with an expiration date of January 19, 2017. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants. The shares beneficially owned by Migdal Insurance Company are held for members of the public through, among others, provident funds, mutual funds, pension funds and insurance policies, which are managed by subsidiaries of Migdal Insurance Company. Each of subsidiary operates under independent management and makes independent voting and investment decisions.

(9) 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.

(10) 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.

As of February 18, 2015, 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 ordinary shares, as the shares of all shareholders listed on the TelAviv Stock Exchange are recorded in the name of our Israeli share registrar, Bank Leumi Le'Israel Registration Company Ltd. There were no record holders of our ordinary shares in the U.S. as of February 18, 2015. Based on information obtained from the Tel Aviv Stock Exchange Clearing House Ltd., as of February 18, 2014, residents of Israel beneficially owned approximately 44% of our shares and residents of the U.S. beneficially owned approximately 29.0% of our shares.

B. Related Party Transactions

February 2011 Initial Public Offering

In February 2011, we completed our initial public offering in Israel, under which Dr. Cabilly invested $975,000, Mr. Swenden invested $535,000, Mr. Shilo invested $29,000 and Dr. Reed invested $24,000 out of a total amount of approximately $14 million. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources".

Please see "Item 6. Directors, Senior Management and Employees – B. Compensation – Executives and Director Compensation" for a description of our employment agreements with Dror Ben-Asher and Ori Shilo.

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, 2014.

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
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				
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
2013				
Fourth quarter	3.87	3.23	1.11	0.92
Third quarter	3.79	3.35	1.04	0.91
Second quarter	3.99	3.5	1.10	0.96
First quarter	4.29	3.64	1.15	0.99
Most Recent Six Months				
February 2015 (through February 22, 2015)	5.88	4.89	1.49	1.26
January 2015	6.16	5.10	1.57	1.31
December 2014	5.38	3.41	1.38	0.86
November 2014	3.47	3.00	0.91	0.78
October 2014	4.82	3.38	1.32	0.90
September 2014	5.41	4.71	1.50	1.29
August 2014	5.09	4.18	1.43	1.20

On February 22, 2015, the last reported sales price of our ordinary shares on the TASE was NIS 5.07 per share, or $1.31 per share (based on the exchange rate reported by the Bank of Israel for such date). On February 22, 2015 the exchange rate of the NIS to the U.S. dollar was $1.00 = NIS 3.861, as reported by the Bank of Israel.

ADSs

Our ADSs have been trading on the Nasdaq Capital Market under the symbol "RDHL" since December 26, 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		
2014	19.20	8.03
2013	13.60	8.31
Quarter		
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
2013		
Fourth quarter 2013	11.80	9.51
Third quarter 2013	10.73	8.31
Second quarter 2013	11.94	10.00
First quarter 2013	13.60	8.46
Most Recent Six Months		
February 2015 (through February 22, 2015)	15.18	12.52
Jan-15	15.92	13.79
Dec-14	13.40	8.78
Nov-14	9.29	8.03
Oct-14	13.09	9.20
Sep-14	15.89	13.07
Aug-14	15.00	12.14

On February 22, 2015, the last reported price of our ADSs on the Nasdaq Capital Market was $13.01 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 200,000,000 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.

Private Placements

For information on private placements, see "Item 10. Additional Information - B. Memorandum and Articles - Private Placements."

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**

Securities Purchase Agreements with OrbiMed and Broadfin

On December 30 and December 31, 2013, we entered into Securities Purchase Agreements with OrbiMed Israel Partners Limited Partnership ("OrbiMed") and Broadfin Healthcare Master Fund, LTD. ("Broadfin") for the sale of 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. The warrants are exercisable for 357,896 ADSs in the aggregate (each representing 10 ordinary shares) at an exercise price of $11 per ADS. The parties closed the transaction on January 8, 2014.

The Warrants are immediately exercisable, have a three year term expiring on January 6, 2017 and may be exercised either for cash or on a cashless basis. The exercise price of the Warrant and the number of shares issuable upon exercise of the Warrant are subject to adjustments for stock dividends, stock splits, reverse splits or similar events, for dividends or other distributions to Company shareholders of Company assets (or rights to acquire assets), and for grants to Company shareholders of convertible securities or rights to purchase securities or property. Upon the occurrence of a transaction involving a change in control of the Company in which the consideration is all cash, the Warrant, if not previously exercised, will be cancelled and the holder would receive the cash it would have received had it exercised the Warrant immediately prior to the transaction. For all other changes in control transactions, the successor entity must assume the entire obligation under the Warrant and the successor entity must be a public company traded on a US exchange.

Under the agreements, until we have raised an aggregate of $28 million ($25.5 million in the agreement with Broadfin, which was for an investment of $2.5 million and signed a day after the agreement with OrbiMed) from the sale and issuance of securities, including ordinary shares, any other of our capital stock, ADSs, or any evidences of indebtedness or other securities representing or directly or indirectly convertible into or exchangeable for our capital stock (whether issued alone or together as "units") (the "Additional Securities"), if we issue Additional Securities at a price per Additional Security of less than $9.50 (such lower price, the "Subsequent Offering Price"), upon each such issuance we will issue to the investors a number of additional ADSs as necessary to reduce the effective price per Unit to the Subsequent Offering Price. If ordinary shares and/or ADSs are offered with any other rights, the "Subsequent Offering Price" will 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. An adjustment will also apply to the issuance of convertible securities or warrants at a conversion or exercise price per share of less than $9.50 (adjusted for Ordinary Share-ADR ratio). "Additional Securities" excludes securities issued under our stock option plan, ordinary shares issued upon the exercise of currently outstanding options or warrants, ordinary shares issued for acquisition of any entity or other reorganization or joint venture, and securities issued (i) in connection with the acquisition of, or licensing arrangements for, pharmaceutical products, (ii) to suppliers or third party service providers in connection with the provision of goods or services or (iii) in connection with sponsored research, collaboration, technology license, development, OEM, marketing or other similar agreements or strategic partnerships, in each case if approved by the board and not in connection with a capital raising transaction.

As of February 22, 2015, following the additional capital raisings by us, the anti-dilution protection described above expired.

We agreed to file with the Securities and Exchange Commission a registration statement covering the ADS to be issued to the investors as well as the ADS issuable upon exercise of the Warrant. We filed the registration statement with the Securities and Exchange Commission, and it was declared effective on February 4, 2014.

Share Purchase Agreements with Israeli Institutional and other Investors

On January 14, 2014, we entered into Share Purchase Agreements with 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 for the sale of 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). The parties closed the transaction on January 21, 2014.

We undertook, for a period of six months from the execution of the Share Purchase Agreements, not to issue additional ordinary shares to investors unless the effective price per ordinary share in the future issuance is equal to or greater than NIS 3.455 (approximately $0.98 based on the representative U.S. dollar – NIS rate of exchange of 3.51 on February 23, 2014) per share. For purposes of the agreements, "effective price" refers to the price per share at which shares will be issued by us, and in the case of the issuance of shares together with warrants for no additional consideration, the price per share will be reduced by the value of the warrant calculated in accordance with the Black & Scholes model. The limitation described in this paragraph will apply to issuance of securities to new investors only, whether in a private or public offering, but will not apply to issuance of shares to other investors in the private placement, issuances of shares pursuant to a share option plan for advisors, officers, directors and employees of ours, issuances of shares upon exercise of warrants outstanding on the date of the share purchase agreements, and similar issuances. Following completion of such six month period, we will be permitted to raise additional financing without any limitation.

The Warrants are immediately exercisable and expire on January 19, 2017. The exercise price of the Warrant and/or the number of shares issuable upon exercise of the Warrant are subject to adjustments for stock splits, reverse splits or similar events, for cash dividends or distribution of bonus shares to our shareholders, and for grants to our shareholders of rights to acquire securities of ours of any kind.

For a description of other material agreements, please see also "Information on the Company – B. Business Overview – Acquisition and License Agreements" and "Information on the Company – B. Business Overview – Manufacturing Agreements - Manufacturing Agreement Related to RHB-104."

D. Exchange Controls

Israeli law and regulations do not impose any material foreign exchange restrictions on non-Israeli holders of our ordinary shares. In May 1998, a new "general permit" was issued under the Israeli Currency Control Law, 1978, which removed most of the restrictions that previously existed under the law and enabled Israeli citizens to freely invest outside of Israel and freely convert Israeli currency into non-Israeli currencies. 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 (the "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

As of January 1, 2014 and thereafter, the Israeli corporate tax rate applicable to Israeli resident companies is 26.5%.

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 2014 and thereafter for corporations, and a marginal tax rate of up to 50% in 2014 and thereafter 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 United States and the Government of the State of Israel with respect to Taxes on Income (the "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 United States 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 United States resident in Israel.

Excess Tax

Individual holders 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 811,560 for 2014, which is approximately $210,000)), 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 (the "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 United States.;
- 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 United States 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 have been approved for listing 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, 2014:

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	54	134	5,892	(134)	(54)
Bank deposits	-	-	17,129	-	-
Accounts receivable	2	4	3,074	(4)	(24)
Accounts payable and accrued expenses	(7)	(17)	(1,720)	17	7
Total loss	49	121		(121)	(49)

(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, 2014, these deposits carry annual interest of 0.03%-1.00%. 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, 2014 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, 2014.

(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, 2014 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 Aliza Rotbard, Dan Suesskind and Ofer Tsimchi are audit committee financial experts. Ms. Rotbard, Mr. Tsimchi and Mr. Suesskind 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/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,	
	2013	2014
Services Rendered	(U.S. dollars in thousands)	
Audit (1)	99	122
Audit related services (2)	4	20
Tax (3)	-	24
Total	103	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 registration on Form F-3 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. Furthermore, Israeli law does not require, nor do our independent directors conduct, regularly scheduled meetings at which only our independent directors are present.

- *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 111.

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 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.

Carvedilol - a non-selective beta blocker/alpha-1 blocker indicated in the treatment of hypertension and/or congestive heart failure (CHF).

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.

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.

Pivotal 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.

Rizatripan™ - 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.

Triptans - serotonin 5-hydroxytryptamine (5-HT) receptor agonists drugs used for the treatment of migraine.

REDHILL BIOPHARMA LTD.
2014 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, 2014 and 2013 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, 2014. 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, 2014 and 2013 and the results of its operations, changes in equity and cash flows for each of the three years in the period ended December 31, 2014, in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Tel-Aviv, Israel
February 25, 2015

/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		
		2014	2013	2012
		U.S. dollars in thousands		
REVENUES:				
Licensing revenue	18	7,000	-	-
Other revenue		14	12	16
TOTAL REVENUES		7,014	12	16
COST OF REVENUE		1,050	-	-
RESEARCH AND DEVELOPMENT EXPENSES, net	19	12,700	8,100	(6,455
GENERAL AND ADMINISTRATIVE EXPENSES	20	4,011	2,684	2,601
OTHER INCOME		100	-	-
OPERATING LOSS		10,647	10,772	9,040
FINANCIAL INCOME		319	158	197
FINANCIAL EXPENSES		383	14	1,483
FINANCIAL INCOME (EXPENSES), net	21	64	144	1,286
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR		10,711	10,628	10,326
LOSS PER ORDINARY SHARE (U.S. dollars):	22			
Basic		0.12	0.17	0.20
Diluted		0.13	0.17	0.20

The accompanying notes are an integral part of these financial statements.

REDHILL BIOPHARMA LTD.
STATEMENTS OF FINANCIAL POSITION

	Note	December 31 2014	December 31 2013
		U.S. dollars in thousands	
CURRENT ASSETS:			
Cash and cash equivalents	5	5,892	11,851
Bank deposits	5	17,053	19
Financial assets at fair value through profit or loss	6	-	243
Prepaid expenses and receivables	7	3,074	488
		26,019	12,601
NON-CURRENT ASSETS:			
Bank deposits		76	81
Fixed assets	8	146	103
Intangible assets	9	2,615	1,555
		2,837	1,739
TOTAL ASSETS		28,856	14,340
CURRENT LIABILITIES:			
Accounts payable and accrued expenses	11	1,720	2,415
NON-CURRENT LIABILITIES:			
Derivative financial instruments	16	2,125	-
TOTAL LIABILITIES		3,845	2,415
COMMITMENTS	13		
EQUITY:	15		
Ordinary shares		240	174
Additional paid-in capital		65,461	43,144
Warrants		1,528	1,867
Accumulated deficit		(42,218)	(33,260)
TOTAL EQUITY		25,011	11,925
TOTAL LIABILITIES AND EQUITY		28,856	14,340

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, 2012	142	-	31,168	2,686	(15,209)	18,787
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2012:						
Comprehensive loss	-	-	-	-	(10,326)	(10,326)
Exercise of options into ordinary shares	1	-	301	-	-	302
Cash receipt on account of ordinary shares and warrants	-	5,661	-	587		6,248
Settlement of the royalty obligations, see note 12	-	2,359	-	-	-	2,359
Share-based compensation to employees and service providers	-	-	-	-	1,648	1,648
BALANCE AT DECEMBER 31, 2012	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

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, 2014	174	43,144	1,867	(33,260)	11,925
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2014:	-	-	-	(10,711)	(10,711)
Comprehensive loss					
Exercise of warrants and options into ordinary shares, net	11	5,696	(702)	-	5,005
Issuance of ordinary shares and warrants, see notes 15a(4) and 15a(5)	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

The accompanying notes are an integral part of these financial statements.

REDHILL BIOPHARMA LTD.
STATEMENTS OF CASH FLOWS

	Year ended December 31		
	2014	2013	2012
	U.S. dollars in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Comprehensive loss	(10,711)	(10,628)	(10,326)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	1,753	1,255	1,648
Fair value gain on derivative financial instruments	(200)	-	-
Depreciation	27	24	24
Cost of out-licensing of intangible assets	50		
Fair value gains on financial assets at fair value through profit or loss	-	(54)	(57)
Revaluation of bank deposits	(29)	(16)	(4)
Accretion and settlement of royalty obligations to investors	-	-	1,473
Exchange differences in respect of cash and cash equivalents	237	(64)	(12)
Changes in assets and liability items:			
Increase in prepaid expenses and receivables	(2,586)	(290)	(109)
Increase (decrease) in accounts payable and accrued expenses	(770)	1,337	568
Net cash used in operating activities	(12,229)	(8,436)	(6,795)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of fixed assets	(70)	(14)	(8)
Purchase of intangible assets	(1,035)	(210)	(100)
Changes in investment in current bank deposits	(7,000)	477	2,529
Investment in non-current bank deposits	(10,000)	-	-
Purchase of financial assets at fair value through profit or loss	-	-	(1,032)
Proceeds from sale of financial assets at fair value through profit or loss	243	876	1,588
Net cash provided by (used in) investing activities	(17,862)	1,129	2,977
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares, warrants and derivative financial instruments, net	19,364	100	6,248
Exercise of warrants and options into shares, net of expenses	5,005	2,180	302
Net cash provided by financing activities	24,369	2,280	6,550
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(5,722)	(5,027)	2,732
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	(237)	64	12
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	11,851	16,814	14,070
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	5,892	11,851	16,814
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	118	30	126
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:			
Settlement of the royalty obligations	-	-	2,359
Purchase of intangible assets	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 and is active in the pharmaceutical industry. The Company is focused primarily on the development and acquisition of late clinical-stage, proprietary drug candidates for the treatment of inflammatory and gastrointestinal diseases, including gastrointestinal cancers (the "Drug Candidates"). Additionally, the Company's strategy is to commercialize these Drug Candidates, possibly through cooperation with other pharmaceutical and biotechnology companies, and to acquire rights to additional drug candidates.

In February 2011, the Company listed its securities on the Tel-Aviv Stock Exchange ("TASE") and they have been traded on the TASE since then. 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 therapeutic candidates and to date has out-licensed only one of its therapeutic candidates. Accordingly, there is no assurance that the Company's business will generate positive cash flow. Through December 31, 2014, 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 therapeutic 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 therapeutic candidates. Management expects that the Company will incur more losses as it continues to focus its resources on advancing its therapeutic 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. See subsequent event note 24 for capital raised in February 2015.

If the Company is unable to commercialize or further out-license its remaining therapeutic 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 therapeutic 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 25, 2015.

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, 2014 and 2013 and for each of the three years in the period ended on December 31, 2014 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 are recognized as assets only if (a) it is probable that future economic benefits associated with the item will flow to the Company and (b) the cost of the item can be measured reliably.

Fixed assets items are initially recognized at acquisition cost. Fixed assets items are stated at cost less accumulated depreciation and impairment losses.
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.
The assets' residual values, useful lives and depreciation method are reviewed, and adjusted if appropriate, at least once a year.

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.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued):

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, 2014 and 2013, the Company has not yet capitalized development costs.

3) Amounts paid to purchase intellectual property of Drug Candidates are capitalized and carried 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 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. 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.

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.

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 carried 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 carried 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 income or expenses".

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 15a(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 handled 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 carried to accumulated deficit under 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 as follows:

Share-based payments to employee by reference to the fair value of the options granted at date of grant.
Share-based payments to service providers by reference to the fair value of the service provided.

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, with 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 OCI and fair value through P&L. 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 OCI not recycling. There is now a new expected credit losses model that 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 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, 2017 with earlier adoption permitted. The Company is currently assessing the impact of adopting IFRS 15.

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, reporting and presentation currency of the Company). 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 $125,000, $96,000, and $74,000 in profit or loss for the years ended, December 31, 2014, 2013 and 2012, respectively.

Price risk: the Company is sometimes exposed to equity securities price risk because of investments held by the Company and classified on the statement of financial position as financial assets at fair value through profit or loss. To manage its price risk arising from investments in equity securities, the Company invests in marketable securities with high ratings and diversifies its investment portfolio.

Portfolio diversification is done based on risk level limits set by the Company.

(b) Credit and interest risks

Credit and interest risks arise from cash and cash equivalents, deposits with banks, as well as accounts receivable. 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, 2014 and 2013, the Company's non-derivative financial liabilities include accounts payable and accrued expenses 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):

The following table presents Company assets and liabilities measured at fair value:

	Level 1	Level 2	Level 3	Total
	U.S. dollars in thousands			
December 31, 2014 -				
Liabilities -				
Derivative financial instruments	-	-	2,125	2,125
December 31, 2013 -				
Assets -				
Financial assets at fair value through profit or loss	243	-	-	243

The following table presents the change in instruments measured at level 3 for the year ended December 31, 2014:

	Derivative financial instruments
	U.S. dollars in thousands
Proceeds received during the reported period	2,325
Amounts recognized in profit or loss	(200)
Balance at December 31, 2014	2,125

The fair value of the above-mentioned derivative financial instruments 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 that have been issued in 2014, see note 16.

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

b. Classification of financial instruments by groups:

	Assets at fair value through profit or loss	Loans and receivables	Total
	U.S. dollars in thousands		
As of December 31, 2014:			
Cash and cash equivalents	-	5,892	5,892
Bank deposits	-	17,129	17,129
Receivables (except prepaid expenses)	-	2904	2,904
	-	25,925	25,925
As of December 31, 2013:			
Cash and cash equivalents	-	11,851	11,851
Bank deposits	-	100	100
Financial assets at fair value through profit or loss	243	-	243
Receivables (except prepaid expenses)	-	427	427
	243	12,378	12,621

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortized cost	Total
	U.S. dollars in thousands		
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
As of December 31, 2013 -			
accounts payable and accrued expenses	-	2,415	2,415

NOTE 4 - FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT (continued):

c. Composition of financial instruments by currency:

	U.S. Dollar	Other currencies (mainly NIS)	Total
	U.S. dollars in thousands		
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
As of December 31, 2013:			
Assets:			
Cash and cash equivalents	9,712	2,139	11,851
Bank deposits	-	100	100
Financial assets at fair value through profit or loss	-	243	243
Receivables (except prepaid expenses)	365	62	427
	10,077	2,544	12,621
Liabilities:			
Accounts payable and accrued expenses	2,143	272	2,415
	7,934	2,272	10,206

NOTE 5 - CASH AND CASH EQUIVALENTS AND BANK DEPOSITS:

a. Cash and Cash Equivalents:

	December 31	
	2014	2013
	U.S. dollars in thousands	
Cash in bank	4,590	7,711
Short-term bank deposits	1,302	4,140
	5,892	11,851

The carrying amounts of the cash and cash equivalents approximate their fair values.

b. Bank Deposits

The bank deposits include deposits invested for terms of three months to one year and current maturities of deposit invested for term of 15 months. The bank deposits bear interest at annual rates of between 0.55% - 1.00%.

NOTE 6 - FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS:

These financial assets as of December 31, 2013 represented a portfolio of Israeli, NIS-denominated marketable securities, which was managed and valued by the Company based on the fair value of all portfolio securities.

Taking into consideration the manner of management of the portfolio and the evaluation of its performances, the Company classified the entire investment in marketable securities as financial assets at fair value through profit or loss. The fair value of the securities was based on their exchange market price at the end of the reporting date trading day.

NOTE 7 - PREPAID EXPENSES AND RECEIVABLES:

	December 31	
	2014	2013
	U.S. dollars in thousands	
Advances to suppliers	1,840	-
Discount from Service Provider - see note 19b	987	363
Prepaid expenses	170	61
Government institutions	77	62
Other	-	2
	3,074	488

The fair value of receivables, which constitute financial assets, approximates their carrying amount.

NOTE 8 - FIXED ASSETS:

The composition of assets and accumulated depreciation, grouped by major classifications:

	Cost		Accumulated depreciation		Depreciated balance	
	December 31		December 31		December 31	
	2014	2013	2014	2013	2014	2013
	U.S. dollars in thousands					
Office furniture and equipment (including computers)	137	84	51	36	86	48
Leasehold improvements	99	82	39	27	60	55
	236	166	90	63	146	103

NOTE 9 - 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		
	2014	2013	2012
	U.S. dollars in thousands		
Cost:			
Balance at beginning of year	1,555	1,345	1,245
Additions during the year	1,110	210	100
Cost of out-licensing	(50)		
Balance at end of year	2,615	1,555	1,345

For further details, see note 13.

As of December 31, 2014 the Company did not record impairment of these intangible assets.

NOTE 10 - 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 2014, 2013 and 2012 were $88,000, $62,000 and $58,000, respectively. Of those amounts, approximately half were charged to general and administrative expenses and half to research and development expenses.

NOTE 11 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

	December 31	
	2014	2013
	U.S. dollars in thousands	
Trade payables	66	884
Expenses payable	1,334	1,263
Employees and employees institutions	261	203
Government institutions	59	65
	1,720	2,415

The fair value of the accounts payable and accrued expense balances approximates their carrying amounts.

NOTE 12 - ROYALTY OBLIGATIONS TO INVESTORS:

As part of the mandatory convertible loan agreements with investors from August 2010, the investors were entitled to royalties equal to 5% of future revenue from two therapeutic candidates purchased by the Company.

On December 26, 2012, a General Shareholders Meeting of the Company approved the acquisition and settlement of the royalty rights granted to the investors in exchange for the issuance of an aggregate of 2,317,186 Company ordinary shares.

On the date of the approval, the Company was relieved of its royalty obligations and the associated liability was derecognized. The fair value of the shares to be issued was approximately $2.4 million. The excess between the fair value of the shares over the amortized cost of the liability as of the approval date was recorded on the statement of comprehensive loss under financial expenses. The shares were issued on January 10, 2013.

NOTE 13 - COMMITMENTS:

a. Agreements to purchase intellectual property:

1) On November 18, 2009, the Company entered into an agreement with a Danish company to provide the Company with the exclusive rights to a drug candidate intended to treat congestive heart failure, left atrium dysfunction and high blood pressure. According to the agreement, the Company paid the Danish company an initial amount of $100,000, and undertook to transfer to the Danish company additional amounts of up to $700,000 based on achieving regulatory milestones as agreed between the parties. Under the agreement, the Company agreed to pay the Danish company royalties at 30% of the Company's revenues generated by the drug candidate, less specified amounts incurred in the 12 years from the date marketing begins, or until the patent expires, whichever is the earliest in each country where the drug candidate will be marketed. Through December 31, 2014, the Company paid the Danish company the initial amount of $100,000.

2) 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 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, 2014, the Company paid the U.S. company the initial amount of $100,000.

   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.

NOTE 13 - COMMITMENTS (continued):

3) 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 an initial amount of $500,000 on the date of signing the agreement, and undertook under the agreement to transfer additional amounts of up to $800,000 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 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. The agreement is for an indefinite period and is subject to certain termination conditions.

   Through December 31, 2014, 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, 2014, the Company participated in the drug candidate research and development costs in the amount of approximately $1.3 million that was recorded in the statements of comprehensive loss under research and development expenses.

4) 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. Through December 31, 2014, the Company paid the Australian company a total of $1.5 million. See also note 18 in connection with the license agreement for one of the Drug Candidates.

5) On September 18, 2011, the Company entered into an agreement with a U.S. academic institution (hereinafter – "the Academic Institution") to acquire exclusive rights to a diagnostic test (hereinafter – the "Test") for certain bacteria relatively prevalent among patients of a certain condition of the gastrointestinal tract.

   Under the agreement, in addition to an initial payment of $45,000, the Company undertook to pay the Academic Institution royalties in the range of 7% - 20% of the amount received by the Company from revenues resulting from rights to the Test and other potential payments in immaterial amounts. Through December 31, 2014, the Company paid the Academic Institution a total amount of $70,000.

   The acquisition of rights was intended to allow the Company to screen patients for clinical trials and, in the future, may be used commercially, if and when approved for marketing, in combination with treatment with one of the drug candidates that was purchased from the Australian company.

NOTE 13 - COMMITMENTS (continued):

6) 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 net revenues, 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, 2014, the Company paid the German company the initial amount of $1 million.

7) 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 is for one year period, which may be extended by the Company under certain agreed terms 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 net revenues, ranging from single-digit to mid-teens. Through December 31, 2014, the Company paid an amount of $20,000 in consideration of the option period for the first year. If the Company will exercise the option, such amount will be fully deducted from the up-front payment of $100,000, as described above.

b. Operating lease agreement

The Company entered into an operating lease agreement for the offices it uses. The agreement will expire on January 31, 2017 (hereafter "Date of End of the Rental Period") with an option to extend the rental period by an additional 3 years. The projected rental payments until the Date of End of the Rental Period, at rates in effect as of December 31, 2014, are $195,000 per year.

As of December 31, 2014, an amount of $76,000 was deposited with a bank to secure the lease payments.

NOTE 14 - 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 and 2012 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% from 2014 and thereafter.

c. Carryforward losses

The balance of carryforward losses as of December 31, 2014 is $25 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.

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, 2014 and 2013, were $13 million and $8 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 2009 tax year are considered to be final.

NOTE 15 - 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	
	2014	2013
	In thousands	
Authorized	200,000	200,000
Issued and paid	87,884	64,400

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, 2014 was $13.33 per ADS on the NASDAQ and $1.38 per share on the TASE (based on the exchange rate reported by the Bank of Israel for such date).

2) Exercise of warrants

During 2013, the Company received notifications on the exercise of warrants that had been granted to investors as part of conversion of mandatory convertible loans. Accordingly in 2013, the Company issued 2,550,865 ordinary shares for $2.2 million, net of direct issuance costs. The remaining 629,995 unexercised warrants expired in 2013 along with any right or claim whatsoever of the holder.

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.

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.

NOTE 15 - EQUITY (continued)**:**

3) Exercise of options

During 2013, the Company received notifications of exercise with respect to options that had been issued to a consultant in August 2010 and in February 2011. Accordingly, the Company issued 60,000 ordinary shares for $13,000.

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.

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. As of February 18, 2015, following additional capital raisings by the Company of $11.7 million (see (5) below) and $14.4 million (see note 24), the Price Protection Rights expired.

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. 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 carried 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.

NOTE 15 - EQUITY (continued)**:**

For information regarding the terms of the warrants, see note 16a 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.

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 16 - DERIVATIVE FINANCIAL INSTRUMENTS:

a. Warrants

The warrants issued under the investment agreement, as described in note 15a(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 15a(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%.

NOTE 17 - 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 2010 and 2011 to increase the Option Plan to allow the Company to allocate 22,080,000 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 2014:

	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)	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) Each option is exercisable into one ordinary share at an exercise price of $1.48 per share. 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 all options on the date of grant was $2.56 million. The fair value of the options was computed using the binominal model and 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 exercise: seven years.

NOTE 17 - SHARE-BASED PAYMENTS (continued):

b. Following is information on options granted in 2013:

	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)	To directors (1)	Total		
May 2013	1,930,000	-	1,930,000	1.12	1,104
July 2013	* 550,000	300,000	850,000	1.12	445
	2,480,000	300,000	2,780,000		1,549

* 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 all options on the date of grant was U.S. $1.5 million. 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: $0.98- $1.067, expected volatility: 66.08%-66.55%, risk-free interest rate: 1.4%-1.95% and expected useful life to exercise: seven years.

NOTE 17 - SHARE-BASED PAYMENTS (continued):

c. Changes in the number of shares and weighted averages of exercise prices are as follows:

	Year ended December 31			
	2014		2013	
	Number of options	Weighted average of exercise price	Number of options	Weighted average of exercise price
Outstanding at beginning of year	14,735,000	0.60	12,015,000	0.47
Exercised	(150,000)		(60,000)	
Granted	3,740,016	1.48	2,780,000	1.12
Outstanding at end of year	18,325,016	0.78	14,735,000	0.60
Exercisable at end of year	14,152,921	0.60	11,596,667	0.49

d. The following is information about exercise price and remaining useful life of outstanding options at year-end:

December 31, 2014			December 31, 2013		
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
18,325,016	0.17-1.48	4.13	14,735,000	0.17-1.12	4.58

e. Expenses recognized in profit or loss for the options are as follows:

Year ended December 31		
2014	2013	2012
U.S. dollars in thousands		
1,753	1,255	1,648

The remaining compensation expenses as of December 31, 2014 are $1.73 million and will be expensed in full by April 2018.

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 18 - REVENUES:

On February 27, 2014, the Company entered into an exclusive agreement by which Salix Pharmaceuticals, Inc. ("Salix") 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 19 - RESEARCH AND DEVELOPMENT EXPENSES, net**:**

a.

	Year ended December 31		
	2014	**2013**	**2012**
	U.S. dollars in thousands		
Payroll and related expenses	573	426	529
Professional services	1,685	1,272	933
Share-based payments	951	753	862
Clinical trials	9,187	6,019	3,620
Intellectual property development	556	233	240
Other	382	363	271
Discount from Service Provider, see b. below	(634)	(966)	-
	12,700	8,100	6,455

b. In 2013 and 2014, the Company received notifications from its Canadian service provider ("Service Provider") that the Canadian authorities had successfully completed their review of the Service Provider's request for certain incentive cash benefits related to research and development activities provided by the Service Provider for the Company. Accordingly, the Company received a discount from the Service Provider for services provided by them.

NOTE 20 - GENERAL AND ADMINISTRATIVE EXPENSES:

	Year ended December 31		
	2014	2013	2012
	U.S. dollars in thousands		
Payroll and related expenses	943	754	517
Share-based payments	802	501	787
Professional services	1,662	997	879
Office related expenses	187	131	122
Other	417	301	296
	4,011	2,684	2,601

NOTE 21 - FINANCIAL EXPENSES (INCOME), net**:**

	Year ended December 31		
	2014	2013	2012
	U.S dollars in thousands		
Financial income:			
Fair value gain on derivative financial instruments	200	-	-
Fair value gain on financial assets at fair value through profit or loss	-	54	57
Income from changes in exchange rates	-	74	21
Interest from securities and bank deposits	119	30	119
	319	158	197
Financial expenses:			
Accretion and settlement of royalty obligations to investors	-	-	1,473
Loss from changes in exchange rates	361	-	-
Other	22	14	10
	383	14	1,483
Financial expenses (income) - net	64	(144)	1,286

NOTE 22 - 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		
	2014	**2013**	**2012**
Loss (U.S. dollars in thousands)	10,711	10,628	10,326
Weighted average of ordinary shares outstanding during the period (in thousands)	86,610	62,379	52,595
Basic loss per share (U.S. dollars)	0.12	0.17	0.20

b. Diluted

The diluted loss per share for the years ended December 31, 2012 and 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 to assume 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		
	2014	**2013**	**2012**
Loss (U.S. dollars in thousands)	10,711	10,628	10,326
Adjustment for financial income of warrants	463	-	-
Loss used to determine diluted loss per share	11,174	10,628	10,326
Weighted average number of ordinary shares outstanding during the period (in thousands)	86,610	62,379	52,595
Adjustment for - warrants	612	-	-
Weighted average number of ordinary shares for diluted loss per share (in thousands)	87,222	62,379	52,595
Diluted loss per share (U.S. dollars)	0.13	0.17	0.20

NOTE 23 - 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		
	2014	2013	2012
	U.S. dollars in thousands		
Key management compensation:			
Salaries and other short-term employee benefits	628	555	373
Post-employment benefits	60	48	44
Share-based payments	726	515	974
Other long-term benefits	31	25	22
Transactions with key management -			
Accretion and settlement of royalty Obligations to investors	-	-	637

b. Balances with related parties:

	December 31	
	2014	2013
	U.S. dollars in thousand	
Current liabilities -		
Credit balance in "accounts payable"	155	146

NOTE 24 - EVENTS SUBSEQUENT TO DECEMBER 31, 2014

In February 2015, the Company completed an underwritten public offering in the U.S. of an aggregate of 1.15 million ADSs at a price of $12.50 per ADS for gross proceeds to the Company of $14.4 million before underwriting discounts and commissions and other offering expenses. Net proceeds to the Company from the offering, following underwriting discounts and other offering expenses, were approximately $13.2 million.

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.
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.
4.7*	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).
4.8	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).
4.9*	Manufacturing Agreement, dated October 21, 2012, by and between 7810962 Canada Inc. and the Registrant (regarding RHB-104) (incorporated by reference to Exhibit 4.14 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.10†	Manufacturing Agreement Amendment 1, dated October 29, 2014, by and between 7810962 Canada Inc. and the Registrant (regarding RHB-104).

4.11†	Manufacturing Agreement, dated October 28, 2014, by and between Canadian Manufacturer and the Registrant (regarding RHB-104).
4.12*	Clinical Services Agreement, dated June 15, 2011, by and between RedHill 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).
4.13*	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).
4.14†	Third Amendment to Clinical Services Agreement, dated December 7, 2014, by and between the Registrant and 7810962 Canada Inc.
4.15†	Fourth Amendment to Clinical Services Agreement, dated December 17, 2014, by and between the Registrant and 7810962 Canada Inc.
4.16†	Master Service Agreement and Extension to Master Service Agreement, dated July 5, 2011 and Manufacturing Agreement, dated July 5, 2011, by and between 7810962 Canada Inc. and the Registrant, as amended (regarding RHB-105).
4.17†	First Amendment to Manufacturing Agreement, dated August 17, 2011, by and between the Registrant and 7810962 Canada Inc. (regarding RHB-105)
4.18†	Second Amendment to Manufacturing Agreement, dated September 30, 2011, by and between the Registrant and 7810962 Canada Inc. (regarding RHB-105)
4.19†	Third Amendment to Manufacturing Agreement, dated April 19, 2012, by and between the Registrant and 7810962 Canada Inc. (regarding RHB-105)
4.20†	Clinical Services Agreement, dated October 29, 2012, by and between RedHill and Clinipace, Inc. and (regarding RHB-105).
4.21†	Amendment 1 to Attachment A-1, dated August 12, 2014, of the Clinical Services Agreement by and between RedHill and Clinipace, Inc. (regarding RHB-105).
4.22†	Clinical Trials Global Master Service Agreement, dated December 27, 2012 by and between the Registrant and Quest Diagnostics (regarding RHB-104).
4.23	Global Master Service Agreement amendment, dated June 20, 2014 by and between the Registrant and Quest Diagnostics (regarding RHB-104).
4.24†	Master Agreement Work Order, dated May 13, 2014, by and between the Registrant and Quest Diagnostics (regarding RHB-104).
4.25†	Change Specification Forms by and between Registrant and Quest Diagnostics (regarding RHB 104) dated August 9, 2013, October 14, 2013, October 21, 2013, December 23, 2013, March 30, 2014, July 7, 2014, July 14, 2014, and December 18, 2014.
4.26	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).
4.27	2010 Stock Option Plan, as amended.

4.28 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).

4.29 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).

4.30 Form of Share Purchase Agreement, dated January 13, 2014 by and between the Registrant and each of the investors (together with Form of Warrant attached as Exhibit A) (unofficial English translation) (incorporated by reference to Exhibit 4.19 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2014).

4.31 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).

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, 2014

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")

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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 I 1 (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 2,000,000, divided into 200,000,000 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.

* * *

Exhibit 4.4

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT TO ASSET PURCHASE AGREEMENT

This Amendment to Asset Purchase Agreement (this "**Amendment**") is made as of 27 February 2014 (the "**Amendment Effective Date**"), by and among RedHill Biopharma Ltd., an Israeli company having its principal place of business at 21 Ha'arba'a Street, Tel-Aviv 64739, Israel ("**RedHill**"), and Giaconda Limited ACN 108 088 517, an Australian public limited company having its registered office at Ground Floor, 44 East Street, Five Dock, NSW 2046, Australia ("**Giaconda**"). Each of RedHill and Giaconda is sometimes referred to individually herein as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Giaconda and RedHill are the parties to that certain Asset Purchase Agreement, dated as of 11 August 2010 (the "**Original Asset Purchase Agreement**") , which in Section 13.2 thereof contains provisions that impose certain restraints on the ability of Giaconda and [****] (as defined below) and their respective affiliates to supply or grant certain goods, services or rights;

WHEREAS, [****], and RedHill in connection with the execution and delivery of the Original Asset Purchase Agreement and the consummation of the transactions contemplated thereby, entered into, and are now the parties to, that certain Agreement, dated as of 11 August 2010 (the "**ROFR Agreement**"), which in Section 4.2 thereof contains provisions that impose certain restraints on the ability of [****] and [****] affiliates to supply or grant certain goods, services or rights;

WHEREAS, [****], together with [****] (collectively, including [****], the "**Inventors**"), has conducted work in the field of colonic purgatives, laxatives, and gastrointestinal cleansers and has in connection therewith developed certain know-how and intellectual property with respect thereto;

WHEREAS, Salix Pharmaceuticals, Inc. ("**Salix**") and the Inventors wish to enter into an Assignment and License Agreement simultaneously herewith, pursuant to which Salix will acquire certain rights;

WHEREAS, RedHill and Salix are entering into an Agreement (the "**Salix/RedHill Agreement**") dated simultaneously herewith;

WHEREAS, as required by the Salix/RedHill Agreement, RedHill has agreed to amend the Original Asset Purchase Agreement to revise the restraints it places on the ability of Giaconda, [****] and their affiliates to supply or grant certain goods, services, rights and information to Salix; and

WHEREAS, [****] and RedHill are entering into a Deed of Variation dated simultaneously herewith that will amend the ROFR Agreement;

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby amend the Original Asset Purchase Agreement as follows:

SECTION 1. **Additional Definitions**. The following new definitions shall be inserted into the Section 1 of the Original Asset Purchase Agreement in their correct alphabetical order:

"**Designated Products**" means all Products other than Purgative Products.

"**Designated Technology**" means all Technology other than Technology that relates to the Purgative Field.

"**Designated Technology Intellectual Property**" means all Technology Intellectual Property other than Technology Intellectual Property that relates to the Purgative Field.

"**Purgative Field**" means the development, manufacturing, and commercialization, making, having made, using, offering to sell, selling, or importing of Purgative Products.

"**Purgative Product**" means any substance or product, including the [****], intended for use as a [****] (including in, or for the purpose of, the [****]) in humans or non-human animals, but not, for the avoidance of doubt, any of [****].

SECTION 2. **Non-Competition**.

2.1 Section 13.2.1 of the Original Asset Purchase Agreement is hereby amended and replaced in its entirety by the following:

> "Restraint. Seller agrees and undertakes that neither Seller or its Affiliates (excluding [****]) , will, without the prior written consent of Buyer directly or indirectly, as owner, part-owner, financier, partner, joint venturer, stockholder, employee, broker, agent, principal, corporate officer, director, licensor or in any other capacity whatever (a) supply or grant services or rights similar to or competing with the Designated Products or the Designated Technology; or (b) supply goods or services that assist any other person, entity, or organization in competing or in preparing to compete with the Designated Products or the Designated Technology. The foregoing restrictions do not prevent Seller from selling, licensing, or dealing with Hepaconda or Ibaconda provided that those patents and associated intellectual property are not the subject of the Charges. The foregoing restrictions do not apply if Seller proposes to exercise or exercises its Buy Back Option. "

2.2 Section 13.2.5 of the Original Asset Purchase Agreement is hereby amended and replaced in its entirety by the following:

This Section 13.2.1 does not restrict:

a) Seller or its Affiliates holding 1% or less of any class of stock or securities of a publicly listed company, provided that Seller or its Affiliates have no active role in that company;

b) Seller or its Affiliates recruiting a person through a recruitment agency (except if the agency targets Buyer's employees) or as a response to a newspaper, web page or other public employment advertisement;

c) Seller or its Affiliates from selling, licensing, or dealing with Hepaconda or Ibaconda provided that those patents and associated intellectual property are not the subject of the Charges or part of the Technology Intellectual Property or licensed to Buyer under Section 4 hereto;

d) Seller from proposing to exercise or exercising its Buy Back Option;

e) Seller from enjoying the full incidents of ownership of the Relevant Therapy acquired by it as a result of exercising its Buy Back Option.

2.3 Section 13.2.6 of the Original Asset Purchase Agreement is added as follows:

> "Notwithstanding any clause in this agreement, nothing in this agreement restricts [****] or [****] Affiliates from taking any action or conducting any activities with respect to Purgative Products or otherwise in the Purgative Field."

2.4 **Release** The Buyer irrevocably and unconditionally releases and forever discharges the Seller and its Affiliates from any and all claims (including any present or future causes of action, expenses, including legal fees, claim, liabilities, damages, declaration, demand, loss or suit whether arising in contract, tort, statue, equity or otherwise whether known or unknown) that the Buyer or its Affiliates may have in connection with any acts or omissions of [****] relating to Section 13.2 of the Original Asset Purchase Agreement prior to the amendment of Section 13.2 under this Agreement.

SECTION 3. **Confidentiality**. Section 14.2 of the Original Asset Purchase Agreement is hereby amended by adding a new sentence at the end thereof reading as follows:

> "Notwithstanding anything in this Article 14 to the contrary, nothing in this Article 14 shall operate to limit or qualify the right and ability of Seller, [****] and their respective Affiliates to use and to disclose to Salix Pharmaceuticals, Inc. information, including information that would otherwise constitute Confidential Information subject to the restrictions and limitations set forth in this Article 14, to the extent (but only to the extent) the same relates to Purgative Products or the Purgative Field."

SECTION 4. **Condition Precedent.** The parties agree and acknowledge that this Amendment is interdependent with those agreements and deeds set forth on Annex 1 hereto (the "**Interdependent Documents"**) and that, except as may otherwise be agreed by the parties in writing, (a) no provision of this Amendment other than this Section 4 will come into effect until a counterpart of each of the other Interdependent Documents has been duly executed and delivered by all parties thereto but (b) simultaneously with the execution and delivery by each party thereto of a counterpart of each of the other Interdependent Documents all provisions of this Amendment shall, without further action by any of the parties, come into full force and effect.

SECTION 5. **Effective Date; Incorporation of Terms; Continuing Effect.** Subject to Section 4, this Amendment shall be deemed effective for all purposes as of the Amendment Effective Date. The amendment set forth in this Amendment shall be deemed to be incorporated in, and made a part of, the Original Asset Purchase Agreement, and the Original Asset Purchase Agreement and this Amendment shall be read, taken and construed as one and the same agreement (including with respect to the provisions set forth in Article 18 of the Original Asset Purchase Agreement, which shall, as applicable, be deemed to apply to this Amendment (including with respect to the governing law)). Except as otherwise expressly amended by this Amendment, the Original Asset Purchase Agreement shall remain in full force and effect as so amended in accordance with its terms and conditions and does not prejudice any accrued rights or obligations which the parties to the Original Asset Purchase Agreement have under that agreement.

SECTION 6. **Counterparts.** This Amendment may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which, taken together, shall constitute one and the same instrument. This Amendment may be executed by the electronic or telephonic delivery of a facsimile of an executed signature page hereof with the same effect as the delivery of the original of such executed signature page.

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, the parties, intending to be bound, have caused this Amendment to be executed on their behalf by their duly authorized agent to be effective as of the Amendment Effective Date.

RedHill Biopharma Ltd.

By:
/s/_____
Name:

Title: _____

Executed by **Giaconda Limited** ACN 108 088 517 in accordance with Section 127 of the *Corporations Act 2001*

/s/_____
Signature of director

Name of director:_____

/s/_____
Signature of director/company secretary

Name of director/company secretary:_____

Signature Page to Amendment to Asset Purchase Agreement

ANNEX 1

Interdependent Documents

Core Transactional Documents

1. Assignment and License Agreement by and among [****]
2. Agreement between RedHill Biopharma Ltd. and Salix Pharmaceuticals, Inc.

Giaconda / Redhill Arrangements

3. This Amendment to Asset Purchase Agreement by and between RedHill Biopharma Ltd. and Giaconda Limited ACN 108 088 517
4. Deed of Waiver, Confirmation, Termination, and Amendment by and between Giaconda Limited ACN 108 088 517, [****], RedHill Biopharma Ltd., and Salix Pharmaceuticals, Inc.

[****]*/ RedHill Arrangements*

5. Deed of Variation by and between RedHill Biopharma Ltd. and [****]
6. Deed of Termination by and between RedHill Biopharma Ltd and [****]
7. Deed of Termination by and between RedHill Biopharma Ltd and [****]

General Facilitating Documents

8. Deed of Waiver and Confirmation by and among [****]
9. Deed of Waiver and Confirmation by and between [****]
10. Research Services Agreement by and between [****]
11. Deed of Waiver and Confirmation, [****]
12. Letter agreement, between [****]

[****]*Salix Arrangements*

13. Deed of Waiver and Confirmation by and among [****]
14. Ibaconda Assignment Agreement by and between [****]

[****] *Arrangements*

15. Releases for Salix Deed, dated 23 December 2013, by and between [****]

16. Deed of Assignment and License, dated on or about 25 January 2013, between [****]

17. Letter agreement, dated 23 December 2013, between [****]

18. Termination Deed, dated 23 December 2013, between [****]

Exhibit 4.6

STRICTLY CONFIDENTIAL

Execution Version

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AGREEMENT

by and between

REDHILL BIOPHARMA LTD.

and

SALIX PHARMACEUTICALS, INC.

Dated as of 27 February 2014

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AGREEMENT

This Agreement (the "**Agreement**") is made and entered into to be effective as of 27 February 2014 (the "**Effective Date**") by and between RedHill Biopharma Ltd., an Israeli company ("**RedHill**"), and Salix Pharmaceuticals, Inc., a California corporation ("**Salix**"). RedHill and Salix are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Giaconda Limited ACN 108 088 517 ("**Giaconda**") and RedHill are the parties to that certain Asset Purchase Agreement, dated as of 11 August 2010 (the "**Asset Purchase Agreement**"), which in Section 13.2 thereof contains provisions that impose certain restraints on the ability of Giaconda and [****] (as defined below) and their respective affiliates to supply or grant certain goods, services or rights;

WHEREAS, [****], and RedHill in connection with the execution and delivery of the Asset Purchase Agreement and the consummation of the transactions contemplated thereby, entered into, and are now the parties to, that certain Agreement, dated 11 August 2010 (the " **ROFR Agreement**"), which in Section 4.2 thereof contains provisions that impose certain restraints on the ability of [****] and [****] affiliates to supply or grant certain goods, services or rights;

WHEREAS, [****], together with [****] (collectively, including [****], the "**Inventors**") have conducted work in the field of colonic purgatives, laxatives and gastrointestinal cleansers and have in connection therewith developed certain know-how and intellectual property with respect thereto;

WHEREAS, Salix and the Inventors wish to enter into an Assignment and License Agreement in the form set forth in Appendix A hereto (with the redacted portions to be completed by agreement between Salix and the Inventors) (the "**License Agreement**") simultaneously herewith, pursuant to which Salix will acquire certain rights in and to such know-how and intellectual property rights, and certain know-how and intellectual property rights that may in the future be developed by the Inventors in respect of colonic purgatives, laxatives and gastrointestinal cleansers, to develop, manufacture and commercialize colonic purgatives, laxatives and gastrointestinal cleansers on a worldwide basis, in each case in accordance with the terms and conditions set forth in the License Agreement;

WHEREAS, pursuant to the Asset Purchase Agreement and the ROFR Agreement certain intellectual property rights were transferred by Giaconda and [****] to RedHill, certain of which intellectual property rights are relevant to Salix's desire to develop and commercialize products in the field of colonic purgatives, laxatives and gastrointestinal cleansers and to Salix's ability to fully exploit the licenses and other rights granted to Salix under the License Agreement;

WHEREAS, Salix wishes to obtain the licenses, waivers and other rights from RedHill set forth herein solely in order better to develop and commercialize colonic purgatives, laxatives and gastrointestinal cleansers and in connection therewith to assure its ability to fully exploit the licenses and other rights granted to it under the License Agreement;

WHEREAS, Salix is not willing to enter into the License Agreement without the assurances provided by this Agreement that the licenses and other rights granted to Salix thereunder do not conflict with, and are not limited or constrained by, Giaconda's and [****]'s obligations to RedHill under Section 13.2 of the Asset Purchase Agreement, [****]'s obligations to RedHill under Section 4.2 of the ROFR Agreement, or any other contractual undertaking of any of Giaconda, the Inventors, or the Listed Affiliates (as hereinafter defined) to RedHill; and

WHEREAS, RedHill is willing to provide Salix with the assurances, licenses, waivers and other rights set forth herein for the sole purpose as set forth herein;

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. "**Acquisition**," with respect to a Party, means a merger, acquisition (whether of all of the stock or all or substantially all of the assets of a Person or any operating or business division of a Person) or similar transaction by or with the Person, other than a Change in Control of the Party.

1.2. "**Affiliate**" means, with respect to a Person, any 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, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) 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). The Parties acknowledge that in the case of certain entities organized under the laws of certain countries outside of the United States, the maximum percentage ownership permitted by law for a foreign investor may be less than fifty percent (50%), and that in such case such lower percentage shall be substituted in the preceding sentence, *provided* that such foreign investor has the power to direct the management or policies of such entity.

1.3. "**Agreement**" has the meaning set forth in the preamble hereto.

1.4. "**Applicable Law**" means applicable laws, rules, and regulations, including any rules, regulations, guidelines, or other requirements of Regulatory Authorities that may be in effect from time to time.

1.5. "**Arbitrator**" has the meaning set forth in Section 6.7.

1.6. "**Asset Purchase Agreement**" has the meaning set forth in the preamble hereto.

1.7. "**Board of Directors**" has the meaning set forth in Section 1.13.

1.8. [****].

1.9. "**Breaching Party**" has the meaning set forth in Section 12.2.

1.10. "**Business Day**" means a day other than a Friday, Saturday or Sunday on which banking institutions in New York, New York and Tel Aviv, Israel are open for the conduct of regular banking business at their counters.

1.11. "**Calendar Quarter**" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter shall end on the last day of the Term.

1.12. "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the year in which the Effective Date occurs and the last Calendar Year of the Term shall end on the last day of the Term.

1.13. "**Change in Control**," with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:

1.13.1. any "person" or "group" (as such terms are defined below) (a) is or becomes the "beneficial owner" (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("**Voting Stock**") of such Party representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party or (b) has the power, directly or indirectly, to elect a majority of the members of the Party's board of directors or similar governing body ("**Board of Directors**"); or

1.13.2. such Party enters into a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (a) the members of the Board of Directors of such Party immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party or such surviving Person immediately following such transaction or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party immediately prior to such transaction; or

1.13.3. such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party's consolidated total assets; or

1.13.4. the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change in Control, (a) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act, (b) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act, and (c) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

1.14. "**Combination Product**" means a Licensed Product that is comprised of or contains a Licensed Product together with one or more other active ingredients and is sold either as a fixed dose or as separate doses in a single package.

1.15. "**Commercialization**" means, in respect of a product, any and all activities directed to the preparation for sale of, offering for sale of, or sale of such product, including activities related to marketing, promoting, distributing, exporting and importing such product, and interacting with Regulatory Authorities regarding any of the foregoing. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization, and "**Commercialized**" has a corresponding meaning.

1.16. "**Competitor**" means any Person set forth on Schedule 1.16 or any of their direct or indirect subsidiaries or any successor thereto or any Person that is engaged in the business of [****].

1.17. "**Confidential Information**" has the meaning set forth in Section 8.2.

1.18. "**Consideration Term**" means, with respect to each Licensed Product and each country worldwide, (i) the U.S. Consideration Term with respect to sales of such Licensed Product in the United States and (ii) the Ex-U.S. Consideration Term with respect to sales of such Licensed Product in each country outside the United States.

1.19. "**Control**" means, with respect to any item of Information, Regulatory Documentation, material, Patent, or other intellectual property right, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise (other than by operation of the license and other grants in Section 3.2), to transfer, assign, or grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent, or other intellectual property right as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.20. "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, clinical studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of INDs, Drug Approval Applications and other regulatory applications, filings or submissions, regulatory affairs with respect to the foregoing, and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Marketing Approval. When used as a verb, "**Develop**" means to engage in Development.

1.21. "**Dollars**" or "**$**" means United States Dollars.

1.22. "**Drug Approval Application**" means a New Drug Application ("**NDA**"), as defined in the FFDCA, or any corresponding application in a jurisdiction other than the United States, including, with respect to the European Union, a Marketing Authorization Application filed with the EMA pursuant to the centralized approval procedure or with the applicable Regulatory Authority of a country in Europe with respect to the mutual recognition or any other national approval procedure or any application for any equivalent approval or authorization in respect of a device.

1.23. "**Effective Date**" means the effective date of this Agreement as set forth in the preamble hereto.

1.24. "**EMA**" means the European Medicines Agency and any successor agency thereto.

1.25. "**Ex-U.S. Consideration Term**" means, with respect to each Licensed Product in each country worldwide outside the United States, the period beginning on the Effective Date and ending on the earlier of:

1.25.1. the latest of:

(a) [****] following the First Commercial Sale of such Licensed Product anywhere worldwide outside the United States;

(b) [****] that includes a [****] in such country such that if [****] for such Licensed Product in such country; and

(c) [****] in such country for such Licensed Product; and

1.25.2. the last day of the first Calendar Quarter in which a [****].

1.26. "**Excluded RedHill Know-How**" means Information reasonably necessary or useful for the Exploitation of an Excluded RedHill Product and not for the Exploitation of a Licensed Product.

1.27. "**Excluded RedHill Patents**" means Patents that are reasonably necessary or useful (or, with respect to Patent applications, would be reasonably necessary or useful if such Patent applications were to issue) for the Exploitation of an Excluded RedHill Product in the relevant country and that do not contain a Valid Claim that would be infringed by the Exploitation of a Licensed Product in the relevant country.

1.28. "**Excluded RedHill Products**" means each of [****].

1.29. "**Excluded RedHill Regulatory Rights and Information**" means all Regulatory Marketing Approvals, Regulatory Documentation or Study Data that is related to the Exploitation of any Excluded RedHill Product and not to the Exploitation of any Licensed Product.

1.30. "**Exploit**" means to Develop, Manufacture, Commercialize, make, have made, use, offer to sell, sell or import; and "**Exploitation**" means Developing, Manufacturing, Commercializing, making, having made, using, offering to sell, selling or importing.

1.31. "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.32. "**FFDCA**" means the United States Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.33. "**First Commercial Sale**" means, with respect to a particular product and a particular country, the first sale for monetary value for use or consumption by the end user of such product in such country after any required Regulatory Marketing Approval for such sale of such product has been obtained in such country. Without limiting, qualifying or otherwise affecting the definition of "Net Sales" set forth in Section 1.60, sales prior to receipt of Regulatory Marketing Approval for such product, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.34. "**GAAP**" means United States generally accepted accounting principles consistently applied.

1.35. "**Giaconda**" has the meaning set forth in the preamble hereto.

1.36. "**Heliconda**" (RedHill's RHB-105) means a product [****].

1.37. "**IND**" means (a) an Investigational New Drug application filed with the FDA for authorization to commence clinical studies and its equivalent in other countries or regulatory jurisdictions, and (b) all supplements and amendments that may be filed with respect to the foregoing.

1.38. "**Information**" means all technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other materials, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays; chemistry, manufacturing and controls (CMC) information; and biological methodology; in each case whether or not confidential, proprietary, patented or patentable and whether in written, electronic or any other form now known or hereafter developed.

1.39. "Inventors" has the meaning set forth in the preamble hereto.

1.40. "**Invoiced Sales**" has the meaning set forth in Section 1.60.

1.41. "**Joint Know-How**" has the meaning set forth in the License Agreement.

1.42. "**Joint Patent**" has the meaning set forth in the License Agreement.

1.43. "**Knowledge**" means, with respect to RedHill, the good faith understanding of the facts and information of [****].

1.44. "**LIBOR**" means the London Interbank Offered Rate for deposits in United States Dollars having a maturity of one month published by the British Bankers' Association, as adjusted from time to time on the first London business day of each month.

1.45. "**License Agreement**" has the meaning set forth in the preamble hereto.

1.46. "**Licensed Product**" means a Purgative Product the Exploitation of which by Salix in the relevant country would, but for the licenses granted or assignments made by RedHill to Salix hereunder, or by the Inventors under the License Agreement at any time during the Term, infringe one or more Valid Claims of either a Licensed RedHill Patent, a Licensor Patent, a Joint Patent, or a Licensor-Derived Salix Patent; *provided, however*, that the Licensed Products shall not include the [****].

1.47. "**Licensed Product Generic Product**" means, with respect to a Licensed Product, any product that (a) is sold by a Third Party that is not a licensee or Sublicensee of Salix or its Affiliates, or any of their licensees or Sublicensees, under a Regulatory Marketing 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 Licensed 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 such Licensed 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 Salix or its Affiliates (i.e., an authorized generic product) will not constitute a Licensed Product Generic Product.

1.48. "**Licensed RedHill Know-How**" means all Information owned or otherwise Controlled by RedHill or its Affiliates as of the Effective Date (or which comes under the Control of RedHill or its Affiliates after the Effective Date and to which RedHill or its Affiliates, as applicable, had the right to obtain ownership or Control as of the Effective Date) that is not generally known and is reasonably necessary or useful for the Exploitation of a Purgative Product, *but excluding* any Information to the extent it is covered or claimed by published Licensed RedHill Patents and any Excluded RedHill Know-How. For the avoidance of doubt, Licensed RedHill Regulatory Rights and Information (but not Transferred RedHill Regulatory Rights and Information) constitutes Licensed RedHill Know-How.

1.49. "**Licensed RedHill Patents**" means (a) the Referenced Patents (without regard to whether they are owned or otherwise Controlled by RedHill) and (b) all Patents owned or otherwise Controlled by RedHill or its Affiliates as of the Effective Date (or which come under the Control of RedHill or its Affiliates after the Effective Date and to which RedHill or its Affiliates, as applicable, had the right to obtain ownership or Control as of the Effective Date) that are reasonably necessary or useful (or, with respect to Patent applications, would be reasonably necessary or useful if such Patent applications were to issue) for the Exploitation of a Purgative Product; *provided, however*, that the Licensed RedHill Patents shall not include any Excluded RedHill Patent.

1.50. "**Licensed RedHill Regulatory Rights and Information**" means any Regulatory Marketing Approvals, Regulatory Documentation or Study Data that RedHill or its Affiliates own or otherwise Control as of the Effective Date (or which comes under the Control of RedHill or its Affiliates after the Effective Date and to which RedHill or its Affiliates, as applicable, had the right to obtain ownership or Control as of the Effective Date) that is related to the Exploitation of any Purgative Product, including all [****], *but excluding* any Transferred RedHill Regulatory Rights and Information and any [****].

1.51. "**Licensor-Derived Salix Patent**" has the meaning set forth in the License Agreement.

1.52. "**Licensor Know-How**" has the meaning set forth in the License Agreement.

1.53. "**Licensor Patents**" has the meaning set forth in the License Agreement.

1.54. "**Listed Affiliates**" means [****].

1.55. "**Major Countries**" means each of Australia, Canada, the countries of the European Union as constituted as of the Effective Date (which are, for the avoidance of doubt, Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom), Argentina, Brazil, China, Russia, Egypt, India, Indonesia, Israel, Japan, Malaysia, Mexico, New Zealand, Norway, Pakistan, Saudi Arabia, South Africa, South Korea, Switzerland, Thailand, Turkey, UAE, Ukraine, the United States, Venezuela and Vietnam.

1.56. "**Manufacture**" and "**Manufacturing**" means, in respect of a compound or product, all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, shipping, and holding of such compound or product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance, and quality control.

1.57. "**Mono Product**" has the meaning set forth in Section 1.60.

1.58. "**Myoconda**" (RedHill's RHB-104) means a product [****].

1.59. "**NDA**" has the meaning set forth in Section 1.22.

1.60. "**Net Sales**" means, for any period and in respect of any particular Licensed Product in a country, the gross aggregate amount invoiced by Salix and its Affiliates and Sublicensees for sales of such Licensed Product in such country during such period (the "**Invoiced Sales**"), less deductions, provided the same are fully, clearly and formally documented, for:

1.60.1. normal and customary trade, quantity and cash discounts and sales returns and allowances, actually allowed and taken, including (a) those granted on account of price adjustments, billing errors, rejected goods, damaged goods and returns, (b) administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, pharmacy benefit management organizations, health care insurance carriers and other institutions, (c) allowances, rebates and fees paid to distributors, and (d) chargebacks;

1.60.2. freight, postage, shipping and insurance expenses to the extent that such items are included in the Invoiced Sales;

1.60.3. customs and excise duties and other duties related to the sales to the extent that such items are included in the Invoiced Sales;

1.60.4. rebates and similar payments made with respect to sales paid for by any governmental or regulatory authority;

1.60.5. sales and other taxes and duties directly related to the sale or delivery of such Licensed Product, including that portion of the annual fee on prescription drug manufacturers imposed by the United States Patient Protection and Affordable Care Act, Pub. L. No. 111,148 (as amended) and reasonably allocable to sales of such Licensed Product, but not including franchise taxes or taxes assessed against the income derived from such sale;

1.60.6. product placement and similar fees paid to pharmacies and coupons, co-pay cards and similar price reductions and discounts provided to consumers; and

1.60.7. distribution expenses to the extent that such items are included in the Invoiced Sales and are identified as or accounted for as a discount to the selling price for such Licensed Product,

all as they apply to such Licensed Product (collectively, "**Permitted Deductions**"), in each case as accounted for in accordance with GAAP. Any Permitted Deduction listed above that involves a payment by Salix or its Affiliates or Sublicensees shall be taken as a deduction in the Calendar Quarter in which the payment is accrued by such entity, and, if such accrual is reversed, a corresponding credit will be made to Net Sales in the Calendar Quarter in which the reversal is made. For purposes of determining Net Sales, a Licensed Product shall be deemed to be sold when invoiced and a "sale" shall not include limited and reasonable transfers or dispositions of such Licensed Product for charitable, promotional, pre-clinical or clinical purposes or regulatory or governmental purposes to the extent no financial consideration is received by Salix or its Affiliates or Sublicensees in connection therewith, directly or indirectly.

For purposes of calculating Net Sales, sales between or among Salix and its Affiliates and Sublicensees (other than to the extent such entities are the end-users of the applicable Licensed Product) shall be excluded from the computation of Net Sales, but sales by Salix and its Affiliates and Sublicensees to Third Parties shall be included in the computation of Net Sales.

During the Term, Salix shall not, and shall not permit its Affiliates or Sublicensees to, "bundle" a Licensed Product for sale together with one or more other products or offer a Licensed Product for sale as a "loss leader" to encourage the sale of one or more other product(s) without first entering into a signed, written agreement with RedHill, to be negotiated between Salix and RedHill in good faith, in respect of the appropriate allocation, in accordance with Applicable Law, of the gross amount invoiced for such group or bundle of products between the Licensed Product and other products in the bundle or group.

With respect to sales which are not at *bona fide* arms-length, the term "Net Sales" means the total amount that would have been due in an arms-length sale made in the ordinary course of business and according to the then current market conditions for such sale or, in the absence of such current market conditions, according to market conditions for sale of products similar to the Licensed Products.

In the event a Licensed Product is a Combination Product, the Net Sales for such Combination Product shall be calculated as follows:

a) If Salix, its Affiliate, or Sublicensee separately sells in such country, (x) a Licensed Product (the "**Mono Product**") and (y) products containing active ingredients other than those contained in such Licensed Product as their sole active ingredients, the Net Sales attributable to such Combination Product shall be calculated by [****].

b) If Salix, its Affiliate, or Sublicensee separately sells in such country the Mono Product but does not separately sell in such country products containing as their sole active ingredients the other active ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by [****].

c) If Salix, its Affiliates, and Sublicensees do not separately sell in such country the Mono Product but do separately sell products containing as their sole active ingredients the other active ingredients contained in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by [****].

d) If Salix, its Affiliates, and Sublicensees do not separately sell in such country both the Mono Product and the other active ingredient or ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be determined by [****].

1.61. "**Non-Prescription Competitive Product**" means, in respect of a particular Licensed Product in a particular country, any

1.61.1. over-the-counter product containing [****] that is labeled, advertised, marketed, promoted or intended for use in such country for any use or indication that is the same or substantially the same as any use or indication for which such Licensed Product is labeled, advertised, marketed, promoted and intended for use in such country or

1.61.2. product containing [****] that is a dietary supplement or food product and is advertised, marketed, promoted or intended for use in such country for any use that is the same or substantially the same as any use for which such Licensed Product is labeled, advertised, marketed, promoted and intended for use in such country that in either case (Section 1.61.1 or 1.61.2) is first launched in such country following the First Commercial Sale of such Licensed Product in such country.

1.62. "**Party**" and "**Parties**" has the meaning set forth in the preamble hereto.

1.63. "**Patents**" means (a) all national, regional and international patents and patent applications, including provisional patent applications; (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention; (d) any and all extensions (including patent term extensions) or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, refilings, renewals, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b), and (c)); and (e) any similar rights, including so-called pipeline protection or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any of such foregoing patent applications and patents, including any equivalents of the foregoing in any part of the world.

1.64. "**Permitted Deduction**" has the meaning set forth in Section 1.60.

1.65. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.66. "[****] **Licensed Product**" means any Licensed Product that contains [****] as an active pharmaceutical ingredient.

1.67. "[****] **Study Data**" means any and all Study Data currently available to or reasonably obtainable by RedHill from studies, including Phase I and Phase II studies, conducted by RedHill prior to the Effective Date in respect of a Purgative Product containing [****] as an active pharmaceutical ingredient.

1.68. "**Product Information**" has the meaning set forth in Section 8.1.

1.69. "**Purgative Product**" means any substance or product intended for use as a colonic purgative, laxative or gastrointestinal cleanser (including in, or for the purpose of, the prevention, diagnosis, staging, monitoring, treatment or maintenance of any disease or condition) in humans or non-human animals, but not, for the avoidance of doubt, [****].

1.70. "**Quarterly Activity Report**" has the meaning set forth in Section 6.5.1.

1.71. "**RedHill**" has the meaning set forth in the preamble hereto.

1.72. "**RedHill Territory**" means [****].

1.73. "**Referenced Patents**" means those Patents set forth on Schedule 1.73 and any continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications, divisionals, reexaminations, reissues, revalidations, substitutes, extensions and renewals of any of the foregoing Patents, including any Patents claiming priority to such Patents, together with any and all foreign counterpart Patents in respect thereof, whether or not such foreign counterpart Patents are listed on Schedule 1.73.

1.74. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local regulatory agencies, departments, bureaus, commissions, councils, or other government entities.

1.75. "**Regulatory Documentation**" means, in respect of a particular product, all (a) applications (including all INDs and Drug Approval Applications), filings, submissions, registrations, licenses, authorizations, and approvals (including Regulatory Marketing Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes of meetings and telephonic conferences and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all regulatory drug lists, product labeling, advertising and promotion documents, adverse event files, and complaint files; (c) all Study Data, and (d) other data contained or relied upon in any of the foregoing, in each case ((a), (b), (c) and (d)) relating to such product.

1.76. "**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 Salix or its Affiliates or Sublicensees have the exclusive right to market, price, and sell a Licensed 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.

1.77. "**Regulatory Marketing Approval**" means, with respect to a particular country and a particular product, any and all approvals, licenses, registrations, or authorizations of any Regulatory Authority necessary to commercially distribute, sell, or market such product in such country, including, where applicable, (i) pricing or reimbursement approval in such country, (ii) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), and (iii) labeling approval.

1.78. "**ROFR Agreement**" has the meaning set forth in the preamble hereto.

1.79. "**Salix**" has the meaning set forth in the preamble hereto.

1.80. "**Salix Option Products**" means each of the following products: the [****] and other products containing [****] and other products containing [****]. For the avoidance of doubt, Salix Option Products shall not include [****].

1.81. "**Study Data**" means all Information with respect to any Purgative Product made, collected, or otherwise generated under or in connection with pre-clinical or clinical studies, including any data, reports, and results with respect thereto.

1.82. "**Sublicensee**" means a Person, other than an Affiliate of Salix, that is granted a license or sublicense by Salix under this Agreement or the License Agreement, as well as any Person granted a further sublicense under this Agreement or the License Agreement by any such Sublicensee

1.83. "**Term**" has the meaning set forth in Section 12.1.1.

1.84. "**Third Party**" means any Person other than RedHill, Salix and their respective Affiliates.

1.85. "**Transferred RedHill Regulatory Rights and Information**" means all Regulatory Marketing Approvals, Regulatory Documentation or Study Data transferred or assigned to Salix pursuant to Section 3.1.

1.86. "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).

1.87. "**U.S. Consideration Term**" means, with respect to each Licensed Product in the United States, the period beginning on the Effective Date and ending on the earlier of:

1.87.1. the later of:

(a) [****] that includes a [****] in the United States [****] Products for such Licensed Product in the United States; and

(b) [****] in the United States for such Licensed Product; and

1.87.2. [****] in the United States.

1.88. "**Valid Claim**" means a claim of any pending patent application or issued and unexpired Patent 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 [****] 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, at which point it shall again become a Valid Claim in accordance with this Section 1.88.

1.89. "**Voting Stock**" has the meaning set forth in Section 1.13.

ARTICLE 2
CONSENT TO LICENSE AGREEMENT

2.1. Consent to License Agreement. Subject to timely receipt of the consideration pursuant to ARTICLE 6, RedHill, for itself and any Affiliates that it may have and for the benefit of Salix, hereby consents to the License Agreement and waives any and all rights of first refusal that it may have, whether under Section 4.2 of the ROFR Agreement, any other contract or agreement between it and any of the Inventors or any Listed Affiliate, Section 13.2 of the Asset Purchase Agreement, any other contract or agreement between it and Giaconda or any of its Affiliates, or otherwise, in respect of the licenses and other rights granted by the Inventors to Salix under the License Agreement or that would limit, qualify or restrain the right and ability of the Inventors fully and faithfully to perform each and every one of their obligations under the License Agreement.

2.2. Waiver of Rights. Subject to timely receipt of the consideration pursuant to ARTICLE 6, RedHill hereby waives for the benefit of Salix any and all rights that it has or may have, whether under the ROFR Agreement, any other contract or agreement between it and any of the Inventors or their Affiliates, the Asset Purchase Agreement, any other contract or agreement between it and Giaconda or any of its Affiliates, or otherwise, in respect of (a) any inventions, discoveries, know-how or information made, created or developed by the Inventors or their Affiliates in respect of Purgative Products for use in humans or non-human animals and (b) any activities conducted by, or the supply of any good or services or the grant of any rights, in respect of the making, creation, or development by the Inventors or their Affiliates of any inventions, discoveries, know-how or information described in clause (a) or the exploitation thereof; *provided, however*, that for the avoidance of doubt this Section 2.2 shall not be deemed a waiver of any rights RedHill or its Affiliates may have in respect of the Excluded RedHill Products.

2.3. Release of Claims.

2.3.1. Subject to timely receipt of the consideration pursuant to ARTICLE 6, and other than in respect of any breach or threatened breach of the terms of this Agreement, RedHill, for itself and its Affiliates, hereby releases and forever discharges Salix from all claims, whether present or future, actual or contingent, in contract or in tort, at law or in equity, or otherwise, that RedHill or its Affiliates have or may have in connection with or in any way arising from the activities conducted by Salix or its Affiliates or the Inventors or their Affiliates or any of them in respect of the inventions that are claimed in the Licensor Patents, Joint Patents, or Licensor-Derived Salix Patents or included in Licensor Know-How or Joint Know-How, that gave rise to any Regulatory Marketing Approvals, Regulatory Documentation or Study Data transferred or licensed by Inventors to Salix pursuant to the License Agreement or as to which Salix is granted a right of reference under the License Agreement, or that are otherwise the source of intellectual property licensed by the Inventors to Salix pursuant to the License Agreement; *provided, however*, that for the avoidance of doubt this Section 2.3.1 shall not be deemed a release of any claims RedHill or its Affiliates may have in respect of their rights in and to the Excluded RedHill Products.

2.3.2. Subject to timely receipt of the consideration pursuant to ARTICLE 6, and other than in respect of any breach or threatened breach of the terms of this Agreement, RedHill shall not, and shall cause its Affiliates not to, bring any action of any kind or nature, whether at law or in equity, against Salix or its Affiliates or any of them in respect of the activities conducted by Salix or its Affiliates, the Inventors or their Affiliates, or any of them in respect of the inventions that are claimed in the Licensor Patents, Joint Patents, or Licensor-Derived Salix Patents or included in Licensor Know-How or Joint Know-How, that gave rise to any Regulatory Marketing Approvals, Regulatory Documentation or Study Data transferred or licensed by Inventors to Salix pursuant to the License Agreement or as to which Salix is granted a right of reference under the License Agreement, or that are otherwise the source of intellectual property licensed by the Inventors to Salix pursuant to the License Agreement; *provided, however*, that for the avoidance of doubt this Section 2.3.2 shall not restrict the right of RedHill and its Affiliates to bring actions in respect of their rights in and to the Excluded RedHill Products.

2.4. Acknowledgement. RedHill acknowledges that it is aware that it or its advisors, agents or lawyers may discover facts different from or in addition to the facts that it now knows or believes to be true with respect to the subject matter of this Agreement, but that any such discovery shall not limit, qualify, limit or otherwise affect the terms or provisions of Sections 2.1, 2.2, and 2.3.

ARTICLE 3
TRANSFER AND GRANT OF RIGHTS

3.1. Transfer and Assignment to Salix.

3.1.1. Subject to timely receipt of the consideration pursuant to ARTICLE 6, to the maximum extent permitted by Applicable Law, RedHill shall, and does hereby, effective as of the Effective Date, sell, convey, transfer and assign to Salix any and all of RedHill's and RedHill's Affiliates' (to the extent RedHill has any Affiliates) right, title and interest in and to any Regulatory Marketing Approvals, Regulatory Documentation, and Study Data that is related to the Exploitation of any Purgative Product, including [****] Study Data, *but excluding* any Excluded RedHill Regulatory Rights and Information.

3.1.2. RedHill shall (and shall cause its Affiliates), if requested to do so by Salix, promptly enter into confirmatory instruments of assignment or other instruments in substantially the form reasonably requested by Salix for purposes of recording the transfers and assignments effected under Section 3.1.1 with such Regulatory Authorities as Salix considers appropriate. As of the Effective Date and until the execution of any such confirmatory instruments, so far as may be legally possible, RedHill and Salix shall have the same rights in respect of the Transferred RedHill Regulatory Rights and Information and be under the same obligations to each other in all respects as if the said confirmatory instruments had been executed.

3.2. Grants to Salix. Without in any way limiting or qualifying the provisions of Section 3.1, RedHill (for itself and on behalf of its Affiliates) hereby grants to Salix:

3.2.1. an exclusive (including with regard to RedHill and its Affiliates), worldwide, royalty-bearing license (or sublicense), with the right to grant sublicenses through multiple tiers, under the Licensed RedHill Patents and the Licensed RedHill Know-How to Exploit Purgative Products; and

3.2.2. an exclusive (including with regard to RedHill and its Affiliates) worldwide, royalty-bearing license (or sublicense) and right of reference, with the right to grant sublicenses and further rights of reference through multiple tiers, under the Licensed RedHill Regulatory Rights and Information to Exploit Purgative Products.

RedHill shall, if requested to do so by Salix, promptly enter into confirmatory license agreements or other instruments in substantially the form reasonably requested by Salix for purposes of recording the licenses and rights of reference granted under this Section 3.2 with such patent offices or other Regulatory Authorities as Salix considers appropriate. As of the Effective Date and until the execution of any such confirmatory licenses, so far as may be legally possible, RedHill and Salix shall have the same rights in respect of the Patents, know-how, intellectual property, Information, Regulatory Marketing Approvals and Regulatory Documentation licensed pursuant to this Section 3.2 and be under the same obligations to each other in all respects as if the said confirmatory licenses or other instruments had been executed.

3.3. Sublicenses. Salix shall give RedHill written notice of any intended Sublicense, including the name of the Sublicensee and the material terms thereof. Any Sublicense by Salix of the rights granted to it under this Agreement shall be consistent with the terms of this Agreement and shall contain provisions necessary to effectuate the terms of this Agreement in all respects as applicable to Sublicensees.

3.4. Non-Assertion of RedHill's Rights. Subject to timely receipt of the consideration pursuant to ARTICLE 6, RedHill shall not, and shall cause its Affiliates not to, bring any action against the Inventors or Salix asserting that the exercise or other exploitation by Salix of the rights granted by the Inventors to Salix under the License Agreement, ongoing development or other activities undertaken by the Inventors as contemplated by the License Agreement, or Salix's or Salix's Affiliates' Exploiting Purgative Products anywhere in the world infringes or would infringe any Patent, Regulatory Marketing Approval or other intellectual property right owned or otherwise Controlled by RedHill or its Affiliates as of the Effective Date (or as to which RedHill or its Affiliates have a right, current or contingent, to obtain ownership or Control as of the Effective Date); *provided, however*, that this Section 3.4 shall not be deemed to limit RedHill's rights with respect to the Excluded RedHill Products.

3.5. Delivery of Licensed RedHill Know-How and Transferred RedHill Regulatory Rights and Information. Simultaneously with the execution and delivery of this Agreement, RedHill shall deliver to Salix full, complete and correct copies of the Licensed RedHill Know-How and Transferred RedHill Regulatory Rights and Information set forth in Schedule 3.5 (the "**Initial RedHill Delivery Materials**") and any other Licensed RedHill Know-How and Transferred RedHill Regulatory Rights and Information then in the possession or control of RedHill or its Affiliates, *provided, however*, that RedHill shall deliver to Salix copies of Licensed RedHill Know-How and Transferred RedHill Regulatory Rights and Information received by RedHill from Giaconda in the context of RedHill's due diligence review in connection with the Asset Purchase Agreement and ROFR Agreement, within a reasonable time following execution and delivery of this Agreement. Thereafter, RedHill shall work cooperatively and in good faith to investigate any reasonable inquiries that Salix may make in respect of any Licensed RedHill Know-How or Transferred RedHill Regulatory Rights and Information that Salix believes has not previously been delivered by RedHill to Salix and to ensure the prompt delivery of any missing Licensed RedHill Know-How or Transferred RedHill Regulatory Rights and Information to Salix. Information delivered by RedHill to Salix pursuant to this Section 3.5 shall not thereafter constitute Confidential Information of RedHill for purposes of ARTICLE 8 but shall instead be deemed the Confidential Information of Salix; *provided, however*, that in acknowledgement of RedHill's rights to receive rights in such Information in the event of certain terminations of this Agreement, Salix hereby agrees to treat all such Information received pursuant to this Section 3.5 in a confidential manner similar to how it would treat its own information of a similar nature.

3.6. Limitations on Development, Manufacture, or Commercialization of Purgative Products by RedHill and its Affiliates.

3.6.1. During the Term, RedHill shall refrain, and shall cause its then-current Affiliates to refrain, from, whether directly or indirectly and whether alone or in concert with any other Person, (a) engaging in the Exploitation, anywhere in the world, of any Purgative Product (except as agreed by the Parties in the RedHill Territory in accordance with the provisions of ARTICLE 4), (b) licensing, authorizing, appointing, or otherwise enabling any Person other than Salix and its Affiliates to, directly or indirectly, Exploit any Purgative Product anywhere in the world, or (c) lending assistance (financial or otherwise) to any Person other than Salix and its Affiliates in respect of the Exploitation, anywhere in the world, of any Purgative Product; *provided, however*, that holding up to five percent (5%) of any actual or effective interests in any publicly-traded entity, or a non-controlling interest in, while not being involved in the management of, any Person, where the primary activity of such Person is to make, select, hold or manage investments in businesses, using funds provided by multiple investors (including investment funds and other similar vehicles), that is engaged, directly or indirectly, in any of the foregoing activities shall not be deemed a breach of this undertaking; *provided, further*, that the limitations set forth in this Section 3.6.1 shall not be deemed to prohibit the Exploitation of any Excluded RedHill Product for indications other than colonic purgation, laxation, or gastrointestinal cleansing if colonic purgation, laxation or gastrointestinal cleansing would be an ancillary effect of the use of such Excluded RedHill Product for such indications.

3.6.2. The Parties recognize and acknowledge that Salix would not have entered into this Agreement but for the covenants set forth in Section 3.6.1.

3.6.3. The Parties recognize that the Applicable Law of various jurisdictions may differ as to the validity and enforceability of covenants similar to those set forth in Section 3.6.1. It is the intention of the Parties that the provisions of Section 3.6.1 be enforced to the fullest extent permissible under the Applicable Law of each jurisdiction in which enforcement may be sought and that the unenforceability of any provisions of Section 3.6.1 shall not render unenforceable, or impair, the remainder of the provisions of Section 3.6.1 or any other provision of this Agreement.

3.7. No Implied Rights; Disclaimer of Certain Warranties.

3.7.1. Except as expressly provided herein, neither Party grants any rights to the other Party and neither Party undertakes any obligations to the other Party; and no rights or obligations shall be implied, including in respect of either Party's intellectual property or the Exploitation of any compound, product or process, beyond those expressly set forth herein.

3.7.2. Without limiting the provisions of Section 3.7.1, the Parties acknowledge and agree that (a) Salix has no obligation to Develop or Commercialize any Licensed Product or any obligation to satisfy the conditions to the milestone payments set forth in Section 6.2 or to achieve any particular level of additional consideration or other payments (or any additional consideration or other payments) payable to RedHill under Section 6.3 and (b) RedHill's only remedy for failure by Salix to Develop a Licensed Product is the right of termination of this Agreement set forth in Section 12.3 as and to the extent provided in such Section.

3.7.3. Without limitation to the provisions set forth in ARTICLE 9, nothing contained herein shall be deemed to be a warranty by RedHill that either it or Salix will be able to obtain patents on patent applications or that any Patents will afford adequate or commercially worthwhile protection or that any commercially viable product will result from the Development of the Licensed Products and the Licensed RedHill Know-How and Licensed RedHill Patents associated therewith.

3.7.4. For the avoidance of doubt, the grants set forth in Section 3.2 shall not be deemed to limit RedHill's right, to fully Exploit any Licensed RedHill Know-How, Licensed RedHill Patents and Licensed RedHill Regulatory Rights and Information for its own benefit and/or to grant licenses to do so to any Third Party, in both cases other than in respect of Purgative Products, and to do so without any compensation to Salix, its Affiliates, the Inventors or any other Third Party. The provisions of this Section 3.7.4 are without prejudice to the provisions of ARTICLE 7 and ARTICLE 8.

ARTICLE 4
REDHILL RIGHT TO COMMERCIALIZE

4.1. Right to Commercialize in RedHill Territory. In the event RedHill desires to commercialize pursuant to a distributorship arrangement in the RedHill Territory any of the Salix Option Products, then, to the extent such Salix Option Products are available to be distributed by RedHill or its Affiliates in the RedHill Territory without violating Applicable Law or any contractual commitment to which Salix or its Affiliates is then obligated, Salix agrees to receive and consider in good faith any proposal that RedHill may make for a potential exclusive distribution arrangement between Salix and RedHill in respect of such Salix Option Products in the RedHill Territory.

4.2. Negotiation Period.

4.2.1. During the [****] period following the Effective Date, Salix shall not offer or enter into or continue discussions or negotiations to offer to any Third Party the right to commercialize or distribute in the RedHill Territory any Salix Option Products.

4.2.2. During the [****] (and, in respect of rights relating to Israel, [****]) period following RedHill's delivery of a proposal to Salix pursuant to Section 4.1, Salix (a) shall negotiate in good faith with RedHill in respect of such proposal and (b) shall not offer or enter into or continue any discussions or negotiations to offer to any Third Party the right to commercialize or distribute in any country in the RedHill Territory that is the subject of the RedHill proposal any Salix Option Product that is the subject of the RedHill proposal.

4.3. Certain Limitations. Nothing in this ARTICLE 4 shall obligate Salix or RedHill to enter into any agreement in respect of any Salix Option Product addressed hereby or, in the event the Parties do not enter into an agreement, limit Salix's right to pursue discussions with any other Person or enter into any agreements with any Person with respect to the distribution and commercialization of Salix Option Products in the RedHill Territory, subject only to the exclusive negotiation period for which provision is made in Section 4.2.

4.4. One Proposal Per Product. For the purposes of proposals submitted pursuant to Section 4.1, RedHill may submit only a single proposal in respect of each Salix Option Product pursuant to Section 4.1. Once RedHill has submitted a proposal to Salix in respect of a Salix Option Product and Salix has complied with the terms of this ARTICLE 4, the provisions of this ARTICLE 4 shall expire, and have no further force or effect, in respect of such Salix Option Product.

4.5. Proposal Financial Terms. The Parties confirm that it is their expectation that any proposal made and accepted in accordance with the foregoing provisions of this ARTICLE 4 will provide for consideration to Salix that would be determined on the basis of actual Salix Option Product sales after appropriate allowances for agreed selling costs.

ARTICLE 5
DILIGENCE

5.1. Costs of [****]. As of the Effective Date, Salix assumes those obligations of RedHill in respect of arrangements for the Development of the [****] Licensed Product that are set forth in Schedule 5.1 (and no others).

5.2. Regulatory Marketing Approvals and Regulatory Documentation. Salix, its Affiliates and Sublicensees shall have the sole right to prepare, submit, seek approval of, maintain and update marketing approval applications, marketing approvals and other Regulatory Marketing Approvals and Regulatory Documentation with respect to the Licensed Products (including the [****] Licensed Product). Salix, its Affiliates or Sublicensees, as applicable, shall solely own, apply for and be the holder or owner of record for all such Regulatory Marketing Approvals and Regulatory Documentation. Salix, its Affiliates and Sublicensees shall have the sole right to Exploit Licensed Products during the Term.

5.3. Development Records; Reports.

5.3.1. Salix shall maintain records of the development process (including clinical development) of the Licensed Products in such detail and in good scientific manner as is generally practiced for similar products and in accordance with standard industry practice.

5.3.2. Within thirty (30) days following the end of each Calendar Quarter during the Term, Salix shall provide RedHill with an informal report, which may be either written or oral (including by telephone), regarding the Development (including clinical Development) of the Licensed Products and Salix's reasonably fixed future plans for the Licensed Products, which report shall cover those topics set out in Schedule 5.3.2; *provided, however*, that in the event of a Change in Control or Acquisition of or by RedHill that results in RedHill being under the control of, under common control with, or controlling (as such terms are used in Section 1.13) a Competitor, Salix shall have no further obligation to provide any such reports to RedHill, its Affiliates, successors or assigns; provided, however, that the foregoing shall not be applicable in the event of a Change in Control or Acquisition by RedHill that results in RedHill controlling (as such term is used in Section 1.13) a direct or indirect subsidiary of a Competitor that is not, by itself following such Change in Control or Acquisition by RedHill, engaged in the business of [****].

5.3.3. Without limiting the provisions of Section 5.3.2, Salix shall, within thirty (30) days following the end of each Calendar Quarter ending during the period beginning six (6) months following the Effective Date and ending on the date on which both milestones contemplated by Section 6.2 have been paid by Salix to RedHill, provide RedHill with information in respect of Salix's Development of the Licensed Products sufficient to permit RedHill to make determinations relevant to the exercise its rights under Section 12.3, including a one-page summary report of such information.

ARTICLE 6
PAYMENTS AND RECORDS

6.1. Upfront Payment. No later than five (5) days following the Effective Date, Salix shall pay RedHill the sum of Six Million Dollars ($6,000,000). Salix shall pay RedHill an additional sum of One Million Dollars ($1,000,000) on the later of (a) five (5) days following the Effective Date and (b) the second Business Day following the date on which RedHill has provided to Salix written confirmation, in the English language and otherwise in form and substance reasonably acceptable to Salix, from a bank or similar financial institution that a wire transfer in the amount of One Million Dollars ($1,000,000) has been initiated following the Effective Date from a RedHill account to the following bank account:

Account name:	[****]
Financial institution:	[****]
Branch address:	[****]
BSB number:	[****]
Account number:	[****]
SWIFT Code:	[****]

Both such payments are non-refundable and shall be non-creditable against any other payments due hereunder. The value of the upfront payments shall be attributed as set forth in Schedule 6.1 and such attribution shall not affect payment thereof.

6.2. Regulatory Milestones. In partial consideration of the rights granted by RedHill to Salix hereunder and subject to the terms and conditions set forth in this Agreement, Salix shall pay to RedHill the following milestone payments within thirty (30) days after the first achievement of each of the following milestones:

6.2.1. [****] Dollars ($[****]) upon the earlier to occur of (i) the first [****] and (ii) [****]; and

6.2.2. [****] Dollars ($[****]) upon the earlier of (i) [****] and (ii) the first [****].

Each milestone payment in this Section 6.2 shall be payable only upon the first achievement of such milestone and no amounts shall be due for subsequent or repeated achievements of such milestone. The maximum aggregate amount payable by Salix pursuant to this Section 6.2 is Five Million Dollars ($5,000,000). Each milestone payment shall be made within thirty (30) days after achievement of each of the applicable milestone achievement criteria. The value of each milestone payment shall be attributed as set forth in Schedule 6.1 and such attribution shall not affect payment thereof.

6.3. Additional Consideration.

6.3.1. Additional Consideration Rate. As further consideration for the assignments, licenses, rights, consents and waivers granted to Salix hereunder, subject to Sections 6.3.2 and 6.4, Salix shall pay RedHill additional consideration on Net Sales of each Licensed Product at a rate of:

(a) in respect of any [****] Licensed Product in the United States, [****] of Net Sales;

(b) in respect of any [****] Licensed Product in any country other than the United States, [****] of Net Sales; and

(c) in respect of Licensed Products other than [****] Licensed Products (for the avoidance of doubt, on a worldwide basis), [****] of Net Sales.

6.3.2. Reductions.

(a) The additional consideration payable pursuant to Section 6.3.1 in respect of any Licensed Product in a particular country shall be reduced by [****] if, following the First Commercial Sale (by a Person other than Salix or its Sublicensees (in their capacity as such) or any of its or their respective Affiliates) in such country of a product that constitutes a Non-Prescription Competitive Product with respect of such Licensed Product, aggregate quarterly commercial sales of units of the Licensed Product in such country (as determined based on data generated by, as Salix may determine, Wolters Kluwer or IMS International (or if such data is not available from either of such sources, another reliable data source that is mutually agreed by the Parties by mutual written consent)) in any two (2) consecutive Calendar Quarters during the first three (3) years following such First Commercial Sale in such country of such Non-Prescription Competitive Product are less than [****] of the average aggregate quarterly commercial sales of units of the Licensed Product in such country for the four (4) Calendar Quarters immediately preceding such First Commercial Sale in such country of such Non-Prescription Competitive Product.

(b) The additional consideration payable pursuant to Section 6.3.1 in respect of any Licensed Product with respect to any country worldwide other than the United States shall be reduced by [****] during all times when the Ex-U.S. Consideration Term for such Licensed Product in such country is continuing, in a situation where the event described in Section 1.25.2 has not occurred, solely by virtue of the provisions of Section 1.25.1(a).

6.4. Consideration Term. Salix shall have no obligation to pay any consideration pursuant to Section 6.3.1 with respect to Net Sales of a particular Licensed Product in a particular country (but not any other country) after the Consideration Term for such Licensed Product in such country has expired (but not if earlier terminated). Upon expiration (but not termination) of the Consideration Term with respect to a Licensed Product in a particular country, the licenses and other rights granted to Salix pursuant to Section 3.2 in respect of such Licensed Product in such country (but not any other country) shall become fully paid-up, perpetual, sublicensable through multiple tiers, and irrevocable (including as a result of the expiration or termination of this Agreement).

6.5. Payments and Reports.

6.5.1. Reports and Payments. Within [****] days after the first day of each Calendar Quarter following the First Commercial Sale of a Licensed Product in a country, Salix shall submit to RedHill a written report with respect to the preceding Calendar Quarter (the "**Quarterly Activity Report**") stating: (a) the gross sales and Net Sales of each Licensed Product sold by Salix and its Affiliates and Sublicensees in each country during the Calendar Quarter just ended, making reference to the specific deductions taken in accordance with the definition of Net Sales; (b) the currency exchange rates used in determining gross sales, Net Sales, and amounts payable under Section 6.3.1 for the Calendar Quarter just ended; and (c) a calculation of the amounts due to RedHill pursuant to Section 6.3.1 in respect of the Calendar Quarter just ended. All payments due under Section 6.3.1 shall be due and payable within [****] Business Days following the distribution of each Quarterly Activity Report. The obligation of Salix to provide Quarterly Activity Reports under this Section 6.5.1 shall cease to apply once Salix has no further obligation to make payments under Section 6.3.1.

6.5.2. Taxes and Withholding. All payments under this Agreement will be made without any deduction or withholding for or on account of any taxes, duties, levies, or other charges unless such deduction or withholding is required by Applicable Law to be assessed against the payee. The Parties acknowledge that in accordance with bi-lateral tax treaties between the United States and Israel they do not anticipate that any such deduction or withholding will be required. Salix shall consult in good faith with RedHill's tax advisors (whose fees shall be borne solely by RedHill) prior to deducting or withholding any amounts as aforesaid. If the payor of any such payment is so required to make any deduction or withholding from payments due to the payee, the payor shall (a) promptly notify the payee of such requirement, (b) pay to the relevant authorities on payee's behalf the full amount required to be deducted or withheld promptly upon the earlier of determining that such deduction or withholding is required or receiving notice that such amount has been assessed against the payee, and (c) promptly forward to payee an official receipt (or certified copy) or other documentation reasonably acceptable to payee evidencing such payment to such authorities.

6.5.3. Currency. All payments under this Agreement shall be made in Dollars. As applicable, Net Sales and any deductions taken from Invoiced Sales or other adjustments made for purposes of determining Net Sales shall be translated into Dollars at the average daily purchase price for Dollars using the relevant currency during the most recently ended Calendar Quarter prior to the date of the relevant transaction, using for such purpose daily purchase prices as reported in the Wall Street Journal as published for the New York City market.

6.5.4. Record Keeping. Salix shall keep, and shall cause its Affiliates and Sublicensees to keep, books and accounts of record in connection with the sale of Licensed Products by Salix and its Affiliates and Sublicensees in accordance with GAAP and in sufficient detail to permit accurate determination of all figures necessary for verification of additional consideration to be paid by Salix to RedHill under Section 6.3.1. Salix and its Affiliates shall maintain such records for a period of at least [****] years after the end of the Calendar Quarter in which they were generated, *provided, however*, that if any records are in dispute and Salix has received notice from RedHill of the records which are in dispute, Salix shall keep such records until the dispute is resolved.

6.5.5. Mode of Payment. Except if otherwise specified by RedHill as contemplated by Section 6.9, all payments under this Agreement shall be made by the wire transfer of immediately available funds to such bank account as the payee may from time to time designate by notice to the payor.

6.5.6. Interest on Late Payments. If any payment due to a Party under this Agreement is not paid when due, then the payor shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [****] basis points above LIBOR, such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

6.6. Audit. At the request of RedHill, Salix shall, and shall cause its Affiliates and Sublicensees to, permit an independent auditor designated by RedHill and reasonably acceptable to Salix, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 6.5.4 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (a) be conducted for any Calendar Quarter more than [****] years after the end of such Calendar Quarter, (b) be conducted more than once in any [****] month period (unless a previous audit during such [****] month period revealed an underpayment with respect to such period) or (c) be repeated for any Calendar Quarter. Except as provided below, the cost of this audit shall be paid by RedHill unless the audit reveals a variance of more than [****] from the reported amounts, in which case Salix shall bear the cost of the audit. Unless disputed pursuant to Section 6.7 below, if such audit concludes that (a) additional amounts were owed by Salix, Salix shall pay the additional amounts, with interest from the date originally due as provided in Section 6.5.6, or (b) excess payments were made by Salix, RedHill shall reimburse such excess payments, in either case ((a) or (b)), within [****] days after the date on which such audit is completed by the independent auditor.

6.7. Audit Dispute. In the event of a dispute with respect to any audit under Section 6.6, RedHill and Salix shall work in good faith to resolve the disagreement. If RedHill and Salix are unable to reach a mutually acceptable resolution of any such dispute within [****] days, then the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by Salix and RedHill or to such other Person as Salix and RedHill shall mutually agree (the "**Arbitrator**"). The decision of the Arbitrator shall be final and the costs of such arbitration as well as the initial audit shall be allocated among the Parties in such manner as the Arbitrator shall determine. Not later than [****] days after such decision and in accordance with such decision, Salix shall pay the additional amounts, with interest from the date originally due as provided in Section 6.5.6, or RedHill shall reimburse the excess payments, as applicable.

6.8. Confidentiality. RedHill shall treat all information subject to review under this ARTICLE 6 in accordance with the confidentiality provisions of ARTICLE 8 and the Parties shall cause the Arbitrator to enter into a reasonably acceptable confidentiality agreement with Salix obligating such Arbitrator to retain all such financial information in confidence pursuant to such confidentiality agreement.

6.9. Payments to RedHill; Account Information. All payments made by Salix to RedHill shall be paid to the bank account specified in the wire instructions and bank account information set forth in Schedule 6.9. RedHill may amend Schedule 6.9 from time to time by providing written notice to Salix in accordance with Section 13.6.

ARTICLE 7
INTELLECTUAL PROPERTY

7.1. Maintenance and Prosecution of Patents.

7.1.1. Maintenance and Prosecution of Licensed RedHill Patents.

(a) As between RedHill and its Affiliates and Salix, Salix shall have the sole right to prepare, file, prosecute and maintain the Licensed RedHill Patents worldwide.

(b) Salix shall use commercially reasonable efforts, in accordance with industry practice and to the extent permitted under Applicable Law and commercially reasonable, to prepare, file, prosecute and maintain the Licensed RedHill Patents in the Major Countries, at Salix's sole cost and expense, during the Term. The provisions of this Section 7.1.1(b) shall not apply in respect of those Referenced Patents that are identified on Schedule 1.73 as relating to the [****] product.

(c) Salix shall, to the extent permitted by Applicable Law and Salix's contractual commitments with any Third Party, keep RedHill reasonably informed with regard to the preparation, filing, prosecution, and maintenance of the Licensed RedHill Patents.

(d) In the event that Salix decides not to prepare, file, prosecute, or maintain a Licensed RedHill Patent in a country, Salix shall, to the extent permitted by Applicable Law, provide reasonable prior written notice to RedHill of such intention (which notice shall, in any event, be given no later than [****] days prior to the next deadline for any action that may be taken with respect to such Patent in such country). Until the date of payment of both milestone payments set forth in Section 6.2, RedHill shall thereupon have the right, to the extent permitted by Applicable Law, to assume the control and direction of the preparation, filing, prosecution, and maintenance of such Patent at RedHill's expense in such country. Following the date of payment of both milestone payments set forth in Section 6.2, RedHill may thereupon present Salix with a proposal pursuant to which RedHill would, to the extent permitted by Applicable Law and Salix's contractual commitments with any Third Party, assume the control and direction of the preparation, filing, prosecution, and maintenance of such Patent at RedHill's expense in such country. Salix may accept or decline any such proposal in its sole and absolute discretion.

7.1.2. Cooperation. RedHill agrees to cooperate fully with Salix in the preparation, filing, prosecution, and maintenance of the Licensed RedHill Patents, and applications for extensions or supplementary protection certificates or filings or listings with Regulatory Authorities in respect of any such Patent, as contemplated in this Section 7.1. Cooperation shall include:

(a) executing all papers and instruments, or requiring its employees or contractors to execute such papers and instruments, so as to (i) enable Salix to apply for and to prosecute Patent applications; and (ii) enable Salix to obtain and maintain any Patent extensions, supplementary protection certificates, filings and listings with Regulatory Authorities, and the like with respect to the Licensed RedHill Patents;

(b) assisting in any license or assignment registration processes with applicable governmental authorities that may be available for the protection of Salix's interests under this Agreement in respect of the Licensed RedHill Patents; and

(c) promptly informing Salix of any matters coming to RedHill's attention that may materially affect Salix's preparation, filing, prosecution, or maintenance of any Licensed RedHill Patent.

7.1.3. Patent Term Extension and Supplementary Protection Certificate.

(a) As between RedHill and its Affiliates and Salix, Salix shall have the sole right to apply for any extension or supplementary protection certificate with respect to Licensed RedHill Patents worldwide. Salix shall use commercially reasonable efforts, in accordance with industry practice and to the extent permitted and productive under Applicable Law, to apply for any extension or supplementary protection certificate that may be available with respect to the Licensed RedHill Patents in Major Countries, at Salix's sole cost and expense, during the Term. The provisions of the preceding sentence shall not apply in respect of those Referenced Patents that are identified on Schedule 1.73 as relating to the [****] product. RedHill shall provide prompt and reasonable assistance, as requested by Salix, including by taking such action as Patent holder as is required under any Applicable Law to obtain such patent extension or supplementary protection certificate. Salix shall pay all expenses in regard to obtaining the extension or supplementary protection certificate.

(b) In the event that Salix decides not to apply for any extension or supplementary protection certificate described in Section 7.1.3(a) with respect to the Licensed RedHill Patents in a country, Salix shall, to the extent permitted by Applicable Law, provide reasonable prior written notice to RedHill of such intention (which notice shall, in any event, be given no later than [****] days prior to the next deadline for any action that may be taken with respect to such Patent in such country). Until the date of payment of both milestone payments set forth in Section 6.2, RedHill shall thereupon have the right, to the extent permitted by Applicable Law, to assume the control and direction of the application for any extension or supplementary protection certificate in respect of such Patent at RedHill's expense in such country. Following the date of payment of both milestone payments set forth in Section 6.2, RedHill may thereupon present Salix with a proposal pursuant to which RedHill would, to the extent permitted by Applicable Law and Salix's contractual commitments with any Third Party, assume the control and direction of the application for any extension or supplementary protection certificate in respect of such Patent at RedHill's expense in such country. Salix may accept or decline any such proposal in its sole and absolute discretion.

7.1.4. Patent Listings.

(a) As between RedHill and its Affiliates and Salix, Salix shall have the sole right to make all filings with Regulatory Authorities with respect to the Licensed RedHill Patents, whether as required or as allowed, (i) in the United States, in the FDA's Orange Book and, (ii) outside the United States, under the national implementations of Article 10.1(a)(iii) of Directive 2001/EC/83 or other international equivalents. RedHill shall (i) provide to Salix all Information, including a correct and complete list of Licensed RedHill Patents owned or otherwise Controlled by RedHill or its Affiliates covering any Licensed Product, necessary or useful to enable Salix to make such filings or listings with Regulatory Authorities, and (ii) cooperate with Salix's reasonable requests in connection therewith, including meeting any submission deadlines, in each case ((i) and (ii) of this sentence), to the extent required or permitted by Applicable Law.

(b) In the event that Salix decides not to make any filing or listing described in Section 7.1.4(a) with respect to the Licensed RedHill Patents in a country, Salix shall, to the extent permitted by Applicable Law, provide reasonable prior written notice to RedHill of such intention (which notice shall, in any event, be given no later than [****] days prior to the next deadline for any action that may be taken with respect to such filing or listing in such country). Until the date of payment of both milestone payments set forth in Section 6.2, RedHill shall thereupon have the right, to the extent permitted by Applicable Law, to assume the control and direction of the filing or listing at RedHill's expense (but in Salix's name) in such country. Following the date of payment of both milestone payments set forth in Section 6.2, RedHill may thereupon present Salix with a proposal pursuant to which RedHill would, to the extent permitted by Applicable Law and Salix's contractual commitments with any Third Party, assume the control and direction of the filing or listing at RedHill's expense (but in Salix's name) in such country. Salix may accept or decline any such proposal in its sole and absolute discretion.

7.2. Enforcement of Patents.

7.2.1. Notice. If either Party hereto becomes aware of any infringement, anywhere in the world, of any issued Patent within the Licensed RedHill Patents (including any alleged or threatened assertion of invalidity or unenforceability of any such Licensed RedHill Patent by a Third Party), then such Party shall promptly notify the other Party in writing to that effect. Any such notice shall include any available evidence to support an allegation of such infringement.

7.2.2. Enforcement of Patents.

(a) As between RedHill and its Affiliates and Salix, Salix shall have the sole right, but not the obligation, at its own expense, to take action (or cause or permit to be taken action) to obtain a discontinuance of an infringement described in Section 7.2.1 or bring suit against a Third Party infringer of any Licensed RedHill Patent. Salix may join RedHill as party plaintiff to any action or suit resulting from Salix's exercise of such rights, provided that Salix bears all of RedHill's reasonable costs and expenses associated with same. Salix shall bear all the expenses of any such action or suit brought by it claiming infringement of any Licensed RedHill Patent.

(b) RedHill shall reasonably cooperate (including by executing any documents required to enable Salix to initiate such litigation) with Salix in any action or suit for infringement of any Licensed RedHill Patent brought by Salix against a Third Party in accordance with this Section 7.2.2. Neither Party shall incur any liability directly to the other Party as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any Licensed RedHill Patent invalid or unenforceable. However, Salix shall indemnify and hold RedHill harmless from any liability to a Third Party as a consequence of any such action or suit or any unfavorable decision resulting therefrom.

(c) Any recovery obtained by Salix as a result of any such proceeding against a Third Party infringer shall be allocated [****].

(d) In the event that Salix decides not to pursue proceedings in respect of any infringement described in Section 7.2.2(a) or to grant any such infringer a license, then Salix shall, to the extent permitted by Applicable Law and Salix's contractual commitments with any Third Party, provide reasonable prior written notice to RedHill of such decision. RedHill may thereupon present Salix with a proposal pursuant to which RedHill would, to the extent permitted by Applicable Law and Salix's contractual commitments with any Third Party, assume the control and direction, at RedHill's expense, of proceeding against the infringer. Salix may accept or decline any such proposal in its sole and absolute discretion.

7.2.3. Defense Against Claims of Infringement.

(a) In the event that either RedHill or Salix, or both of them, are sued by a Third Party alleging that the use of the Licensed RedHill Patents or Licensed RedHill Know-How or the Commercialization of any Licensed Product infringes upon, or would require a license to, any intellectual property rights of such Third Party, the Party being so sued shall immediately give the other Party notice of same. Any such notice shall set out in reasonable detail the relevant facts and include all available evidence to support an allegation of such infringement.

(b) Salix shall keep RedHill reasonably informed of all material developments in connection with any such claim, suit, or proceeding described in Section 7.2.3(a). Salix agrees to provide RedHill with copies of all pleadings filed in such action and to allow RedHill reasonable opportunity to participate in the defense of the claims.

(c) In the event that Salix decides not to defend proceedings described in Section 7.2.3(a) brought against Salix or obtain a license from the complaining Third Party, then Salix shall, to the extent permitted by Applicable Law, provide reasonable prior written notice to RedHill of such decision. RedHill shall thereupon have the right, to the extent permitted by Applicable Law, to assume the control and direction of defending such proceeding at RedHill's cost and expense.

7.3. Restriction on Challenging Patents.

7.3.1. Under no circumstances shall RedHill, whether directly or indirectly through any of its Affiliates or any Third Party, institute, prosecute, or otherwise participate in, at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action, or cause of action for declaratory relief, damages, or any other remedy, or for an enjoinment, injunction, or any other equitable remedy, including any interference, re-examination, opposition, or any similar proceeding, alleging that any claim in a Licensed RedHill Patent, a Licensor Patent, a Joint Patent, or a Licensor-Derived Salix Patent is invalid, unenforceable, or otherwise not patentable.

7.3.2. Under no circumstances shall Salix, whether directly or indirectly through any of its Affiliates or any Third Party, institute, prosecute, or otherwise participate in, at law or in equity or before any administrative or regulatory body, including the U.S. Patent and Trademark Office or its foreign counterparts, any claim, demand, action, or cause of action for declaratory relief, damages, or any other remedy, or for an enjoinment, injunction, or any other equitable remedy, including any interference, re-examination, opposition, or any similar proceeding, alleging that any claim in a Licensed RedHill Patent, a Licensor Patent, a Joint Patent, or a Licensor-Derived Salix Patent is invalid, unenforceable, or otherwise not patentable.

7.3.3. The provisions of Sections 7.3.1 and 7.3.2 shall be applicable only to the extent permitted by Applicable Law.

ARTICLE 8
CONFIDENTIALITY AND PUBLIC ANNOUNCEMENTS

8.1. Confidentiality. RedHill recognizes that by reason of, *inter alia*, Salix's status as an assignee and an exclusive licensee in respect of certain Patents, intellectual property, know-how and Regulatory Documentation pursuant to the assignments and grants under

ARTICLE 3 and the other rights and obligations set forth herein, Salix has an interest in RedHill's retention in confidence of certain information of RedHill related to the Transferred RedHill Regulatory Rights and Information, the Licensed RedHill Know-How, and the Licensed RedHill Patents. Accordingly, during the Term, RedHill shall, and shall cause its Affiliates to, keep completely confidential and not publish or otherwise disclose, and not use directly or indirectly for any purpose other than to fulfill RedHill's obligations to Salix hereunder and to exercise RedHill's rights hereunder, the Transferred RedHill Regulatory Rights and Information, the Licensed RedHill Know-How, and any Information relating to any Licensed RedHill Patent (the "**Product Information**"); *except* to the extent (a) the Product Information is in the public domain through no fault of RedHill or its Affiliates; (b) such disclosure or use is expressly permitted under Section 8.4, or (c) such disclosure or use is otherwise expressly permitted by the terms of this Agreement. For purposes of Section 8.4, Salix shall be deemed to be the disclosing Party with respect to Product Information under Section 8.4 and RedHill shall be deemed to be the receiving Party with respect thereto. For further clarification, (a) without limiting this Section 8.1, to the extent Product Information is disclosed by RedHill to Salix pursuant to this Agreement, such information shall, subject to Section 3.5 and the other terms and conditions of this ARTICLE 8, also constitute Confidential Information of RedHill with respect to the use and disclosure of such Information by Salix, but (b) the disclosure by RedHill to Salix of Product Information shall not cause such information to cease to be subject to the provisions of this Section 8.1 with respect to the use and disclosure of such Confidential Information by RedHill. In the event this Agreement is terminated, then, except as provided in the following sentence, this Section 8.1 shall have no continuing force or effect. In the event of a termination of this Agreement by Salix pursuant to Section 12.2 or 12.5 or the expiration of this Agreement, the provisions of this Section 8.1 shall survive such termination or expiration.

8.2. Confidentiality Obligations. At all times during the Term and for a period of [****] years following termination or expiration hereof (or such longer period as may apply under Section 8.3), each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to such Party (as determined in respect of Product Information in accordance with the provisions of Section 8.1), directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is reasonably necessary or useful for the performance of, or the exercise of such Party's rights under, this Agreement. " **Confidential Information**" means any technical, business, or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on, or after the Effective Date, including information relating to the terms of this Agreement and the License Agreement or the scientific, regulatory or business affairs or other activities of the disclosing Party. Notwithstanding the foregoing, the confidentiality and non-use obligations under this Section 8.2 with respect to any Confidential Information shall not include any information that:

8.2.1. is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault or negligence on the part of the receiving Party;

8.2.2. can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;

8.2.3. is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information; or

8.2.4. can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

8.3. Trade Secrets. Confidential Information that constitutes a trade secret under Applicable Law or the Uniform Trade Secrets Act and is so identified to the receiving Party by the disclosing Party in writing shall be kept confidential indefinitely.

8.4. Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

8.4.1. made in response to a valid order of a court of competent jurisdiction or other Regulatory Authority of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; *provided, however*, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment 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 the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

8.4.2. made by or on behalf of the receiving Party to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Marketing Approval or activities in support thereof; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

8.4.3. made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Patent; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or

8.4.4. made by the receiving Party to its or their attorneys, auditors, advisors, consultants, contractors, manufacturers, suppliers, existing or prospective collaboration partners, licensees, sublicensees, lenders, investors or acquirers, or other Third Parties as may be necessary or useful in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement or (in the case of Salix) the License Agreement or its enforcement of rights or pursuit of claims, whether under this Agreement or the License Agreement or not, against the other Party or its Affiliates; *provided, however*, that any person to whom disclosure is to be made pursuant to this Section 8.4.4 shall prior to such disclosure be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this ARTICLE 8.

8.5. Public Announcements. Except as (a) required by Applicable Law, including, without limitation, stock exchange rules, (b) required pursuant to compulsory legal process, (c) necessary for the exercise or enforcement of the rights granted to the Parties under this Agreement, or (d) as expressly permitted under this ARTICLE 8, neither of the Parties shall publicly announce or otherwise disclose to any Third Party (other than the Inventors) any of the terms of this Agreement without the prior written approval of the other Party, not to be unreasonably withheld or delayed. Except as otherwise provided in this Section, the Parties shall only release public announcements of the execution of this Agreement in forms to be mutually agreed by the Parties. Notwithstanding the foregoing, if a Party is disclosing information relating to this Agreement because it is required to do so to comply with Applicable Law or compulsory legal process, including its reporting requirements under the United States Securities Exchange Act of 1934, as amended, or equivalent Israeli securities laws and regulations, such Party intending to make such disclosure shall give the other Party at least three (3) Business Days' prior notice in writing of the text of the intended disclosure, unless such Applicable Law or compulsory legal process would require earlier disclosure, in which event the notice shall be provided as early as practicable. A Party that determines that it is required to file this Agreement with the United States Securities and Exchange Commission or any other governmental authority shall request confidential treatment with respect to the terms of this Agreement, shall consult in good faith with the other Party regarding such confidential treatment, and shall use commercially reasonable efforts to have redacted from any publicly available version such provisions as the Parties may agree. Notwithstanding anything to the contrary above, each Party may disclose the terms of this Agreement to its respective Affiliates and its and their respective attorneys, auditors, advisors, consultants, contractors, manufacturers, suppliers, existing or prospective collaboration partners, licensees, sublicensees, lenders, investors or acquirers, or other Third Parties as may be necessary or useful in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement or (in the case of Salix) the License Agreement or its enforcement of rights or pursuit of claims, whether under this Agreement or the License Agreement or not, against the other Party or its Affiliates, subject to any such Person being bound by reasonable confidentiality obligations.

ARTICLE 9
REPRESENTATIONS AND WARRANTIES

9.1. Representations and Warranties of Salix. Salix represents and warrants to RedHill, as of the Effective Date, as follows:

9.1.1. It is a corporation duly organized, validly existing, and in good standing under the laws of the State of California, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

9.1.2. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (i) Salix's charter documents, bylaws, or other organizational documents, (ii) in any material respect, any agreement, instrument, or contractual obligation to which Salix is bound, (iii) any requirement of any Applicable Law, or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to Salix.

9.1.3. This Agreement is a legal, valid, and binding obligation of Salix enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

9.1.4. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

9.1.5. It has the financial capacity, as well as the necessary experience and expertise, to reasonably carry out all its obligations hereunder, and shall, in carrying out such obligations, obtain or procure all approvals and consents required under Applicable Law in order for it to do so.

9.2. Representations and Warranties of RedHill. RedHill represents and warrants to Salix, as of the Effective Date, as follows:

9.2.1. It is a corporation duly organized, validly existing, and in good standing under the laws of Israel, and has all requisite power and authority, corporate or otherwise, to execute, deliver, and perform this Agreement.

9.2.2. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action, and do not violate (i) RedHill's charter documents, bylaws, or other organizational documents, (ii) in any material respect, any agreement, instrument, or contractual obligation to which RedHill is bound, (iii) any requirement of any Applicable Law, or (iv) any order, writ, judgment, injunction, decree, determination, or award of any court or governmental agency presently in effect applicable to RedHill.

9.2.3. This Agreement is a legal, valid, and binding obligation of RedHill enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance, and general principles of equity (whether enforceability is considered a proceeding at law or equity).

9.2.4. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement, or that would impede the diligent and complete fulfillment of its obligations hereunder.

9.2.5. To the Knowledge of RedHill, none of the provisions of the ROFR Agreement, the provisions of any other contract or agreement between RedHill and its Affiliates and any of the Inventors or their Affiliates, the provisions of the Asset Purchase Agreement, the provisions of any other contract or agreement between RedHill and its Affiliates or Giaconda or its Affiliates, or any other rights that RedHill and its Affiliates may hold or have the right to acquire, whether in the form of Patents, trade secrets or otherwise, in each case as existing on the Effective Date, will, after giving effect to the terms of this Agreement, limit or restrict Salix's right and ability to Exploit Purgative Products anywhere in the world.

9.2.6. To the Knowledge of RedHill, the Referenced Patents constitute all of the Licensed RedHill Patents.

9.2.7. To the Knowledge of RedHill, no claim or litigation has been brought or threatened by any Person alleging that (a) any of the Licensed RedHill Patents is invalid or unenforceable, (b) any of the Licensed RedHill Patents or any of the Transferred RedHill Regulatory Rights and Information or Licensed RedHill Regulatory Rights and Information violates, infringes, or otherwise conflicts or interferes with, or would violate, infringe, or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person or (c) the disclosing, copying, making, assigning or licensing of any of the Licensed RedHill Patents, Transferred RedHill Regulatory Rights and Information, or Licensed RedHill Know-How as contemplated herein or in the License Agreement violates, infringes, or otherwise conflicts or interferes with, or would violate, infringe, or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person.

9.2.8. Neither RedHill nor any of its Affiliates has previously entered into any agreement, whether written or oral, with respect to, or otherwise assigned, transferred, licensed, conveyed, or otherwise encumbered, any right, title, or interest that it may have in or to the Licensed RedHill Patents, the Transferred RedHill Regulatory Rights and Information, or Licensed RedHill Know-How (including by granting any covenant not to sue with respect thereto) or any Patent or other intellectual property or proprietary right or Information that would be Licensed RedHill Patents, Transferred RedHill Regulatory Rights and Information, or Licensed RedHill Know-How but for such assignment, transfer, license, conveyance, or encumbrance, and during the Term neither RedHill nor its Affiliates will enter into any such agreement or grant any such right, title, or interest to any Person with respect to the Licensed RedHill Patents, Transferred RedHill Regulatory Rights and Information, or Licensed RedHill Know-How that is inconsistent with the rights and licenses granted to Salix under this Agreement.

9.2.9. RedHill has obtained from its Affiliates the assignments, licenses and other rights necessary for RedHill to effect the assignments and grant to Salix the rights and licenses provided herein and otherwise for RedHill to perform its obligations hereunder.

ARTICLE 10
LIMITATION OF LIABILITY

Except in the case of damages, liabilities, claims, costs, charges, judgments and expenses (including reasonable attorneys' fees) that may be sustained, suffered or incurred as a result of (i) breach by either Party of ARTICLE 8, (ii) the gross negligence, fraud or willful misconduct of a Party or (iii) breach of Sections 3.6 or 7.3, in no event shall either Party be liable to the other Party or any of its Affiliates for any consequential, incidental, indirect, special, punitive or exemplary damages (including, without limitation, 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 this Agreement.

ARTICLE 11
INSURANCE

11.1. Salix Insurance. Salix shall have and maintain during the Term such types and amounts of liability insurance, including clinical trial and product liability insurance, as is normal and customary in the industry generally for parties similarly situated. Upon request by RedHill, Salix undertakes to send evidence of its compliance with this Section 11.1. Salix shall promptly, and in any event within ten (10) days, notify RedHill of any notice that Salix may receive from its insurance carriers of any proposed reduction of coverage or other material modification of any of the insurance policies required to be carried by Salix pursuant to this Section 11.1.

11.2. Post-Term Insurance. Salix shall exercise commercially reasonable efforts to cause any insurance policies that Salix carries that are required by Section 11.1 and that are written on a claims made basis to remain in effect for no less than [****] following the end of the Term.

ARTICLE 12
TERM AND TERMINATION

12.1. Term; Effect of Expiry.

12.1.1. Term. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in full force and effect until the date of expiration of the last Consideration Term for the last Licensed Product (such period, the "**Term**").

12.1.2. Effect of Expiration of the Term.

(a) The grants, licenses, rights of reference, waivers, consents and releases made by RedHill to Salix hereunder shall not be affected by any expiration of the Term pursuant to Section 12.1.1 and shall continue in full force and effect thereafter. Without limiting the foregoing, following any expiration of the Term pursuant to Section 12.1.1, the grants, licenses, and rights of reference in Section 3.2 shall become fully-paid, perpetual, royalty-free and irrevocable on a worldwide basis.

(b) Expiration of this Agreement pursuant to Section 12.1.1 shall have no effect on the assignments effected pursuant to Section 3.1, which assignments shall, subject only to Section 12.7.3, constitute a full, final, complete and irrevocable assignment and transfer of all right, title and interest of RedHill and its Affiliates in and to the Transferred Regulatory Rights and Information effective as of the Effective Date.

12.2. Termination for Material Breach. Any material failure by a Party (the "**Breaching Party**") to comply with any of its material obligations contained in this Agreement shall entitle the Party not in default to give to the Breaching Party notice specifying the nature of the default, requiring the Breaching Party to make good or otherwise cure such default, and stating its intention if such default is not cured to terminate this Agreement. If such default is not cured within [****] days after the receipt of such notice (or, if such default cannot be cured within such [****] day period, if the Breaching Party does not commence actions to cure such default within such period and thereafter diligently continue such actions or if such default is not otherwise cured within [****] days after the receipt of such notice, except in the case of a payment default, as to which the Breaching Party shall have only a [****] day cure period), the Party not in default shall be entitled, on notice to the Breaching Party, without prejudice to any other rights conferred on it by this Agreement, and in addition to any other remedies available to it at law or in equity, to terminate this Agreement.

12.3. Additional Termination Rights by RedHill. In the event that Salix should, at any time during the period beginning [****] following the Effective Date and ending on the date on which both milestone payments contemplated by Section 6.2 have been paid by Salix to RedHill, not then be pursuing the Development of one or more Licensed Products (and in any event at least one Licensed Product), then RedHill shall be entitled to give Salix notice requiring Salix to commence or resume Development of at least one Licensed Product and stating RedHill's intention to terminate this Agreement if Salix fails to commence or resume Development of at least one Licensed Product. For the avoidance of doubt, RedHill shall be entitled to give such notice more than once, but any such notice may be given only during the period beginning [****] following the Effective Date and ending on the date on which both milestone payments contemplated by Section 6.2 have been paid by Salix to RedHill. If Salix fails to commence or resume Development of at least one Licensed Product, and give notice of such commencement or resumption to RedHill, within [****] days after its receipt of such notice (or, if relevant Development activities cannot reasonably be commenced or resumed within such [****] day period, if Salix does not commence actions to commence or resume relevant Development activities, and give notice of such commencement to RedHill, within such [****] day period and thereafter diligently continue such actions or if in any event Salix has not commenced or resumed relevant Development activities, and given notice of such commencement or resumption to RedHill, within [****] days after its receipt of such notice), then RedHill shall be entitled, by notice to Salix and without prejudice to any other rights conferred on RedHill by this Agreement and in addition to any other remedies available to RedHill at law or in equity, to terminate this Agreement.

12.4. Additional Termination Rights by Salix. Salix may terminate this Agreement immediately upon notice to RedHill at or after any termination of the License Agreement (including any termination of the License Agreement that may be effected by agreement between Salix and the Inventors).

12.5. Termination for Insolvency. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [****] days after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [****] days of the filing thereof, or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

12.6. Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by RedHill are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Salix, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction.

12.7. Effect of Termination.

12.7.1. Except to the extent otherwise specified in this Section 12.7 or Section 6.4, in the event of a termination of this Agreement (but not in the event of an expiration of the Term pursuant to Section 12.1.1), all rights, waivers and licenses granted by RedHill to Salix hereunder shall immediately terminate.

12.7.2. Notwithstanding the provisions of Section 12.7.1, in the event of

(a) a termination of this Agreement by Salix pursuant to Section 12.2 for RedHill's material breach with respect to ARTICLE 2 or Sections 3.4, 3.6, 7.3, 8.1 and 8.2, or

(b) a termination of this Agreement by Salix pursuant to Section 12.5 where, in connection with the bankruptcy or insolvency events or proceedings giving rise to Salix's right to terminate under Section 12.5, any of RedHill's obligations with respect to ARTICLE 2 or Sections 3.4, 3.6, 7.3, 8.1, or 8.2 have become or, in Salix's reasonable judgment, will become unenforceable by Salix against RedHill, its Affiliates, or any successor to RedHill or its Affiliates, then the rights, waivers and licenses granted by RedHill to Salix hereunder shall become fully-paid, perpetual, royalty-free and irrevocable.

12.7.3. Upon any termination (but not in the event of an expiration of the Term pursuant to Section 12.1.1) of this Agreement other than by Salix pursuant to Section 12.2 or by Salix pursuant to Section 12.5 in the circumstances contemplated by Section 12.7.2(b), Salix shall assign and transfer to RedHill all right, title and interest in and to the Transferred RedHill Regulatory Rights and Information that was originally conveyed by RedHill and its Affiliates to Salix pursuant to Section 3.1 and as further developed since they were originally conveyed. Salix shall (and shall cause its Affiliates to), if requested to do so by RedHill, enter into confirmatory instruments of assignment or other instruments in substantially the form reasonably requested by RedHill for purposes of recording the transfers and assignments effected under this Section 12.7.3 with such patent offices or other Regulatory Authorities as RedHill considers appropriate. Until the execution of any such confirmatory instruments, so far as may be legally possible, Salix and its Affiliates and RedHill and its Affiliates shall have the same rights in respect of the Transferred RedHill Regulatory Rights and Information and be under the same obligations to each other in all respects as if the said confirmatory instruments had been executed. Notwithstanding any assignment and transfer effected pursuant to the preceding provisions of this Section 12.7.3, in respect of any Licensed Product and any country as to which the Consideration Term for such Licensed Product in such country has terminated prior to termination of this Agreement, Salix shall have and hold a fully paid-up, perpetual, sublicensable through multiple tiers, and irrevocable license under and in respect of the Transferred RedHill Regulatory Rights and Information upon the terms set forth in Section 3.2 *mutatis mutandis* and in any event without reference to the exclusion from such licenses, pursuant to the definitions of Licensed RedHill Regulatory Rights and Information and Licensed RedHill Know-How, of the Transferred RedHill Regulatory Rights and Information.

12.8. Post-Termination Additional Consideration. Following any termination of this Agreement, Salix shall not be responsible for any additional consideration payments following the effective date of such termination, *except* with respect to any sales of Licensed Products made by Salix, either itself or through an Affiliate, or by a Sublicensee or Sublicensee's Affiliate, pursuant to Section 12.10.3 following the termination date of this Agreement. For the avoidance of doubt, in the event of an expiration of the Term pursuant to Section 12.1.1, Salix shall in no event be responsible for any further payments to RedHill pursuant to this Section 12.8.

12.9. Remedies. Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

12.10. Accrued Rights; Surviving Obligations.

12.10.1. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement.

12.10.2. Sections 6.5.4, 6.6, 6.7, 6.8, 11.2, 12.1.2, 12.7, 12.8, 12.9, and this Section 12.10 and ARTICLE 1, ARTICLE 2, ARTICLE 8, ARTICLE 9, ARTICLE 10, and ARTICLE 13 shall survive the termination or expiration of this Agreement for any reason.

12.10.3. Notwithstanding the termination of this Agreement, Salix and its Sublicensees and its and their Affiliates shall have the right for [****] after the effective date of such termination to sell or otherwise dispose of all Licensed Products then in its inventory and any in-progress inventory, as though this Agreement had not terminated, and such sale or disposition shall not constitute infringement of RedHill's or its Affiliates' Patent or other intellectual property or other proprietary rights. For the avoidance of doubt, Salix shall continue to make payments thereon as provided in ARTICLE 6 as if this Agreement had not terminated.

ARTICLE 13
MISCELLANEOUS

13.1. Force Majeure. No Party shall be held liable or responsible to any other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes, lockouts, or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Parties of such force majeure within thirty (30) days after such occurrence by giving written notice to the other Parties stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

13.2. Export Control.

13.2.1. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from another Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

13.2.2. Each Party shall procure and maintain all export and other licenses and permits required for the granting to the other Party of the rights and licenses granted hereunder and for the supply to the other Party of all Information required to be delivered by the first Party to the other Party hereunder and shall otherwise comply with all Applicable Law relating to the grant of rights and licenses and the performance of such Party's other obligations under this Agreement as necessary to ensure that the other Party will be entitled to exercise its rights hereunder free of any restriction.

13.3. Assignment.

13.3.1. RedHill may 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, that promptly following the consummation of such transaction RedHill delivers written notice of such transaction to Salix together with a written acknowledgment and assumption by the transferee or assignee of RedHill's obligations set forth in this Agreement, or any part thereof, as the case may be; *provided, further*, that except as otherwise agreed to by Salix in writing, RedHill shall continue to remain responsible for the performance by such assignee of RedHill's rights and obligations hereunder.

13.3.2. Without the prior written consent of RedHill, such consent not to be unreasonably withheld, conditioned, or delayed, Salix shall not 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 Salix may make such an assignment without RedHill's consent to its Affiliate or to a successor, whether in a merger, sale of stock, sale of assets or any other transaction, of the business to which this Agreement relates. With respect to an assignment to an Affiliate, Salix shall remain responsible for the performance by such Affiliate of Salix's rights and obligations hereunder.

13.3.3. Any attempted assignment or delegation in violation of Sections 13.3.1 or 13.3.2 shall be void and of no effect.

13.3.4. All validly assigned and delegated rights and obligations of a Party hereunder shall be binding upon and inure to the benefit of, and be enforceable by and against, the Party's successors and permitted assigns.

13.4. Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable under any present or future law, and if the rights or obligations of none of the Parties under this Agreement will be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid, or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid, or unenforceable provision or by its severance herefrom, and (d) in lieu of such illegal, invalid, or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid, and enforceable provision as similar in terms to such illegal, invalid, or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid, or unenforceable in any respect.

13.5. Governing Law, Disputes.

13.5.1. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

13.5.2. Arbitration. Any dispute arising out of or relating to this Agreement, including the breach, termination or validity thereof, shall be finally resolved by arbitration in accordance with the Rules of Conciliation and Arbitration of the International Chamber of Commerce as then in effect, *provided that*, in the event and to the extent such rules conflict with the terms of this Section 13.5, the terms of this Section 13.5 shall govern. Judgment on the award rendered by the arbitrator(s) may be entered in any court having jurisdiction thereof. The place of arbitration shall be London, England. The arbitration shall be conducted in the English language.

13.5.3. Single Arbitrator. Except as provided in Section 13.5.4, the arbitration shall be held before a single arbitrator, who shall be selected by agreement of Salix and RedHill, or, if Salix and RedHill cannot agree within thirty (30) days after commencement of arbitration, then by the International Chamber of Commerce. The arbitrator selected pursuant to this Section 13.5.3 shall be a practicing or retired lawyer or retired judge and have experience relating to agreements concerning the licensing of intellectual property rights in the pharmaceuticals industry.

13.5.4. Three Arbitrators. Notwithstanding Section 13.5.3, in the event that the dispute that is subject to arbitration is one in which a Party seeks to recover an amount of at least [****] dollars ([****]) from the other Party, then either Salix or RedHill shall have the option, exercisable by written notice to the other given at any time within [****] days after commencement of arbitration, to require that the arbitration be held before a panel of three (3) arbitrators. In such case, within [****] days after the provision of notice described in the preceding sentence, each of Salix and RedHill shall select one person to act as arbitrator. If either Salix or RedHill shall fail within the designated time period to select an arbitrator, then the arbitrator to be so selected shall be selected by the International Chamber of Commerce. The two (2) persons so selected as arbitrators shall select a third arbitrator within [****] days of their appointment. If the two (2) initially selected arbitrators are unable or fail to agree upon the third arbitrator, the third arbitrator shall be selected by the International Chamber of Commerce. Each arbitrator selected pursuant to this Section 13.5.4 shall be a practicing lawyer or retired judge and have experience relating to agreements concerning the licensing of intellectual property rights in the pharmaceuticals industry.

13.5.5. Discovery. Each Party shall, upon the written request of the other Party, promptly provide the other Party with copies of documents relevant to the issues raised by the dispute on which the producing Party may rely in support of, or in opposition to, any claim or defense. Any dispute regarding discovery, or the relevance or scope thereof, shall be determined by the arbitrator(s), which determination shall be conclusive. All discovery shall be completed within [****] days following the appointment of the arbitrator(s).

13.5.6. Schedule. It is the intent of the Parties that, barring extraordinary circumstances, arbitration proceedings will be concluded within [****] months from the date the arbitrator is appointed (or, where a panel of three (3) arbitrators is used, the date upon which the third arbitrator is appointed). The arbitrator(s) may extend this time limit in the interests of justice. Failure to adhere to this time limit shall not constitute a basis for challenging the award.

13.5.7. Confidentiality. Except as may be required by Applicable Law, (including applicable securities laws or rules of a securities exchange) or as may be necessary to enforce the arbitration award or the provisions of this Section 13.5, and except for disclosures made by a Party to its accountants, insurers, consultants, or attorneys or to actual or potential lenders, non-public investors, rating agencies, acquirors, or business partners who are under obligations to the disclosing Party to hold the disclosed information in confidence, neither a Party nor its or his representatives may disclose the existence, content, or results of any arbitration hereunder without the prior written consent of the other Party.

13.5.8. Equitable, Interim or Provisional Relief. Either Party may apply to the arbitrators seeking equitable, interim or provisional relief until the arbitration award is rendered or the dispute is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any interim or provisional relief that is necessary to protect the rights or property of that party or to preserve the subject matter of the dispute, pending the selection of the arbitrator(s) or pending the issuance of an award by the arbitrator(s). The provisions of Sections 13.5.2 through 13.5.9 are without prejudice to the provisions of Section 13.5.10.

13.5.9. Allocation of Costs and Expenses. The arbitrator(s) shall have discretion to allocate the Parties' costs and expenses for the arbitration (including attorneys' fees), the fees of the arbitrator(s), and the administrative fees of arbitration between the Parties in proportion to the extent to which they prevail. Failing such allocation, each Party shall bear its own costs and expenses and Salix and RedHill shall bear an equal share of the fees of the arbitrators and administrative fees of the arbitration.

13.5.10. Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in Sections 2.3.2, 3.4 and 3.6 and ARTICLE 8 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions, and that any breach or threatened breach of any provision of such Sections or Article may result in irreparable injury to such other Party for which there may be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Sections or Article, the non-breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance, and an equitable accounting of all earnings, profits, and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. The Parties agree to waive any requirement that the other (a) post a bond or other security as a condition for obtaining any such relief, and (b) show irreparable harm, balancing of harms, consideration of the public interest, or inadequacy of monetary damages as a remedy. Nothing in this Section 13.5.10 is intended, or should be construed, to limit any Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

13.6. Notices.

13.6.1. Notice Requirements. Any notice, request, demand, waiver, consent, approval, or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 13.6.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 13.6.1. Such Notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. This Section 13.6.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

13.6.2. Address for Notice.

If to Salix, to:

Salix Pharmaceuticals, Inc.
8510 Colonnade Center Drive
Raleigh, North Carolina 27615
U.S.A.
Attention: [****]
Facsimile: +1 919 862 1000

with a copies (which shall not constitute notice) to:

Salix Pharmaceuticals, Inc.
8510 Colonnade Center Drive
Raleigh, North Carolina 27615
U.S.A.
Attention: General Counsel
Facsimile: +1 919 862 1095

Covington & Burling LLP
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
U.S.A.
Attention: Edward C. Britton
Facsimile: [****]

If to RedHill, to:

RedHill Biopharma Ltd.
21 Ha'arba'a Street
Tel-Aviv 64739
Israel
Attention: VP Business Development
Facsimile: +972-3-5413144

with a copy (which shall not constitute notice) to:

Tulchinsky Stern Marciano Cohen Levitski and Co.
4 Berkowitz Street
Museum Tower
Tel Aviv 64238
Attention: [****]
Facsimile: [****]

13.7. Entire Agreement; Amendments. This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises, and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release, or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties and, solely in respect of any amendment, modification, release, or discharge relating to the provisions of ARTICLE 2, the Inventors as well.

13.8. English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

13.9. Waiver and Non-Exclusion of Remedies. 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 shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by any Party hereto of any right hereunder or of the failure to perform or of a breach by another Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

13.10. No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and they shall not be construed as conferring any rights on any other Persons. Notwithstanding the provisions of the preceding sentence, the Inventors are intended third party beneficiaries of the waivers, releases, and covenants not to sue granted by RedHill under ARTICLE 2.

13.11. Further Assurance. Each Party shall 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 or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof, or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

13.12. Counterparts; Facsimile Execution. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile or electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

13.13. References. Unless otherwise specified, (i) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section, and (iii) references to any agreement, instrument, or other document in this Agreement refer to such agreement, instrument, or other document as it may have been amended, replaced, or supplemented from time to time through the Effective Date.

13.14. Schedules. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

13.15. Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend, or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against any Party hereto.

13.16. Relationship of the Parties. The relationship of RedHill and Salix established by this Agreement is that of independent contractors and nothing contained in this Agreement shall be construed to (i) give either Party the power to direct and control the day to day activities of the other Party, (ii) constitute the Parties as partners, joint ventures, co-owners or otherwise as participants in a joint or common undertaking, or (ii) allow any Party to create or assume any obligation on behalf of the other Party for any purpose whatsoever.

13.17. Condition Precedent. The Parties agree and acknowledge that this Agreement is interdependent with the License Agreement, [****] (as each of such terms is defined in the License Agreement) and that, except as may otherwise be agreed by the Parties in writing, (a) no provision of this Agreement other than this Section 13.17 will come into effect until a counterpart of each of the License Agreement, [****] has been duly executed and delivered by all parties thereto but (b) simultaneously with the execution and delivery by each party thereto of a counterpart of each of the License Agreement, [****] all provisions of this Agreement shall, without further action by any of the Parties, come into full force and effect.

[*SIGNATURE PAGE FOLLOWS***]**

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties to be effective as of the Effective Date.

REDHILL BIOPHARMA LTD.		**SALIX PHARMACEUTICALS, INC.**	
By:	/s/	By:	/s/
Name:		Name:	
Title:		Title:	

[Signature Page to Agreement]

Schedule 1.15

Certain Competitors

[****]

Schedule 1.73
Referenced Patents

Re the [****] Licensed Product:

Priority application details	**Country or region**	**Application number**	**Status**	**Patent number**	**Expiry date**
[****]	[****]				
	[****]	[****]	[****]		
	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]		[****]
	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]		[****]
[****]	[****]	[****]	[****]		[****]

Re the [****] product:

[****]

Re the [****] product:

[****]

Schedule 3.5

Initial RedHill Delivery Materials

[****]

Schedule 5.1

[****]

ARTICLE 14 Item	ARTICLE 15 Paid
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

Total: [****]

Schedule 5.3.2

Content of Salix Reports

[****]

Schedule 6.1

Attribution of Value of Payments

[****]

Schedule 6.9

RedHill's Wire Instructions and Bank Account Information

Beneficiary Bank:	[****]
Address:	[****]
ABA Number:	[****]
Swift Code:	[****]
For account of:	
Account Name:	[****]
Address:	[****]
Account Number:	[****]

Appendix A

Redacted Form of License Agreement Between Salix and the Inventors

Exhibit 4.10

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Project Order # 1879 RHB-104 Manufacturing Amendment 1

THIS PROJECT ORDER No. 1879 RHB-104 Manufacturing Amendment 1 is between RedHill Biopharma Ltd. ("SPONSOR") and 7810962 Canada Inc. ("MANAGER") and, upon execution by both parties, shall be incorporated into the Service Agreement signed on 5July2014 between SPONSOR and MANAGER.

SPONSOR agrees that Manager enters into a subcontract with [****] on the terms set out in Amendment 1 of Project Order 1879 to be executed between 7810962 Canada Inc. and [****] as shown below in Exhibit A. For further clarity, SPONSOR agrees with the costs and to the payment schedule as described in Exhibit A.

IN WITNESS WHEREOF, this Proposal has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

REDHILL BIOPHARMA Ltd.

/s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO
Date: 12Aug2014

/s/ Ori Shilo
Name: Ori Shilo
Title: VP Finance and Operations
Date: 12Aug2014

For 7810962 Canada Inc:

/s/ Alain Guimond
Name: Alain Guimond
Title: Senior Director of R&D
Date: 12Aug2014

EXHIBIT A

Service Agreement - G
7810962 Canada Inc. – [****]
Clinical Trial Material manufacture of RHB-104 capsules

AMENDMENT 1 TO THE SERVICE AGREEMENT G is made and entered into this twenty-third (23) day of July, 2014 (the "**Amendment**").

The Client and [****] entered into a service agreement G (document 143-111207rev11) dated the twenty-eight day of July, 2014 (the "**Service Agreement G**").

The Client and [****] entered into a Master Service Agreement dated the fifth day of July, 2011 (the "**MSA**").

The Parties hereto wish to describe the services to be performed in connection with the MSA, subject to the terms and conditions set forth herein and in the MSA.

Unless the context otherwise requires, all capitalized terms used in this Amendment shall have the meanings attributed to them in the MSA and the Service Agreement G.

I. DESCRIPTION OF THE EXTRA WORK TO THE SERVICE AGREEMENT G

The scope of this work is to identify a RHB-104 degradation product.

The estimated cost is as follow:

Part 1
- [****]
- [****]

Part 2
- [****]

II. COST AND PAYMENTS

2.1- The estimated cost of the Services for the Extra Work detailed in section 1 is 6,700 $USD.

2.2- The Client shall pay to [****] in United-States currency ($USD) upon the reception of invoices.

The Parties hereto have requested that this Service Agreement be drafted in the English language. *Les Parties ont exigé que ce contrat de services soit rédigé en anglais.*

IN WITNESS THEREOF, the Parties have executed this Amendment as of the Date written above, by their authorised representatives, who by signing confirm their authority and intention to bind the Parties they represent.

[****]
Per: /s/
Name: [****]
Title: President

7810962 Canada Inc.
Per:/s/ Alain Guimond
Name: Alain Guimond, Ph.D.
Title: Senior Director of Research

ICH Clinical & Statistical Report	$ [redacted]
Subject Compensation	$ [redacted]

Analytical Activities

[redacted]

$ [redacted]

$ [redacted]

$ [redacted]

$ [redacted]

$ [redacted]

$ [redacted]

PK Statistical Analysis $ [redacted]

Statistical plan will be elaborated by Algorithme Pharma

Statistical Analysis and Statistical Report (see above) will be produced by Algorithme Pharma

Project Management $ [redacted]

Quality Assurance $ [redacted]

[redacted]

[redacted]

Sub-Total	**$ 1,418,875.40**
Special Discount	$ (92,384.30)
Total	**$ 1,326,491.10**

Pass-Through fees	Unit price	Unit
Eye examination by optometrist	**$ 197.62**	**per exam**

USD currency rate : 1.01

I confirm that I award this project to Algorithme Pharma Inc. and authorize them to initiate preparation of the project.

Authorized Signature

COMMENTS

1. This quotation is valid for 2 months and is subject to change upon modifications/finalization of the protocol.
2. Actual invoicing will reflect the current exchange rate at the invoice date. The actual amount billed in USD may therefore differ from the amount quoted above.
3. The present quote is based on 3 clinical groups. Based on safety assessment of data to be available on the Test drug doses, [redacted] , etc, it might be required to conduct the study in up to 5 clinical groups. Additional fees will apply.

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Service Agreement - Y
Manufacture of resupply of Clinical Trial Material of [****] RHB-104 capsules

THIS SERVICE AGREEMENT Y is made and entered into this _____ day of October, 2014 (the "**Service Agreement**").

BETWEEN: [****], a corporation duly incorporated under the laws of Canada and having its principal place of business at [****];

(hereinafter referred to as "[****]")

AND **RedHill Biopharma Ltd.**, a company duly incorporated under the laws of Israel, and having its principal place of business at 21 Ha'arba'a St., Tel-Aviv, 64739 Israel;

(hereinafter referred to as the "**Client**")

([****] and the Client are at times referred to individually as the "Party" and collectively the "Parties")

RECITALS

A. The Client and [****] entered into a Master Service Agreement dated on the 7th day of August, 2012 (the "**MSA**").

B. The Parties hereto wish to describe the services to be performed in connection with the MSA, subject to the terms and conditions set forth herein and in the MSA.

C. Unless the context otherwise requires, all capitalized terms used in this Service Agreement shall have the meanings attributed to them in the MSA.

1. INTERPRETATION

The recitals of this Service Agreement as well as all of its Appendices form an integral part of this Service Agreement.

2. DESCRIPTION AND DELIVERABLES

The objective of this Agreement is to GMP manufacture, the warehousing, the analytical release testing and the stability storage and testing of the RHB-104 CTM resupply.

2.1- API, excipients and packaging components reception and storage

2.1 a) API sourcing

It is estimated that sufficient quantities of fully released GMP clarithromycin API and GMP clofazimine API are available at [****] and the Client at its own cost will ship to [****] sufficient quantities of GMP rifabutin API (collectively the clarithromycin API, the clofazimine API and the rifabutin API are called "APIs" and individually "API"). Upon reception of the GMP rifabutin API [****] will execute a full release testing of the material according to GMP requirements. Should additional APIs be required, the sourcing will be the exclusive responsibility of the Client. Upon request by the Client, [****] could characterize and analyze the APIs which will be considered Extra Work.

Cost: [****]

* It is estimated that sufficient quantities of each of GMP clarithromycin API and GMP clofazimine API are available at [****] to execute the manufacture of the CTM. However the Client will source and ship to [****] sufficient quantities of GMP rifabutin API for the manufacture of the Drug product included in this Agreement.

The cost includes:

- the reception of one lot of GMP rifabutin API (i.e., documentation review, material registration in [****] inventory, and material sampling following GMP requirements) (If API lot is in more than one container then the sampling and ID testing of each of the additional containers will be considered Extra Work at 200$/additional container),
- the full testing for the release of one lot of GMP rifabutin API using validated method. (Client will ship the GMP rifabutin API to [****] with the complete certificate of analysis and related documentation to assure API conformity to the appropriate regulatory authorities),
- the GMP warehousing of the Client's Materials (e.g., API, raw material, objects, inactive ingredients) for the period where the Project is active and for a volume not exceeding 1 m^3. If the material need to be stored for a longer period of time or the volume of the material is more than 1 m^3 then the storage cost will be considered Extra Work or the material shipped at Client.

The cost does not include:

- The purchase of the analytical reference materials to be used as a standard, if needed, reference impurities (synthesis by-products, Related Substances, metabolites) of known purity, HPLC columns, and any dedicated peripherals (e.g., guard column) and reagents.
- The release testing of any additional material (i.e., additional API) should the Client change the drug product material specifications or API source or any decision taken by the Client that requires additional analytical testing.
- The repackaging of material (if required) as well as the shipping cost and custom fees, if any.
- The destruction fees of any material after being pre-authorized by the Client.
- Documentation fees for the shipment or reception of GMP API or GMP drug products at 200$/ event (i.e., reception or reception).
- Sampling fees of 200$/ containers.
- The shipping document preparation and shipment of material.

2.1 b) GMP Materials (excipients and packaging components) storage and handling-

[****] will handle the reception, the full release testing, the shipping and the storage of GMP Materials (i.e., excipients and packaging materials) in its cGMP warehouse. All material handling operations and storage conditions will respect the ICH GMP requirements.

Cost: [****]

* The cost includes:

- The reception of 10 lots of excipients and packaging components (i.e., documentation review, material registration in [****] inventory, and material sampling following GMP requirements) as well as their full release testing as per the [****] (The cost is based on the hypothesis that all GMP material will be received in one single shipment at 200$/ shipment and the full release testing of 10 GMP materials at an average cost of [****] of GMP material received. Any additional shipment or reception of GMP material will be considered as Extra Work at [****] or reception. Any additional sampling and testing of GMP material received will be considered Extra Work at [****] of GMP material received.).
- The GMP warehousing of the APIs and the drug product until completion of the study. If the material needs to be stored for a longer period of time then the storage cost will be [****]/ month.
- All the GMP Materials, APIs and RHB-104 drug products must have a volume of less than 1 m3.

The cost does not include:

- The cost of APIs.
- The purchase cost of the reference materials to be used as a standards and reference impurities (synthesis by-products, degradation products, metabolites) of known purity, if required.
- Additional packaging or repackaging of APIs, Drug Products or any GMP material will be considered Extra Work.

2.2- Manufacturing of the Clinical Trial Material (CTM)

The CTM manufacturing process, manufacturing, packaging, equipment calibration and validation, will be done by [****] GMP laboratory. All the manufacturing, packaging and analytical equipments that will be used for the CTM will be calibrated, validated and released for their cleanliness prior to their utilization.

2.2 a) Manufacturing and bulk packaging

[****] will manufacture and package the single dose strength of RHB-104 capsule as per the optimized formulation developed in the execution of Service Agreement N (document 004-140225rev4).

Specifically with respect to manufacturing, packaging and bulk labeling, the followings items will be provided by [****]:

a) Recommendation and justification of specific finished product release specifications,
b) Redaction of Master Manufacturing File (MMF)

c) The CTM will be manufactured and packaged in labeled* double lined sealed LDPE bags inserted in hard shell sealed barrels:
- RHB-104 capsule –[****] units

Cost: 145,000$**

* The labelling on the bags and barrels will include the basic information for GMP drug products (i.e., Name of sponsor, date of manufacturing, Lot number and storage conditions). This Agreement does not include preparation of special packaging and labelling which would require randomization, patient kits preparation of special shipments of clinical supplies.

** The cost is based on the assumption that one batch of [****] RHB-104 capsules will be manufactured and packaged within the same manufacturing campaign. The cost includes the GMP excipients, the GMP packaging materials, the manufacturing, the bulk packaging, the labelling, the cleaning verification of the manufacturing suites and the equipments for one manufacturing campaign. The cost does not include the transportation cost of the clinical supplies, the broker and custom fees, the cost of the APIs. No manufacturing engineering batch of the drug product will have been executed using the new RHB-104 capsule formulation developed by [****] in the execution of Service Agreement N prior to the execution of this GMP manufacturing campaign and thus, [****] could not be held responsible for batch failure unless the failure is du to a [****] negligence or wilful misconduct. Furthermore, the manufacturing campaign will last 10 working days. The manufacturing campaign will start when the APIs are brought in the GMP manufacturing suites and will be terminated when the GMP manufacturing suites will have been released for their cleanliness. Should the manufacturing campaign be delayed by the Client, the Client's suppliers, the Client's APIs or any other factors outside the control of [****], every additional day to the GMP manufacturing campaign will be considered Extra Work at [****]/ day for GMP suite rental and labour cost may also apply in addition to the suite rental.

2.2 b) Packaging and labeling of the Clinical Trial Material (CTM) (optional)

Specifically with respect to packaging and labeling, the followings items will be provided by [****]:

a) Redaction of Master Manufacturing File (MMF); and
b) The RHB-104 capsules of the [****] units batch will be packaged in induction sealed HDPE bottle containing [****]; and
c) Labeling of bottles in a ratio of two RHB-104 bottles to one RHB-104 placebo bottle (i.e., [****]) using the labels to be provided by the Client.

The followings items will be provided by the Client to [****]:

a) About [****]; and
b) The randomization list; and
c) The labels.

Cost: [****]

* This cost is not included in the total cost of the study in section 7 and should Services included in this section required by the Client it will be considered Extra Work and invoiced monthly. The cost is based on the assumption that [****] RHB-104 capsules will be bottled [****] will be labelled with labels to be provided by the Client AND all the bottling and the labelling will be executed within the same manufacturing campaign. The cost includes the GMP packaging materials, the packaging, the labelling, the cleaning verification of the packaging suites and the equipments. The cost does not include the transportation cost of the clinical supplies, the broker and custom fees, the preparation of Patient Kits. If the Services included in this Agreement is executed within the same manufacturing campaign as of the manufacturing of the RHB-104 capsule (Section 2.2 a)) and the bulk packaging is not required then [****]$ will be subtracted from the discounted cost above.

2.2 c) Release testing of CTM and cleaning verification

The validation of the analytical methods for the release testing of the CTM and for the cleaning verification has already been validated. All analysis will be performed using the validated methods. Except for the cleaning verification all of the analyses are outsourced to a [****] qualified third Party laboratory.

Analyses to be performed on CTM are:

- appearance,
- Identification,
- water content (KF),
- assay* and degradation products*,
- microbiology,
- content uniformity,
- dissolution** and disintegration time.

Cost: 10,965$***

* Assay and Related Substances for the three APIs for RHB-104.

** [****].

*** The cost is not discounted as all of the CTM analyses are outsourced to a Third Party qualified laboratory. The cost includes the analysis of [****] (i.e., RHB-104 capsules), the analysis of [****] for cleaning verification for one GMP manufacturing campaign. Except for the cleaning verification all the analytical methods for release testing have been validated by a third Party [****] qualified laboratory.

2.2 d) Stability study of CTM and cleaning verification

The validation of the analytical methods for the analysis of the CTM has already been validated by a qualified third Party laboratory. All analysis will be performed using the validated methods.

The CTM will be stored in cGMP stability chambers at [****], and the samples analyzed using the Client's validated methods. The single strength RHB-104 capsule will be characterized for appearance, assay, related substances, dissolution*, disintegration and water content using the schedule below.

The following stability testing schedule will be used and modified per mutual agreement:

Storage Condition	Time point (Month)									
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	-	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	-	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	-	[****]	[****]	[****]	-	-	-	-	-	-

X: Sample to be analyzed.
Y: Sample removed from chamber and analyzed only at the request of Client.

Cost: 74,120$**

* A dissolution test is [****].

** The cost is not discounted as all of the CTM analyses are outsourced to a Third Party qualified laboratory. The cost is based on the analysis of [****].

2.3- Reports and submission documentation

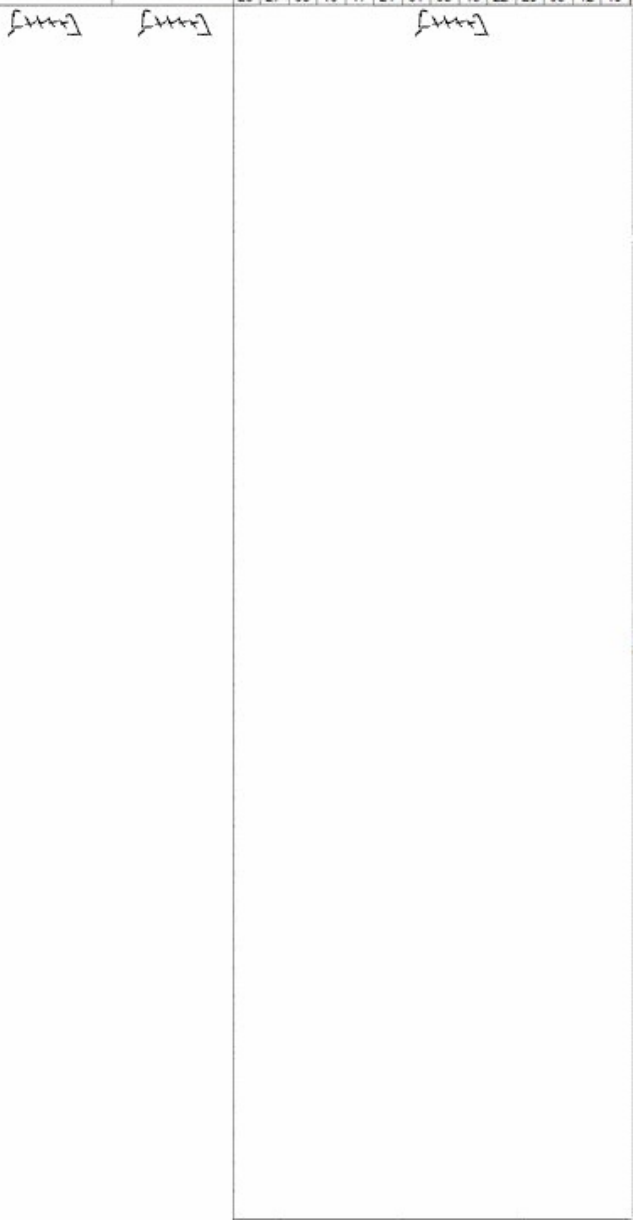
- **Telephone meetings, [****] facility and quality audit** by Client's or Client's representative will be held on an as needed basis.
- **Client or Client's representative** meeting in [****] facility will be held at Client's request.
- **Progress reports** will be provided on a Monthly basis or as needed.
- **Item reports** will be provided as they are completed.
- A **final manufacturing report** will be provided at the end of the study. It will include all the necessary regulatory submission documents related to manufacturing and packaging which include (but not limited to):
  - The finished products release & stability certificate of analysis.
  - In process testing results.
  - QA Reviewed and audited Manufacturing and Packaging/labeling Documents.
  - Certificate of cGMP compliance.
  - Certificate of analysis of raw materials and packaging components.
  - Any atypical report or Out-of-Specification reports.

Cost: 0$*

* Included in the costs of the previous sections.

3. GENERAL PROJECT TIMELINES

ID	Project Items	Start	Finish
1	**2.1-API, excipients and packaging components reception and storage**		
2	**2.1 a) API sourcing**		
3	GMP rifabutin API release testing		
4	**2.1 b) GMP materials storage and handling**		
5	Sourcing of GMP materials		
6	Reception of GMP material		
7	Analysis for release of GMP material		
8	Release of GMP material		
9	**2.2-Manufacturing of the Clinical Trial Material (CTM)**		
10	Justification of RHB-104 specs		
11	Documentation preparation		
12	**2.2 a) Manufacturing and packaging**		
13	Manufacture of the drug product		
14	Packaging of the drug product		
15	Cleaning		
16	**2.2 b) Packaging and labeling of the Clinical Trial Material (CTM)**		
17	Packaging and labeling		
18	Cleaning		
19	**2.2 c) Release testing and cleaning verification**		
20	Analysis of CTM and cleaning verification samples		
21	Release of CTM		
22	**2.2 d)-Stability of CTM**		
23	Material in stability chambers		
24	1 month stability results		
25	3 month stability results		
26	6 month stability results		
27	9 month stability results		
28	12 month stability results		
29	18 month stability results		
30	24 month stability results		
31	30 month stability results		
32	36 month stability results		
33	**2.3-Reports and submission documentation**		
34	Manufacturing report and documentation		
35	**Decision time-points**		
36	Project start time: Agreement signed and API received		
37	Client to confirm RHB-104's specs for CTM		
38	Client to review the MMF and Corealis to issue the Certificate of Manufacture		
39	**Installments**		
40	7.2.1-Signature of the Agreement		
41	7.2.2-Completion of CTM manufacturing		
42	7.2.3-Completion of CTM manufacturing report		



4. STARTING DATE AND COMPLETION

4.1 Notwithstanding the date of signature of this Service Agreement, [****] shall start the performance of the Services within ten (10) business days after [****] satisfaction of the following:

4.1.1 signature by the Client of this Service Agreement; and

4.1.2 complete delivery by the Client of all of the items mentioned at sub-section 6.1 of section 6 hereof entitled "REQUIREMENTS".

4.2 This Service Agreement shall be deemed completed upon full delivery of the Services by [****] and receipt by [****] of the final and last payment for the Services.

5. ASSUMPTIONS

5.1 The RHB-104 optimized formulation containing 95 mg Clarithromycin, 45 mg Rifabutin, and 10 mg Clofazimine will be manufactured for clinical supplies.

5.2 Any subcontractor that will used within this project will need to satisfy the [****] quality audit. Otherwise Extra Work may be required to support subcontractors and/or take actions not to delay the project (e.g., [****] to purchase and release material after approval by the Client). Use of subcontractors must be approved in advance by the Client.

5.3 [****] is not responsible for the qualification of any API manufacturer, any delays in the manufacturing of the APIs, the delivery of the APIs, and for the quality of the APIs purchased by the Client.

5.4 If different lots of APIs are utilized in the execution of the Project and the physical and chemical properties of the different lots are different or, if the physical and chemical properties of the API intended to be utilized in the execution of this Projects differs from the expected API properties when this Agreement was signed by both Parties, then additional formulation development and/or manufacturing process adjustments and/or additional manufacturing time and/or additional sample analysis may be needed and if needed, they will be considered Extra Work and the Project's time lines adjusted accordingly.

5.5 When a decision is required to move the project forward, the Client will provide its decision in writing to [****] within a period of 5 days, or the project may be delayed. [****] will develop a final timeline for this project and all deviations will be immediately reported to the Client. [****] will make its best efforts to correct all deviations in order to maintain the project timeline.

5.6 Any analytical reference materials (e.g., standards and impurities) and dedicated materials (e.g., HPLC columns, speciality reagents) purchased by [****] and utilized solely for the execution of the Client's Project and any other equipments or materials that are damaged by the Client's API or APIs (e.g., corrosion, unusual ware, staining, contamination, loss of operational functions) or becomes dedicated to the Client's Project or requires unusual cleaning efforts and resources due to the nature of the Client's APIs will be considered Extra Work and invoiced at cost to the Client.

5.7 The Client decided not to execute a stability study of the CTM.

5.8 All shipments from [****] to the Client or to a designated location specified by the Client will be invoiced at cost as per the EXW ([****]) Incoterms® 2010. All shipments from Clients or from a designated supplier of the Client to [****] will be invoiced at cost as per the DDP (200 Armand-Frappier boulevard, Laval, Quebec, Canada, H7V 4A6) Incoterms® 2010.

5.9 The Client is responsible to verify that the Services and deliverables provided in the execution of this Service Agreement do not violate or infringe any patent, trade secret or other proprietary or intellectual property right of any third Party.

5.10 During an audit, [****] will allow the Client's representatives to examine the batch records, technical reports, methods and protocols pertaining to the Services. The assistance provided by [****] to the Client during an audit will, under no circumstances, give rise to the payment of additional expenses unless the audit last more than three working days (a working day consist of an 8 hour shift). Should additional time is required for the audit it will be considered Extra Work.

5.11 [****] will allow the Client's representatives to assist to the execution of the Services for a maximum period of one day per manufacturing campaign. Should the Client's representative need additional time and/or if the normal execution of the Services is disturbed by the presence of the Client's representative then [****] may consider it Extra Work.

5.12 If different lots of APIs are utilized in the execution of the Project and the physical and chemical properties of the different lots are different or, if the physical and chemical properties of the API intended to be utilized in the execution of this Project differs from the expected API properties when this Agreement was signed by both Parties, then additional formulation development and/or manufacturing process adjustments may be needed and if needed, they will be considered Extra Work and the Project's time lines adjusted accordingly.

5.13 The costs included in this Agreement for GMP manufacturing are based on the premises that all of the GMP manufacturing operations will be executed within the same manufacturing campaign, unless explicitly specified in section 2. Should the GMP manufacturing campaign be delayed or split in several manufacturing campaigns and where the delays or the split is not caused by [****] or by [****] qualified suppliers, the additional cost that may apply will be considered Extra Work.

5.14 All of the Client's Materials (e.g., API, raw material, objects, inactive ingredients) stored in [****] warehouse will not exceed a volume of 1 m^3. Exceeding storage volume will be considered Extra Work

6. REQUIREMENTS

The Client shall provide to [****], at no cost to [****], the following:

6.1 If the Client send additional APIs to [****] for the manufacture of the RHB-104, the GMP APIs, reference materials to be used as a standard, reference impurities (synthesis by-products, degradation products, metabolites) of known purity, the certificate of analysis, the BSE & TSE statements, the APIs manufacturer GMP certification.

7. COST AND PAYMENTS

7.1 The cost of the Services is 247,701.00 $USD [****]. Any amount exceeding a total of 247,701$ requires a pre-approval in writing by the Client.

7.2 The Client shall pay to [****] the following installments in US currency ($USD):

7.2.1 [****] upon signature of this Agreement; and

7.2.2 [****] at the completion of the CTM manufacturing; and

7.2.3 [****] at the acceptance of the final CTM manufacturing report; and

7.2.4 Stability study of CTM invoiced monthly.

7.3 Each of the above payments is subject to receipt of a non-disputed invoice from [****] and subject to the payment terms detailed in the Master Service Agreement.

7.4 Notwithstanding section 7.1, for any extra work not covered by this Service Agreement and agreed upon in writing between the Parties (the "Extra Work"), the Client shall pay to [****] the relevant sum as agreed in writing. For any such Extra Work [****] will apply the hourly rates and other fees indicated in this Appendix I attached hereto for the performance of the Services (The costs of the Services for the Extra Work and described in section 7.1 are collectively, the "Fees").

7.5 Notwithstanding section 7.2 hereof, [****] will invoice the Client for the Extra Work, on a monthly basis for the Services that (i) have been pre-approved in writing by the Client, and; (ii) that have been delivered or rendered by [****].

8. CONFIDENTIALITY

8.1 Confidentiality issues are covered per the Non Disclosure Agreement and the MSA.

9. REPRESENTATIONS AND WARRANTIES

9.1 [****] hereby represents and warrants to the Client that:

9.1.1 it is a duly organized and validly existing corporation under the laws of the jurisdiction in which it is incorporated;

9.1.2 it has the necessary corporate power, authority, skills, and capacity and is properly authorized to enter into this Service Agreement and to perform its obligations as per the terms and conditions of this Service Agreement. The execution and delivery of this Service Agreement and the performance of the transactions contemplated hereby have been duly authorized.

9.2 The Client hereby represents and warrants to [****] that:

9.2.1 it is a duly organized and validly existing corporation under the laws of the jurisdiction in which it is incorporated;

9.2.2 it has the necessary corporate power, authority, skills, and capacity and is properly authorized to enter into this Service Agreement and to perform its obligations as per the terms and conditions of this Service Agreement. The execution and delivery of this Service Agreement and the performance of the transactions contemplated hereby have been duly authorized;

10. TERMS AND CONDITIONS

10.1 This Service Agreement shall be governed, construed and interpreted according to the laws in force in the [****] and the applicable laws of Canada therein, and the courts of the legal district of [****] (Canada) shall have exclusive jurisdiction to hear any and all disputes arising hereunder.

10.2 This Service Agreement is subject to the terms and conditions provided in the MSA and bind the parties as well as their respective successors, permitted assigns and legal representatives.

10.3 This Service Agreement may be executed in counterparts, each of which shall be deemed to be an original and which together shall constitute one and the same agreement. This Service Agreement may also be executed between the Parties by exchange of facsimile transmissions or electronic transmissions in legible form, including without limitation in a tagged image format file (TIFF) or portable document format (PDF).

10.4 The Parties hereto have requested that this Service Agreement be drafted in the English language. *Les Parties ont exigé que ce contrat de services soit rédigé en anglais.*

IN WITNESS THEREOF, the Parties have executed this Service Agreement as of the Date written above, by their authorised representatives, who by signing confirm their authority and intention to bind the Parties they represent.

[****]
Per: /s/
Name: [****]
Title: President

RedHill Biopharma Ltd.
Per: /s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO

Per: /s/ Ori Shilo
Name: Ori Shilo
Title: VP Finance and Operation

CONFIDENTIAL

Service Agreement - Y

RedHill Biopharma Ltd. – [****]

Manufacture of resupply of Clinical Trial Material of

[****] RHB-104 capsules

Appendix I

Professional Consultation Rates

Professional (Chemist or Engineer)	**Hourly Rate***, ** ($USD)
Senior scientist Scientist Technician	[****] [****] [****]
R&D laboratory overhead (Equipment and supplies)	[****]

Analytical Services

Analyses	**Cost / Sample *** ($USD)
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****] ****	[****]
[****] ****	[****]
[****] ****	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

* Prices can be changed by [****] without any prior notice. Prices apply only for non GMP work and analysis. GMP prices will be supplied on demand.

** All expenses will be charged at cost.

*** Will be invoiced in addition to the professional fees when laboratory work is required.

**** A set-up charge of [****] method will be invoiced in addition to the sample cost.

Exhibit 4.14

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Amendment 3 to Clinical Services Agreement

Sponsor's study drug RHB-104

This Amendment 3 ("**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**");

Is hereby made effective as of September 05, 2014 ("**Effective Date**") and the parties hereby agree as follows:

1. Amendment 3 to Clinical Services Agreement.

   This Change Order constitutes an amendment to the Clinical Services Agreement pursuant to section 3.0 therein. As such, this Amendment 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 Sponsor's study drug RHB-104, in accordance with the Summary of Changes attached hereto and incorporated herein as Exhibit A. [****]

3. Compensation

   [****]

Payment due to Manager for the Services provided under this Amendment 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 Amendment 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 Amendment 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 Amendment and represent that they are authorized to enter into this Amendment on behalf of their respective companies.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd.

/s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO

Date: 01 Dec 2014

RedHill Biopharma Ltd.

/s/ Ori Shilo
Name: Ori Shilo
Title: Deputy CEO Finance & Operations

Date: 01 Dec 2014

For 7810962 Canada Inc.

/s/ Alain Guimond PhD
Name: Alain Guimond PhD
Title: Senior Director of R&D

Date 01 Dec 2014

Exhibit A Summary of Changes

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. EU trial is removed from the study agreement

Change Order 03 for 7810962 Canada Inc. /Red Hill Biopharma Ltd.

Overview of major level changes

Category	Contract	Additional sites & protocol amendments	Rationale for change
Study Start- Up period	[****] months + [****] month hold period	[****] months + [****] month hold period	No change
Enrolment period	[****] months	[****] months	No change
Stats Timeline	[****] weeks	[****] weeks	no change
# of countries	[****]	[****]	no change
# of sites	[****]	[****]	Per client
# of subjects	[****]	[****]	Per client
# of CRF pages/book	[****]	[****]	[****]
# of unique CRF pages	[****]	[****]	[****]
# of PSVs	[****]	[****]	[****]
# of SIVs	[****]	[****]	[****]
# of RMVs	[****]	[****]	[****]
# of COVs	[****]	[****]	[****]
# of internal meetings	[****]	[****]	[****]
# of client telecons	[****]	[****]	[****]
Client Meetings	[****]	[****]	[****]
Investigator Meeting	1 F2F	No Change	
# of vendors	[****]	[****]	[****]
# of edit checks	220	220	No change
# of imports	54	54	No change
# of SAEs	[****]	[****]	No change.
# of SAE Narratives	[****]	[****]	No change.
IVRS	Not Included	Not Included	
eCRF Changes	[****]	[****]	[****]

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)	Additional sites & protocol amendments	Assumption Changes influencing the change in the budget	Additional comments
Site Visit Travel	[****]	[****]	[****]	[****]
Investigators' Meeting Organisation	[****]	[****]	[****]	
Kick-off Meeting Travel/Attendance	[****]	[****]	[****]	
Shipping/Photocopying	[****]	[****]	[****]	
Translation	[****]	[****]	[****]	
Regulatory Fees	[****]	[****]	[****]	[****]
Ethics Committee Fees	[****]	[****]	[****]	
EDC Studies/3G Cards	[****]	[****]	[****]	
DSMB member fees	[****]	[****]	[****]	[****]
EDC Fees (Oracle)	[****]	[****]	[****]	[****]
CRA Face to Face Meeting Travel expenses	[****]	[****]	[****]	
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)**	**Additional sites & protocol amendments**	**Assumption Changes influencing the change in the budget**	**Additional comments**
Pre-study Activities				
Case Report Form Preparation/Review	[****]	[****]	[****]	[****]
Data Management Plan Preparation/Review	[****]	[****]	[****]	
Informed Consent Preparation/Review	[****]	[****]	[****]	[****] [****]

Task	Current (US Dollars)	Additional sites & protocol amendments	Assumption Changes influencing the change in the budget	Additional comments
IRB/Ethics Committee Interactions	[****]	[****]	[****]	[****]
Investigators' Meetings	[****]	No change	No Change	
Investigator Site Contract	[****]	[****]	[****]	[****]

Task	Current (US Dollars)	Additional sites & protocol amendments	Assumption Changes influencing the change in the budget	Additional comments
Investigator Recruitment	[****]	[****]	[****]	[****]
Project Plan Preparation/Review	[****]	[****]	[****]	[****]
Protocol Preparation/Review	[****]	[****]	[****]	[****]
Randomization Schedule Preparation	[****]	[****]	[****]	
Study-Specific Form Preparation	[****]	[****]	[****]	
Training - Project-Specific	[****]	[****]	[****]	[****]
Translations	[****]	[****]	No change	
PROMIS	[****]	[****]	[****]	[****]
Monitoring/Site Management				

Task	Current (US Dollars)	Additional sites & protocol amendments	Assumption Changes influencing the change in the budget	Additional comments
Data Clean-up	[****]	[****]	[****]	
Investigator Grant Administration	[****]	[****]	[****]	[****]
Laboratory Report Review	[****]	[****]	[****]	
Serious/Significant Adverse Event Management	[****]	[****]	[****]	[****]
Site Management	[****]	[****]	[****]	[****]
Remote Monitoring of Site Data	[****]	[****]	[****]	[****]
Site Visits - Pre-study Visits	[****]	[****]	[****]	[****]
Site Visits - Initiation Visits	[****]	[****]	[****]	[****]
Site Visits - Routine Visits conducted on site	[****]	[****]	[****]	[****]
Site Visits - Close-out Visits at each site at Study End	[****]	[****]	[****]	[****]

Task	Current (US Dollars)	Additional sites & protocol amendments	Assumption Changes influencing the change in the budget	Additional comments
Study Master File/Project File Set-up and Maintenance	[****]	[****]	[****]	[****]
Patient/Site Recruitment	[****]	[****]	No change	
Client/CRO meeting	[****]	[****]	[****]	[****]
Regulatory				
Regulatory Documentation Preparation/Review	[****]	[****]	[****]	[****]
Project Management /Project Tracking				
Financial Project Management	[****]	[****]	No change	

Task	Current (US Dollars)	Additional sites & protocol amendments	Assumption Changes influencing the change in the budget	Additional comments
Project Management	[****]	[****]	[****]	[****]
Project Tracking / Communications	[****]	[****]	[****]	[****]
Vendor Management	[****]	[****]	[****]	[****]
Data Management				
Database Archiving	[****]	[****]	[****]	
Data Cleanup (DM)	[****]	[****]	[****]	
Data Management: Database Quality Control Inspection	[****]	[****]	[****]	
Database Design	[****]	[****]	[****]	[****]
Dictionary Coding	[****]	[****]	[****]	
Edit Check Programming	[****]	[****]	[****]	[****]
Electronic Data Import	[****]	[****]	[****]	[****]
Case Report Form Data/Document Transfers	[****]	[****]	[****]	[****]
EDC Fees	[****]	[****]	[****]	
Statistical Analysis and Table Generation				
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				

Task	Current (US Dollars)	Additional sites & protocol amendments	Assumption Changes influencing the change in the budget	Additional comments
Project Team Meetings - Internal Meetings	[****]	[****]	[****].	[****]
Project Team Meetings - Client Teleconferences	[****]	[****]	[****]	[****]
Project Team Meetings - Kick-off Meeting	[****]	[****]	[****]	
Total Direct Costs	**[****]**	**[****]**		

Total Costs

Category	Total Costs($)		
	Current Contract (USD)	Change in Scope #3 (USD)	Revised Total (USD)
Pass-Through Costs	[****]	[****]	[****]
Investigator Grants Costs	[****]		[****]
Professional Fees	[****]	[****]	[****]
Discount	[****]	[****]	[****]
Revised Professional Fees	[****]	[****]	[****]
Grand Total	**[****]**	**[****]**	**[****]**

Exhibit B Payment Schedule

1. PAYMENT TERMS

A. Service Fees:

[****]

2. Pass Through Costs:

(a) CO#2: [****] of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling [****], will be due and payable upon execution of this Agreement. 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: [****] of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling [****], will be due and payable upon execution of this Agreement. 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) Actual pass-through expenses, as provided in the expenses estimate, will be billed as incurred by inVentiv Health Clinical

(d) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

3. Investigator Grants:

(a) [****]

(b) inVentiv Health Clinical will submit invoices for the amounts paid to investigators during the previous month. Any amount exceeding the estimate investigator grant payments will be pre-approved by the Company.

(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 [****]

(d) All services and pass-through payments should be sent via wire or ACH

Exhibit 4.15

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Amendment #4 to Clinical Services Agreement

Sponsor's study drug RHB-104

This Change Order 4 ("**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**");

Is hereby made effective as of September 11, 2014 ("**Effective Date**") and the parties hereby agree as follows:

1. Amendment # 4 to Clinical Services Agreement.

   This Amendment constitutes an amendment to the Clinical Services Agreement pursuant to section 3.0 therein. As such, this Amendment 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

   [****]

   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 Amendment 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 Amendment 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 Amendment on behalf of their respective companies.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd.

/s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO

Date: 01 Dec 2014

For 7810962 Canada Inc.

/s/ Alain Guimond PhD
Name: Alain Guimond PhD
Title: Senior Director of R&D

Date 01 Dec 2014

RedHill Biopharma Ltd.

/s/ Ori Shilo
Name: Ori Shilo
Title: Deputy CEO Finance & Operations

Date: 01 Dec 2014

Exhibit A Summary of Changes

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 4 for 7810962 Canada Inc. /RedHill Biopharma Ltd.

Overview of major level changes

Category	Contract	Start Up Work in [****] and [****]	Rationale for change
# of countries	[****]	[****]	Added [****] and [****]
# of sites	[****]	[****]	[****]
# of PSVs	[****]	[****]	[****]

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)	Start Up Work in [****] and [****]	Assumption Changes influencing the change in the budget	Additional comments
Site Visit Travel	[****]	[****]	[****]	
Investigators' Meeting Organisation	[****]	[****]	No change.	
Kick-off Meeting Travel/Attendance	[****]	[****]	No change.	
Shipping/Photocopying	[****]	[****]	No change	
Translation	[****]	[****]	No change	

Task	Current (USD)	Start Up Work in [****] and [****]	Assumption Changes influencing the change in the budget	Additional comments
Regulatory Fees	[****]	[****]	No change	
Ethics Committee Fees	[****]	[****]	No change	
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)	Start Up Work in [****] and [****]	Change	Assumption Changes influencing the change in the budget	Additional comments
Pre-study Activities					
Case Report Form Preparation/Review	[****]	[****]	[****]	[****]	[****]
Data Management Plan Preparation/Review	[****]	[****]		[****]	
Informed Consent Preparation/Review	[****]	[****]	[****]	[****]	[****]

Task	Current (US Dollars)	Start Up Work in [****] and [****]	Change	Assumption Changes influencing the change in the budget	Additional comments
IRB/Ethics Committee Interactions	[****]	[****]		No change	
Investigators' Meetings	[****]	[****]	[****]	[****]	[****]
Investigator Site Contract	[****]	[****]	[****]	[****]	[****]
Investigator Recruitment	[****]	[****]	[****]	[****]	[****]
Project Feasibility	[****]	[****]	[****]	[****]	[****]
Project Plan Preparation/Review	[****]	[****]	[****]	[****]	[****]
Protocol Preparation/Review	[****]	[****]	[****]	[****]	[****]

Task	Current (US Dollars)	Start Up Work in [****] and [****]	Change	Assumption Changes influencing the change in the budget	Additional comments
Randomization Schedule Preparation	[****]	[****]		No change	
Study-Specific Form Preparation	[****]	[****]		No change	
Training - Project-Specific	[****]	[****]	[****]	[****]	[****]
Translations	[****]	[****]		No change	
PROMIS	[****]	[****]	[****]	[****]	[****]
Monitoring/Site Management					
Data Clean-up	[****]	[****]		[****]	
Investigator Grant Administration	[****]	[****]		[****]	[****]
Laboratory Report Review	[****]	[****]		[****]	
Serious/Significant Adverse Event Management	[****]	[****]		[****]	
Site Management	[****]	[****]		[****]	
Remote Monitoring of Site Data	[****]	[****]		[****]	
Site Visits - Pre-study Visits	[****]	[****]	[****]	[****]	[****]
Site Visits - Initiation Visits	[****]	[****]		[****]	[****]

Task	Current (US Dollars)	Start Up Work in [****] and [****]	Change	Assumption Changes influencing the change in the budget	Additional comments
Site Visits - Routine Visits conducted on site	[****]	[****]		[****]	[****]
Site Visits - Close-out Visits at each site at Study End	[****]	[****]		[****]	[****]
Study Master File/Project File Set-up and Maintenance	[****]	[****]		[****]	[****]
Patient/Site Recruitment	[****]	[****]		[****]	
Client/CRO meeting	[****]	[****]		[****]	
Regulatory					
Regulatory Documentation Preparation/Review	[****]	[****]	[****]	[****]	[****]
Project Management /Project Tracking					
Financial Project Management	[****]	[****]		[****]	
Project Management	[****]	[****]	[****]	[****]	[****]

Task	Current (US Dollars)	Start Up Work in [****] and [****]	Change	Assumption Changes influencing the change in the budget	Additional comments
Project Tracking / Communications	[****]	[****]		[****]	
Vendor Management	[****]	[****]		[****]	[****]
Data Management					
Database Archiving	[****]	[****]		[****]	
Data Cleanup (DM)	[****]	[****]		[****]	
Data Management: Database Quality Control Inspection	[****]	[****]		[****]	
Database Design	[****]	[****]		[****]	[****]
Dictionary Coding	[****]	[****]		[****]	
Edit Check Programming	[****]	[****]		[****]	
Electronic Data Import	[****]	[****]		[****]	
Case Report Form Data/Document Transfers	[****]	[****]		[****]	
EDC Fees	[****]	[****]		[****]	
Statistical Analysis and Table Generation					
Electronic Data Transfer	[****]	[****]		[****]	
Interim Analysis/Report Preparation and Review	[****]	[****]		[****]	
Statistical Analysis Plan Preparation/Review	[****]	[****]		[****]	
Table Generation	[****]	[****]		[****]	
Table/Listings Review	[****]	[****]		[****]	

Task	Current (US Dollars)	Start Up Work in [****] and [****]	Change	Assumption Changes influencing the change in the budget	Additional comments
Clinical Study Report					
Clinical Study Report Preparation/Review	[****]	[****]		[****]	
Team Meetings					
Project Team Meetings - Internal Meetings	[****]	[****]	[****]	[****]	[****]
Project Team Meetings - Client Teleconferences	[****]	[****]		[****]	
Project Team Meetings - Kick-off Meeting	[****]	[****]		[****]	
Total Direct Costs	**[****]**	**[****]**			

Total Costs

Category	Total Costs($)		
	Current Contract (USD)	Change in Scope # 4 (USD)	Revised Total (USD)
Pass-Through Costs	[****]	[****]	[****]
Investigator Grants Costs	[****]		[****]
Professional Fees	[****]	[****]	[****]
Discount	[****]	[****]	[****]
Revised Professional Fees	**[****]**	**[****]**	**[****]**
Grand Total	**[****]**	**[****]**	**[****]**

Exhibit B Payment Schedule

1. PAYMENT TERMS

A. Service Fees:

[****]

2. Pass Through Costs:

(a) CO#2: [****] of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling [****], will be due and payable upon execution of this Agreement. 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.

(a) CO#3: [****] of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling [****], will be due and payable upon execution of this Agreement. 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#4: This is a one time payment of [****] (exclusive of funds for investigator grants), that will be due and payable upon execution of this Agreement.

(c) Actual pass-through expenses, as provided in the expenses estimate, will be billed as incurred by inVentiv Health Clinical

(d) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

3. Investigator Grants:

(a) [****]

(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 [****]

(d) All services and pass-through payments should be sent via wire or ACH

(e) All services and pass-through payments should be sent via wire or ACH

Exhibit 4.16

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Dror Ben-Asher
CEO
RedHill Biopharma ltd.
21 Ha'arba'a Street
Tel Aviv 64739
Israel

July, 5th 2011

Dear Mr Ben-Asher,

Reference is made to Master Service Agreement executed between 7810962 Canada Inc. and Redhill Biopharma Ltd on 28 April 2011 in relation to RedHill's RHB-104 program.

This letter is to confirm that 7810962 Canada Inc agree to extend our undertakings and obligations to the development of RHB-105. The extension of our obligations does not oblige 7810962 Canada Inc. to perform particular studies or services for the development of RHB-105 and any studies or services that we perform for Redhill Biopharma Ltd will be following our written approval.

This letter agreement shall be construed and enforced in accordance with, and the rights of the parties shall be exclusively governed by, the laws of the United Kingdom. Any disputes arising out of this agreement shall be submitted to the exclusive jurisdiction of the courts of London, England and all proceedings shall be drafted and conducted using only the English language.

Yours sincerely,

/s/ Alain Guimond PhD
Name: Alain Guimond PhD
Function: Senior Director of Research
Date: July 5th, 2011

For acknowledgement and agreement:

Name: Dror Ben-Asher
Function: CEO, RedHill Biopharma Ltd.
Date: July 5, 2011

Exhibit 1: Letter Agreement dated 28 April 2011

Exhibit 1 – Terms of Service Agreement with 7810962 Canada Inc

BETWEEN: **7810962 Canada Inc.,** a corporation duly incorporated under the laws of Canada and having its principal place of business at 5320 13e Avenue, Montréal, Québec, H1X 2X8;

(hereinafter referred to as "**7810962**")

AND: RedHill Biopharma Ltd., a corporation duly incorporated under the laws of Israel and having its principal place of business at 21 Ha'arba'a Street, Tel Aviv 64739, Israel;

(hereinafter referred to as the "**Client**")

When signed by both parties, this Exhibit will form an integral part of the Master Agreement executed between them on the date hereof and will set forth the specific services, details and schedule as well as the specific payment terms and conditions under which the Client agrees that 7810962 will provide manufacturing development services for the Client's RHB-105 product.

Terms:

The Client agrees that 7810962 enters into a subcontract with [****] Pharma Inc. on the terms set out in the Proposal to be executed between 7810962 and [****] Inc. as shown below in Exhibits 2. For further clarity, the Client agrees with the cost described in Exhibit 2 and agrees to the payment schedule as described in Exhibit 2.

IN WITNESS WHEREOF, this Proposal has been executed by the parties hereto through their duly authorized officers on the date(s) set forth below.

For the Client:

Name: Dror Ben-Asher
Title: CEO
Date: July 5, 2011

For 7810962:
/s/ Alain Guimond PhD
Name: Alain Guimond PhD
Title: Senior Director of Research
Date: July 5, 2011

Exhibit 2

Service Agreement - A
Formulation development of RHB-105 in oral solid dosage form and manufacture of Phase III Clinical Trial Supplies

THIS SERVICE AGREEMENT is made and entered into this 5th day of July, 2011 (the "**Service Agreement**").

BETWEEN: [****], a corporation duly incorporated under the laws of Canada and having its principal place of business at [****];

(hereinafter referred to as "[****]")

AND **7810962 Canada Inc.,** a corporation duly incorporated under the laws of Canada and having its principal place of business at 5320 13e Avenue, Montréal, Québec, H1X 2X8;

(hereinafter referred to as the "**Client**")

([****] and the Client are at times referred to individually as the "Party" and collectively the "Parties")

RECITALS

A. The Client and [****] entered into a Master Service Agreement dated July 5, 2011 (the "**MSA**").

B. The Parties hereto wish to describe the services to be performed in connection with the MSA, subject to the terms and conditions set forth herein and in the MSA.

C. Unless the context otherwise requires, all capitalized terms used in this Service Agreement shall have the meanings attributed to them in the MSA.

1. INTERPRETATION

The recitals of this Service Agreement as well as all of its Appendices form an integral part of this Service Agreement.

2. DESCRIPTION AND DELIVERABLES

2.1- [****] study
The Drug-Drug compatibility study will be limited to [****] and [****] since [****] these molecules have [****] (i.e. [****] and [****] respectively) and thus it is highly probable that they will [****] the [****] moleculewhich is very [****] in an [****] environment. The [****] and [****] will be [****] under [****] and [****] conditions and stored in [****] and [****] containers under the following conditions of temperature and humidity: The mixture will be and for their (and) at each time points

Storage Condition	Time point (Day)		
	Initial	[****]	[****]
[****]	[****]	[****]	[****]
[****]		[****]	[****]

X: Sample to be analyzed.
Y: Sample removed from chamber and analyzed only at the request of Client if the [****] sample fails in stability.

Cost: [****]
* Cost based on the analysis of the two APIs (i.e., [****] and [****]) for [****] samples ([****] X 4 conditions ([****] [****] [****] and [****]) X 3 time points) at $ [****]/sample AND [****] analytical set-ups ([****] time points [****]/ time point) at $[****]/ set-up.

2.2- Formulation development

Three drug products will be developed:

- [****] ([****] [****] and [****]), and;
- [****] ([****] [****] and [****]), and;
- [****] ([****] [****] and [****]).

The following processes will be considered: [****] followed by [****]. [****] will be [****]. [****] will be assessed by [****] and [****] profile with [****].The formulation should be [****] in capsule [****]. [****] will be considered.

Cost: [****]

2.3- Analytical method development and analysis

[****] will perform the development and optimization of the analytical methods based on [****] The methods are [****], [****], [****], [****], [****] as well as all necessary methods including, but not limited to, [****] and [****] method for the manufacturing of the Phase III CTM (as required by the FDA). Also in support of the formulation development activities (i.e., section 2.2) the [****] analytical group will support the formulators by executing the analyses required for rapid development of the Drug Product.

Cost: [****]

2.4- Stability of prototype formulations

[****] will provide the following:

- Justification of up to [****] for non-GMP stability study;

- Manufacturing and packaging of up to [****];
- Sample incubation under the following conditions of temperature and humidity: [****];
- Justification of finished product specifications;
- Physico-chemical characterization at each of the following conditions (Includes: Appearance, Assay*, Degradation Products*, Dissolution* and Water content).

The samples will be placed in [****] stability chambers and the following stability testing schedule will be used:

Storage Condition	Time point ([****])						
	Initial	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

X: Sample to be analyzed.
Y: Sample removed from chamber and analyzed only at the request of Client.

Cost: $32,016**

* On the [****] APIs.

** The decision of testing the highest and lowest strength only and extrapolating the stability results to the middle dosage strength (bracketing) will be taken by the Client.

*** Based on [****]/ sample using a bracketing study design.

2.5- Manufacturing of the Phase III Clinical Trial Material (CTM)

The CTM manufacturing, packaging, equipment calibration and validation, cleaning and raw material release will be done by [****] GMP laboratory. All the manufacturing, packaging and analytical equipments that will be used for this CTM manufacturing project will be calibrated, validated and released for their cleanliness prior to their utilization.

2.5 a) GMP material storage and handling

[****] will handle the reception, the shipping and the storage of GMP materials in its cGMP warehouse. All material handling operations and storage conditions will respect the ICH GMP requirements.

Cost: $1,455*

* **The cost includes:**

- the reception of one lot of each of the three GMP APIs (i.e., documentation review, material registration in [****] inventory, and material sampling following GMP requirements) (If API lot is in more than one container then the sampling and ID testing of each of the additional containers will be considered Extra Work at [****]/additional container),
- the ID testing for the release of the three lots of APIs (one for each API) using validated methods. (Client will ship the GMP APIs to [****] with the complete certificate of analysis otherwise Extra Work may be required to release the GMP APIs.),
- the GMP warehousing of the API and the drug product until completion of the study. If the material needs to be stored for a longer period of time then the storage cost will be [****].
- the shipping document preparation and shipment of material.

The cost does not include:

- The purchase of the analytical reference materials to be used as a standard, if needed, reference impurities (synthesis by-products, degradation products, metabolites) of known purity estimated cost is [****]. Subject to pre-approval in writing by the Client of the purchasing of the materials, [****] will order the materials. The cost of the materials and any related costs (e.g. transportation or custom fees) will be charged at cost to Client and will not exceed a cap of [****].
- Subject to pre-approval in writing by the Client, repackaging of material (if required) as well as the shipping cost and custom fees, if any, provided not exceeding a cap of [****].

2.5 b) GMP Manufacturing, packaging and labelling

[****] will manufacture and package the CTM from the selected Drug product formulation. The three dose strengths ([****], [****], and [****] or [****], [****],and [****]) of the selected solid dosage form and its matching placebo will be manufactured using the cGMP APIs supplied by Client. The placebo blend will be similar to the active blend except for the APIs. In addition to the CTM manufacture, [****] will perform all necessary receipt and release of required excipients, packaging components, and labels.

Specifically with respect to manufacturing, packaging and labeling, the followings items will be provided by [****]:

a) Recommendation and justification of specific finished product release, in process testing, stability as well as excipients and packaging components specifications,

b) Formulation and process information for the redaction of Master Manufacturing File (MMF)

c) The CTM will be manufactured and packaged/labeled in [****] bottles with induction seal at [****] units per bottle:

- [****] – [****] units*;
- [****] – [****] units*;
- [****] – [****] units*;
- RHB-105 placebo – [****] units*.

d) Monitoring and supervision of the manufacturing, packaging and analytical operations.

Cost: $136,875**,***

* Includes [****] capsules of [****] for the CTM [****] study: [****] bottles of [****] capsules/ time point/ condition and [****] bottles of [****] capsules for [****] (to be done [****]). It includes also [****] of placebo.

** Based on the hypothesis that the [****]. If the [****] then, subject to pre-approval in writing by the Client, the following CTM will be [****] at an additional cost of [****].

- [****] - [****] units;
- [****] - [****] units;
- [****] - [****] units;
- RHB-105 Placebo [****] units.

This same additional cost of [****] will apply in case the decision is taken to [****] detailed in [****].

*** If the manufacture of the placebo units is not needed then cost will be reduced by [****].

2.5 c) Analytical method validation

The analytical methods for the three strengths dosages developed by [****] will be validated in its GMP laboratory. The method will be validated according to ICH guidelines. The method for cleaning verification will also require complete validation.

Cost: $75,100*

* Includes analytical method validation of assay and content uniformity, related substances, and dissolution for the three strengths as well as for cleaning. If required and pre-approved in writing by the Client, the analytical method validation for the microbial limit will be done at an additional cost of [****].

2.5 d) Release testing and cleaning verification

The release of the CTM will be performed by the [****] GMP laboratory as well as the cleaning verification samples (swabs).

The placebo will also be tested for the absence of active.

Analyses to be performed are:

- [****]*,
- [****]*,
- [****],** [****]**,
- [****]**,
- [****]***,
- [****]****.

Cost: $23,383*****

* Analyse done also on placebo.

** For the [****] APIs.

*** A dissolution test is [****].

**** Done only if requested by the Client.

***** Cost includes the release of one lot of each of the three strengths as well as one lot of placebo. If required and pre-approved in writing by the Client, the analysis of microbiolgy will be done at an extra cost of [****].

2.5 a) Stability of the CTM

The CTM will be stored in a cGMP stability chamber at [****]. Two strengths of the finished product (highest and lowest dose strengths)** will be characterized for appearance, assay, related substances, dissolution* and water content using the schedule below. Placebo will be placed at [****] for appearance, water content and used for degradation products background subtraction and will be analyzed only if needed.

The samples will be placed in cGMP stability chambers and analyzed using validated methods. The following stability testing schedule will be used and modified per mutual agreement:

Storage Condition	Time point [****]								
	Initial	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

X: Sample to be analyzed for appearance, assay, related substances, dissolution* and water content.

Y: Sample removed from chamber and analyzed only at the request of Client.

Cost: $88,800***

* A dissolution test is a single time point and six vessels/ time point.

** The decision of testing only the highest and lowest dose strength and extrapolating the stability results to the [****] will be taken by the Client.

*** Based on the analysis of [****] using a bracketing study design. The analyses of placebos [****] will be done only if requested and pre-approved in writing by the Client and they are not included in the cost above.

2.6- Reports and submission documentation

- **Telephone meetings** will be held on a weekly basis on a specific day of the week and at a specific time agreed to by the Parties.
- **Client or Client's representative** meeting in [****] facility will be held at Client's request.
- [****] **facility and quality audit** by Client's or Client's representative will be held at Client's request.
- **Progress reports** will be provided on a weekly basis.
- **Item reports** will be provided as they are completed.

- The **final development report(s)** will include the followings:
  - The methodology and the results;
  - The finished products release & stability specifications, in process specifications and specific APIs, excipients and packaging specifications. Specifications will be provided, for US submissions;
  - The final formulation and manufacturing process.
- A **final manufacturing process report** will be provided at the end of the study. It will include all the necessary submission documents related to manufacturing and packaging which include (but are not limited to):
  - The finished products release & stability certificate of analysis.
  - In process results.
  - QA Reviewed and audited Manufacturing and Packaging Documents.
  - Certificate of cGMP compliance.
  - Certificate of analysis of raw materials and packaging components.
  - Any atypical report or Out-of-Specification reports.

Cost: $[****]*

* Based on a value of[****] of the sub-total of all invoices before taxes. If [****], [****] and [****] are selected for the manufacturing of the CTM, then the cost for section 2.6 will be $[****].

3. GENERAL PROJECT TIMELINES

[****]

4. STARTING DATE AND COMPLETION

4.1 Notwithstanding the date of signature of this Service Agreement, **[****]** shall start the performance of the Services within ten (10) business days after **[****]** satisfaction of the following:

4.1.1 signature by the Client of this Service Agreement; and

4.1.2 complete delivery by the Client of all of the items mentioned at sub-sections 6.1 to 6.3 inclusive of section 6 hereof entitled "REQUIREMENTS".

4.2 This Service Agreement shall be deemed completed upon full delivery of the Services by **[****]** and receipt by **[****]** of the final and last payment for the Services.

5. ASSUMPTIONS

5.1 The target formulation of RHB-105 will be the following drug products with the three actives (The 'APIs') combined with pharmacopeia excipients and compressed or encapsulated:

- [****] with [****], [****], and [****]
- [****] with [****], [****], and [****]
- [****] with [****], [****], and [****]

In the event that **[****]** the **[****]** will be considered **[****]**:

- [****] with [****], [****], and [****]
- [****] with [****], [****], and [****]
- [****] with [****],[****], and [****]

The best efforts will be made by **[****]** to select excipients and processes that will comply with the anticipated cGMP manufacturing site.

5.2 The best efforts will be made by **[****]** to reduce the project timelines.

5.3 When decisions need to be taken to move forward in the project at the decision time point, the Client will provide its decision in writing to **[****]** within a period of 5 days. Otherwise the project may be delayed. **[****]** will develop a final timeline for this project and all deviations will be immediately reported to the Client. **[****]** will make its best efforts to correct all deviations in order to maintain the project timelines.

5.4 All APIs will be sourced by Client. Non-GMP material can be used in the development phase however it should be of identical quality as the GMP material that would be use in the GMP manufacturing.

6. REQUIREMENTS

The Client shall provide to [****], at no cost to [****], the following:

6.1 All the available information on APIs (e.g.: interactions, stability, impurities).

6.2 The APIs, reference materials to be used as a standard, reference impurities (synthesis by-products, degradation products, metabolites) of known purity, certificate of analysis and APIs' MSDS.

6.3 For the formulation development, a minimum quantity of [****] of [****] [****] of [****] and [****] of [****] as well as sufficient quantities of related substances (standards, references, impurities) for each APIs.

6.4 For cGMP manufacturing of CTM, a minimum quantity of [****] of [****] [****] of [****] and [****] of [****] will be required.

7. COST AND PAYMENTS

7.1 The cost of the Services is up to $[****] ($[****] with a rebate of $[****])or up to $[****] if the placebo manufacture are not required (section 2.5 b)). Any amount exceeding a total of $[****] requires a pre-approval in writing by the Client.

7.2 The Client shall pay to **[****]** the following installments in United-States currency ($USD):

7.2.1 $[****] upon signature of this formulation development project Agreement; and

7.2.2 $[****] at the initiation of the stability study for the prototypes; and

7.2.3 $[****] ($[****] if placebo manufacture are not required) at the initiation of the CTM manufacturing; and

7.2.4 $[****] ($[****] if placebo manufacture are not required) at the completion of the CTM manufacturing report issued by [****]; and

7.2.5 $[****] at the acceptance of the final CTM manufacturing process report by the Client in writing as a final report; and

7.2.6 Stability studies (prototypes **[****]** (as per section 2.4) and CTM **[****]** as per section 2.5 e) to be invoiced as per the following schedule of payment.

Installments for the stability of prototype formulations

Expected date that material will be introduced in stability chamber	[****]	Time Point [****]	
	0		1
Date of pull out	[****]		[****]
Date Results available	[****]		[****]
Month of invoice	[****]		[****]
Amount to be invoiced	[****]		[****]

Installments for the CTM stability study

Expected date that material will be introduced in stability chamber		[****]	
		Time Point [****]	
	1		2
Date of pull out	[****]		[****]
Date Results available	[****]		[****]
Month of invoice	[****]		[****]
Amount to be invoiced	[****]		[****]
		Time Point [****]	
	[****]		[****]
Date of pull out	[****]		[****]
Date Results available	[****]		[****]
Month of invoice	[****]		[****]
Amount to be invoiced	[****]		[****]
		Time Point [****]	
	[****]		[****]
Date of pull out	[****]		[****]
Date Results available	[****]		[****]
Month of invoice	[****]2		[****]
Amount to be invoiced	[****]		[****]
		Time Point [****]	
	[****]		[****]
Date of pull out	[****]		[****]
Date Results available	[****]		[****]
Month of invoice	[****]		[****]
Amount to be invoiced	[****]		[****]

7.3 Notwithstanding section 7.1, for any extra work not covered by this Service Agreement and agreed upon in writing between the Parties (the "Extra Work"), the Client shall pay to **[****]** the hourly rates and other fees indicated in this Appendix I attached hereto for the performance of the Services (The costs of the Services for the Extra Work and described in section 7.1 are collectively, the "**Fees**").

7.4 Notwithstanding section 7.2 hereof, **[****]** will invoice the Client for the Extra Work, on a monthly basis for the Services that have been delivered or rendered by **[****]**. The Client shall pay **[****]** for these Services to the extent their performance has been pre-approved in writing by the Client.

8. CONFIDENTIALITY

8.1 Confidentiality issues are covered per the Non Disclosure Agreement and the MSA.

9. REPRESENTATIONS AND WARRANTIES

9.1 **[****]** hereby represents and warrants to the Client that:

9.1.1 it is a duly organized and validly existing corporation under the laws of the jurisdiction in which it is incorporated;

9.1.2 it has the necessary corporate power, authority, skills, and capacity and is properly authorized to enter into this Service Agreement and to perform its obligations as per the terms and conditions of this Service Agreement. The execution and delivery of this Service Agreement and the performance of the transactions contemplated hereby have been duly authorized.

9.2 The Client hereby represents and warrants to [****] that:

9.2.1 it is a duly organized and validly existing corporation under the laws of the jurisdiction in which it is incorporated;

9.2.2 it has the necessary corporate power, authority, skills, and capacity and is properly authorized to enter into this Service Agreement and to perform its obligations as per the terms and conditions of this Service Agreement. The execution and delivery of this Service Agreement and the performance of the transactions contemplated hereby have been duly authorized;

10. TERMS AND CONDITIONS

10.1 This Service Agreement shall be governed, construed and interpreted according to the laws in force in the Province of Quebec and the applicable laws of Canada therein, and the courts of the legal district of Montreal, province of Quebec (Canada) shall have exclusive jurisdiction to hear any and all disputes arising hereunder.

10.2 This Service Agreement is subject to the terms and conditions provided in the MSA and bind the parties as well as their respective successors, permitted assigns and legal representatives.

10.3 This Service Agreement may be executed in counterparts, each of which shall be deemed to be an original and which together shall constitute one and the same agreement. This Service Agreement may also be executed between the Parties by exchange of facsimile transmissions or electronic transmissions in legible form, including without limitation in a tagged image format file (TIFF) or portable document format (PDF).

10.4 The Parties hereto have requested that this Service Agreement be drafted in the English language. Les Parties ont exigé que ce contrat de services soit rédigé en anglais.

IN WITNESS THEREOF, the Parties have executed this Service Agreement as of the Date written above, by their authorised representatives, who by signing confirm their authority and intention to bind the Parties they represent.

[****] Pharma Inc.

Per: /s/
Name:[****]
Title: VP Pharmaceutical R&D

7810962 Canada Inc.

Per: /s/ Alain Guimond PhD
Name: Alain Guimond PhD
Title: Senior Director of Research

[****] Contract Formulation and Process Development

Professional Consultation Rates

Professional (Chemist or Engineer)	**Hourly Rate***, ** ($USD)
Senior scientist Scientist Technician	$240.00 $200.00 $110.00
R&D laboratory overhead (Equipment and supplies)	$ 75.00***

Analytical Services

Analyses	**Cost / Sample *** ($USD)
XRPD	[****]
SEM	[****]
TGA	[****]
DSC	[****]
Water Content (Karl Fisher)	[****]
Single point dissolution test/ vessel ****	[****]
Assay****	[****]
Related Substances****	[****]
Disintegration	[****]
Hygroscopicity (5 conditions)	[****]
Solubility in water at pH 2, 4.5 and 7	[****]
Flow, Grinding and Compressibility	[****]
Particle Size and Distribution	[****]
Bulk and Tap Density	[****]
Organoleptic (texture, color, appearance)	[****]

* Prices can be changed by [****] without any prior notice. Prices apply only for non GMP work and analysis. GMP prices will be supplied on demand.
** All expenses will be charged at cost.
*** Will be invoiced in addition to the professional fees when laboratory work is required.
**** A set-up charge of $[****]/ HPLC method will be invoiced in addition to the sample cost.

Exhibit 4.17

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT 1 TO THE SERVICE AGREEMENT A is made and entered in August 17th, 2011 (the "**Amendment**").

1. DESCRIPTION OF THE EXTRA WORK

Approximately 1 g of [****] lot number [****] was received from [****][****] for supplier qualification.

A supplier qualification analysis will have to be performed and will consist of verification of the results included in the certificate of analysis of the supplier. The following tests will be performed on this lot:

1. IR (90$),
2. Assay (130$),
3. Impurities (190$)
4. Water content (85$).

2. COST AND PAYMENTS

2.1 The cost of the Services for the Extra Work detailed in section 1 is $495 USD.

2.2 The Client shall pay to [****] in United-States currency ($USD) upon the reception of the invoice.

IN WITNESS THEREOF, the Parties have executed this Amendment as of the Date written above, by their authorised representatives, who by signing confirm their authority and intention to bind the Parties they represent.

[****]

Per: /s/
Name: [****]
Title: President

7810962 Canada Inc.

Per: /s/ Alain Guimond PhD
Name: Alain Guimond PhD
Title: Senior director of Research

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Service Agreement – A
Formulation development of RHB-105 in oral solid dosage form and manufacture of clinical supplies
Amendment 2

AMENDMENT 2 TO THE SERVICE AGREEMENT A is made and entered in September 30th, 2011 (the "**Amendment**")

1. DESCRIPTION OF THE EXTRA WORK

Reception, the shipping and the storage of one additional Lot of Rifabutin and Omneprazole in [****]' GMP warehouse as per section (2.5 a) service agreement A

Charges as per the following table:

Description	Amount
Extra Work as per section (2.5 a) service agreement A:	
• Omeprazole customs charges (Ref.: invoice no. 407084173 1-01) ($442.74 CDN x 0.96 (exchange rate))	$425.03
• Omeprazole customs charges & local transportation (Ref.: invoice no. 407084173 1-02) ($ 145.00 CDN x 0.96 (exchange rate))	$139.20
• Rifabutin customs charges (Ref.: invoice no.407083673 1-01) ($ 105.00 CDN x 0.96 (exchange rate))	$100.80
• GMP material storage & handling for 1 additional Lot of Omeprazole	$200.00
• Technical support 0.5 hours ($ 250.00/hours)	$125.00
Total charges ($USD)	$990.03

2. COST AND PAYMENTS

2.1 The cost of the Services for the Extra Work detailed in section 1 is $ 990.03

2.2 The Client shall pay to [****] the following installments in United-States currency ($USD) upon reception of the invoice.

IN WITNESS THEREOF, the Parties have executed this Amendment as of the Date written above, by their authorised representatives, who by signing confirm their authority and intention to bind the Parties they represent.

[****]

Per: /s/
Name: [****]
Title: President

7810962 Canada Inc.

Per: /s/ Alain Guimond PhD
Name: Alain Guimond PhD
Title: Senior director of Research

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Service Agreement – A
Formulation development of RHB-105 in oral solid dosage form and manufacture of clinical supplies
Amendment 3

AMENDMENT 3 TO THE SERVICE AGREEMENT A is made and entered in April 19th, 2012 (the "Amendment").

1. DESCRIPTION OF THE EXTRA WORK

The Client requested that the GMP Omeprazole magnesium API and GMP Amoxicillin API and GMP Rifabutin API would be analyzed by [****] at their reception at the [****] facility for full testing and not only ID testing.

a. GMP Omeprazole magnesium API analytical release testing

ITEM	Cost (USD$)
ID testing	
IR-Method qualification, set-up and analysis*	0$
[****]	200$
Assay	
Method qualification	2,000$
Set-up	605$
Analysis	575$
Related substances	
Method qualification	2,500$
Set-up**	0$
Analysis	795$
Residual solvents	
Method A: [****]	
[****]	14,000$
Analysis	1,200$
Water - Karl Fisher Titration (USP <921>)	
Analysis	165$
Appearance	
Analysis	85$
[****]	
Analysis	75$
[****]	
Analysis	170$
[****]	
Analysis	550$
Report****	688$
Sub total for section 1. a.	23,608$

b. GMP Amoxicillin trihydrate API analytical release testing

ITEM	Cost (USD$)
ID testing	
IR-Method qualification, set-up and analysis*	0$
Assay	
Method qualification	2,000$
Set-up	605$
Analysis	575$
Related substances	
Method qualification	2,500$
Set-up**	0$
Analysis	795$
pH	
Analysis	85$
Residual solvents	
[****]	
[****]	
[****]	
[****]	30,000$
[****]	1,800$
Water - Karl Fisher Titration (USP <921>)	
Analysis	165$
Appearance	
Analysis	85$
Crystallinity	
Analysis	550$
Report****	1,175$
Sub total for section 1. b.	**40,335$**

Service Agreement – A
Formulation development of RHB-105 in oral solid dosage form and manufacture of clinical supplies
Amendment 3

c. GMP Rifabutin API analytical release testing

ITEM	Cost (USD$)
ID testing	
IR-Method qualification, set-up and analysis*	0$
[****]	575$
Assay	
Method qualification	2,000$
Set-up	605$
Analysis	575$
Related substances	
Method qualification	2,500$
Set-up**	0$
Analysis	795$
Water - Karl Fisher Titration (USP <921>)	
Analysis	165$
Limit of N-Iso Butylpiperidone (TLC)	
Qualification, set-up and analysis	1,650$
Residual solvents	
[****]	
[****]	
[****]	24,000$
Analysis	1,800$
Qualification [****] ***	
	2,000$
Appearance	
Analysis	85$
Report**	1,103$
Sub total for section 1. c.	**37,853$**
Total cost of the amendment	**101,795$**

* **Already included in Service Agreement A.**
** **Included in the set-up cost of the Assay.**
*** **Analysis to be outsourced to a [****] qualified vendor. [****] in Toronto using the validated analytical methods of [****].**
**** **Cost for the documentation and the CofA- 3% of the total cost of the analysis.**

Service Agreement – A
Formulation development of RHB-105 in oral solid dosage form and manufacture of clinical supplies
Amendment 3

2. COST AND PAYMENTS

2.1 The cost of the Services for the Extra Work detailed in section 1 is:

2.1.1 $101,795 if the following installments are:

- 50% at the signature of this Agreement; and
- the balance at the completion of the release testing.

OR

2.1.2 $89,783 if $89,783 is paid within 7 days from the signature of this Agreement.

2.2 The Client shall pay to [****] the following installments in United-States currency ($USD):

3. TIMELINES FOR AMENDMENT 3

[****]

IN WITNESS THEREOF, the Parties have executed this Amendment as of the Date written above, by their authorised representatives, who by signing confirm their authority and intention to bind the Parties they represent.

[****]	7810962 Canada Inc.
Per: /s/	Per: /s/ Alain Guimond PhD
Name: [****]	Name: Alain Guimond PhD
Title: President	Title: Senior director of Research

Exhibit 4.20

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

MASTER SERVICES AGREEMENT

This Master Services Agreement ("Agreement") is entered into effective as _____ __, 2012 by Clinipace, Inc. ("Clinipace") a Delaware Corporation located at 3800 Paramount Parkway Suite 100 Morrisville, NC 27560 and RedHill Biopharma LTD ("REDHILL") a pharmaceutical company with offices at 21 Ha'arba'a St. Tel Aviv 64739, Israel.

Recitals:

REDHILL is engaged in the business of developing, manufacturing and/or distributing pharmaceutical products. REDHILL desires to engage Clinipace to provide certain services as described herein subject to the terms and conditions of this Agreement.

Clinipace is engaged in providing clinical trial services, research and related software applications that support the management of clinical research projects. Clinipace possesses the experience, expertise and qualifications to perform the services required herein. Clinipace desires to provide services as described herein subject to the terms and conditions of this Agreement.

Agreement:

In consideration of the mutual covenants and agreements contained herein, the parties hereto agree as follows:

(1) Definitions

(a) Services. The services provided by Clinipace to REDHILL by virtue of this Agreement, as described in article 2 of this Agreement and any other Services specified in any Attachment.

(b) Tempo Website. The term "Tempo Website" shall mean the web pages accessible via the Internet through which among other tools, grant applications, study forms, reports and data are made accessible to REDHILL or authorized REDHILL Designees, and through which Services are provided by Clinipace.

(c) REDHILL Content. The term "REDHILL Content" shall mean all information provided by REDHILL to be included on the Website, or entered by REDHILL Designees via the Website, including without limitation, protocol descriptions, training materials, case report forms, study data, other forms and, images, trademarks, logos, photographs, or information created by Clinipace for the Website based on material provided by REDHILL.

(d) REDHILL Designees. The term "REDHILL Designee" shall mean any person authorized by REDHILL to have access to the Website, for purposes of study conduct including protocol training, entering data, editing data, querying data, and reviewing reports.

(e) Errors. The term "Errors" shall mean any failure of the Tempo Website to conform to the "Specifications," as defined herein. Notwithstanding the foregoing, any nonconformity resulting from the alteration or misuse of the Tempo Website by REDHILL or REDHILL Designees shall be not an Error.

(f) Internet. The term "Internet" shall mean the principal international network interconnecting computers and other networks through the Internet Protocol and all web pages and web sites that can be accessed thereby.

(g) Web Server. The term "Web Server" shall mean all of the shared hardware and software located at Clinipace's location or at such other location as may be designated by Clinipace that are necessary to host the Tempo Website and to make the Tempo Website available to REDHILL Designees on the Internet.

(h) Tempo. The term "Tempo" shall mean the application software that powers the Tempo Website and resides on the Web Server at Clinipace's location.

(i) Agreement. This Master Services Agreement as well as any Attachments to it.

(2) <u>Services</u>.

(a) The Services covered by this Agreement may include strategic planning, expert consultation, clinical trial services, statistical programming and analysis, data processing, data management, regulatory, clerical, project management, central laboratory services, preclinical services, pharmaceutical sciences services, medical device services, electronic data capture and other research and development services requested by REDHILL. Each time REDHILL wants to engage Clinipace to provide Services, a detailed description of the Services will be described in one or more statements of work (each an "Attachment") to be executed by the parties pursuant to this Agreement ("**Attachment** A-1, A-2, A-3 and so on"), which will be attached hereto and incorporated herein. The specific terms and conditions of each engagement will be delineated in the applicable Attachment, which shall be sequentially numbered and incorporated herein by reference. In the event of any conflict between the terms of this Agreement and in any Attachment, the terms of the Attachment shall prevail. For the avoidance of doubt, the mere signature of this Agreement does not result in any obligation on behalf of REDHILL to engage Clinipace to provide any Services.

(b) Once the parties have agreed on the terms and conditions of an Attachment, the following shall apply to any Change Order. Any (a) meaningful change in the details of the scope of Services, even if a fixed price Attachment, or (b) meaningful change in the assumptions upon which the Attachment is based may require changes in the budget and/or time lines, and shall require a written amendment to the scope of Services (a "**Change Order**"). For the avoidance of doubt, any Change Order has to originate from a quantifiable change of scope of the study. A delay in study initiation will not be considered a change to the study's scope so long as Clinipace's provision of Services has not begun. Each Change Order shall detail the requested changes to the applicable task, responsibility, duty, budget, time line or other matter. The Change Order will become effective upon the execution of the Change Order by both parties, and will include a specified period of time (as agreed upon by the parties) within which Clinipace will implement the changes. Both parties agree to act in good faith and promptly when considering a Change Order requested by the other party. Clinipace reserves the right to postpone effecting material changes in the Project's scope until such time as the parties agree to and execute the corresponding Change Order. For any Change Order that affects the scope of the regulatory obligations that have been transferred to Clinipace, if any, Clinipace and REDHILL shall execute a corresponding amendment to any form documenting the transfer of regulatory responsibilities as described in 21 CFR 312.52. REDHILL shall provide all appropriate changes on the FDA 1571 form (Investigational New Drug Application) and will file such amendment where appropriate, or as required by law or regulation.

(3) Term.

Subject to the termination provisions set out in article 15 of this Agreement, this Agreement shall commence as of the effective date and shall continue for a period of three (3) years (the "**Term**") and shall automatically renew for additional one (1) year periods, unless (i) either party provides prior written notice of its intent to terminate thirty (30) days prior to the annual renewal period.

Each individual Attachment issued hereunder will start on the date executed (the project "**Effective Date**") and shall terminate on the later of (i) the date final deliverables are delivered to REDHILL, or (ii) final payment is made to Clinipace by REDHILL; provided, however, that any Attachment may be terminated under the provisions thereof. Unless the specific Attachments provide otherwise, REDHILL shall at all times be entitled to terminate the Services on a project, subject to paying the fees and costs up to the date of such termination, as well as all noncancelable expenses arising as the direct result of the Attachment of the termination thereof.

(4) Fees.

(a) Clinipace shall be paid fees for the Services performed at REDHILL's request pursuant to the fee schedule set forth on any Attachment attached hereto and incorporated herein ("**Fee Schedule**"). Clinipace shall invoice REDHILL according to the invoice schedule set forth on any Attachment, such invoice to include a description of the Services performed at REDHILL's request and the total amount due for such Services pursuant to the Fee Schedule.

(b) The Attachment(s) shall set forth any taxes, duties or other fees that will be payable by REDHILL.

(c) REDHILL will also reimburse Clinipace for reasonable travel and other out-of-pocket expenses incurred in connection with this Agreement, which have the prior written approval of REDHILL (for which email shall suffice). All undisputed payments for expenses shall be made to Clinipace within thirty (30) days of REDHILL's receipt of an itemized statement from Clinipace, reflecting approved expenses, which shall include receipts for any and all expenses. It is understood and agreed that the compensation set forth in this section on Fees, and any relevant Attachment attached hereto and incorporated herein, shall be the total consideration for the Services rendered hereunder.

(c) REDHILL will remit invoice payments via Wire. Wire instructions will be included on A-1, A-2, A-3, etc.

(5) Confidentiality.

Each party acknowledges that they may disclose confidential or proprietary information or knowledge (hereinafter the "**Disclosing Party**"), to the other party (hereinafter the "**Receiving Party**") including, but not limited to, methods, software, product information or formulations, manufacturing information, research and studies, indications, marketing and sampling strategies, techniques and data, sales, customers, clients, personnel, patterns, compilations, survey, solicitation and advertising data, purchasing, pricing, and other financial data, or customer lists and information that (1) derives independent economic value, actual or potential, from not being generally known to, and not readily ascertainable by proper means, by other persons who can obtain economic value from its disclosure or use, and (2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy, and other items which constitute the property of the Disclosing Party ("**Trade Secrets**"). The parties agree not to divulge any Trade Secrets to third parties except as specifically required in performance of this Agreement and as approved in advance of such disclosure by the Disclosing Party. Trade Secrets exclude (i) information which now or hereafter enters the public domain through no action on the part of the Receiving Party in violation of the terms or conditions hereof, (ii) information which the Receiving Party can demonstrate was in his possession at the time of the disclosure and was not acquired directly or indirectly from the Disclosing Party on a restricted, confidential basis, (iii) information otherwise disclosed to others on an unrestricted, non-confidential basis, (iv) information that is independently developed by the Receiving Party without use of, or reference to the Disclosing Party's Trade Secrets, or (v) information which is required to be disclosed in the course of litigation or other legal or administrative proceedings or otherwise required by law; provided that in the event of a proposed disclosure under subsection (v), the Receiving Party shall give the Disclosing Party prompt notice of the pending disclosure and shall cooperate at the sole expense of the Disclosing Party, in attempts to seek an order maintaining the confidentiality of such information. The parties acknowledge that the Trade Secrets, as they may exist from time to time, are valuable, special, and unique assets of each party's business. The parties will not, except as otherwise set forth herein, during or after the Term, disclose such Trade Secrets or any part thereof to any person, firm, corporation, association, or other entity for any reason or purpose whatsoever, except in the limited manner authorized in this section. In addition, neither party will appropriate, disclose, remove, conceal or obliterate any trademark, patent, copyright or other proprietary rights of the other party, including Trade Secrets, without prior written consent of the owner. The parties agree that the Trade Secrets shall be disclosed only to the designated employees, directors, officers, representatives and business associates of each party who i) "need to know such information for the purposes of performance under this Agreement" and ii) are subject to a confidentiality agreement with substantially similar terms as those set out in this Agreement. In the event of a breach or threatened breach of the provisions of this paragraph, the Disclosing Party shall be entitled to an injunction restraining the Receiving Party from disclosing, in whole or in part, such Trade Secrets, or from rendering any services to any person, firm, corporation, association, or other entity to whom such Trade Secrets in whole or in part, have been disclosed or are threatened to be disclosed; in this regard, the parties acknowledge that damages resulting from the breach of this Agreement may well be impossible to measure and that monetary damages will not adequately compensate the Disclosing Party for a breach of this paragraph by the Receiving Party. Nothing herein shall be construed as prohibiting either party from pursuing any other remedies available to it for such breach, including the recovery of damages. The parties agree, upon written request, to return any Trade Secrets, business records and properties of the other party, including all documents or computer files used or prepared in connection with the Services and actions to be performed hereunder, except that one copy of such information shall be retained by the Receiving Party for archival purposes only.

(6) Publication.

Any proposed press release, announcement, disclosure, or publication, whether or not in writing, prepared by or on behalf of Clinipace as part of the Services under this Agreement or that relates to the work performed hereunder must be reviewed and approved in writing by REDHILL prior to dissemination, such approval not to be unreasonably withheld. Notwithstanding anything to the contrary, Clinipace may disclose the relationship of the parties.

(7) Representations and Warranties.

Clinipace warrants and represents that it has the full right and authority to enter into this Agreement, that Clinipace has no obligations or commitments inconsistent with this Agreement and/or its performance hereunder, that Clinipace has sufficient training to perform the Services required in this Agreement and that Clinipace will perform the Services in a professional and workmanlike manner, and in accordance with the standard of care usually and reasonably expected in the clinical and quality research industry, and in compliance with all instructions from REDHILL and all applicable laws and regulations. By signing this Agreement, Clinipace hereby affirms the representations set forth herein.

In addition, Clinipace represents, warrants and agrees as follows:

(a) Clinipace hereby certifies that it has not been disqualified under the provisions of 21 CFR Part 11 or other FDA rules as they may apply to this contract.

(b) Clinipace will use its best efforts to remain in good standing with regulatory authorities.

(c) Clinipace will promptly inform REDHILL of any threat to regulatory good standing.

(d) Clinipace uses and shall continue to use security measures consistent with the generally recognized industry standards in its efforts to ensure the security of the Tempo Website.

(8) REDHILL Responsibilities.

In connection with Clinipace's provision of the Services, an Attachment may specify certain tasks to be performed by REDHILL as a condition to Clinipace's ability to perform its services in full ("REDHILL Responsibilities"). REDHILL understands that Clinipace's performance is dependent and conditioned upon REDHILL's timely and effective completion of REDHILL Responsibilities and timely decisions and approvals by REDHILL. Clinipace's inability to perform Services pursuant to an Attachment which results from REDHILL's failure to perform REDHILL Responsibilities shall not relieve REDHILL from its obligation to pay the Fees provided in such Attachment.

(a) REDHILL shall forward to CLINIPACE in a timely manner all documents, materials and information in REDHILL's possession or control necessary for CLINIPACE to conduct the Services. CLINIPACE shall not be liable to REDHILL nor be deemed to have breached this Agreement or any Work Order for errors, delays or other consequences arising from REDHILL's failure to timely provide documents, materials or information or to otherwise cooperate with CLINIPACE in order for CLINIPACE to timely and properly perform its obligations. So long as Services have not begun, and the scope of the study or the scope of work undertaken by Clinipace is not increased, in the event that the FDA or similar applicable regulatory or governmental authority requires REDHILL to delay or postpone the study or any particular module therein, then REDHILL will be entitled to postpone the initiation of the study or any particular module therein without this having an impact on the fees and without requiring a Change Order. Clinipace will inform RedHill in advance of incurring any expenses which are non-cancelable.: If REDHILL delays a project after the initiation of the performance of any Services from its agreed starting date or suspends performance of a project for a period longer than ten (10) working days, then either: a) REDHILL will pay the standard daily rate of the CLINIPACE's personnel assigned to the project, based on the percentage of their time allocated to the project, for the period of the delay beginning on the eleventh working day, in order to keep the current team members; or, b) CLINIPACE may re-allocate the personnel at its discretion, and REDHILL will pay the costs of retraining new personnel. In addition, REDHILL will pay all non-cancelable costs and expenses incurred by CLINIPACE due to the delay and will adjust all timelines to reflect additional time required due to the delay.

(b) REDHILL warrants and represents that it has the full right and authority to enter into this Agreement, and will comply with all applicable laws and regulations as it relates to the Services contemplated herein. REDHILL shall provide CLINIPACE with all information available to it regarding known or potential hazards associated with the use of any substances supplied to CLINIPACE by REDHILL, and REDHILL shall comply with all current legislation and regulations concerning the shipment of substances by the land, sea or air.

(9) Property Rights.

As between Clinipace and REDHILL, all data and information generated or derived by Clinipace as the direct result of Services performed by Clinipace under this Agreement or directly through the use of or access to REDHILL's Trade Secrets shall be and remain the exclusive property of REDHILL. All data, information, reports, and any discoveries, inventions, works of authorship arising as the direct result of Services performed by Clinipace under this Agreement or directly through the use of or access to REDHILL Trade Secrets (collectively "**Developments**") shall as between Clinipace and REDHILL belong to REDHILL and Clinipace agrees to promptly inform REDHILL of such Developments, and hereby fully assigns to REDHILL all of its rights in all such Developments and any related patents, copyrights and other intellectual property rights.

REDHILL hereby acknowledges and agrees that Clinipace owns all intellectual property rights in and to Clinipace's Trade Secrets, the Tempo Website, and all software residing thereon. REDHILL also acknowledges and agrees that this is an agreement for services only, and Clinipace does not grant to REDHILL any right, title, interest or license in or to the software through which the Website is operated and the Services are performed.

(10) Indemnity Agreement.

(a) Indemnification by Clinipace. Clinipace shall defend, indemnify and hold harmless REDHILL and its directors, officers, employees, and agents against all claims, including without limitation, any tax claims or assessments, lawsuits, liabilities, losses, costs, and expenses (including reasonable attorneys' fees) suffered or incurred as a result of: (i) any acts of negligence or willful misconduct by any employees of Clinipace relating to the Services provided pursuant to this Agreement; (ii) any infringement on any United States patent or copyright or misappropriates the trade secrets of any third party; and (iii) any breach of Clinipace's obligations under this Agreement. For all claims under this section, REDHILL shall give Clinipace prompt written notice of all claims, provide reasonable cooperation in its investigation and defense, and permit Clinipace to defend the claims at its expense with legal counsel of its choice. If a temporary or permanent injunction is obtained against REDHILL's use of the Website as a result of the matters described in this section, Clinipace shall, at its option and expense, either procure for REDHILL the right to continue using the Website or replace or modify the Website or infringing portion thereof so that it no longer infringes the alleged proprietary right. This section sets forth the exclusive remedy of REDHILL against Clinipace with respect to infringement or misappropriation of intellectual property rights of any kind. Clinipace shall not indemnify REDHILL for uses, damages or expenses incurred by REDHILL as a result of claims, actions or proceedings brought by any third party based on code or design specifications provided to Clinipace by REDHILL.

(b) Indemnification by REDHILL. REDHILL shall defend, indemnify and hold harmless Clinipace and its directors, officers, employees, and agents against all claims, including without limitation, any tax claims or assessments, lawsuits, liabilities, losses, costs, and expenses (including reasonable attorneys' fees) suffered or incurred as a result of: (i) any acts of negligence or willful misconduct by any employees of REDHILL relating to the Services provided pursuant to this Agreement; (ii) conduct of the clinical study including personal injury or death of study participants; and (iii) code or design specifications provided by REDHILL to Clinipace in connection with Clinipace's performance hereunder, and (iv) any breach of this Agreement by REDHILL. REDHILL will indemnify Clinipace and its directors, officers, employees, and agents against its reasonable attorneys' fees and any money damages or costs awarded in respect of any such claim(s) and any suit raising any such claim(s). For all claims under this section, Clinipace shall give REDHILL prompt written notice of all claims, provide reasonable cooperation in its investigation and defense, and permit REDHILL to defend the claims at its expense with legal counsel of its choice.

(11) Disclaimer and Limitation of Liability

(a) Disclaimer. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED HEREIN, CLINIPACE DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS, IMPLIED, OR STATUTORY, OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, REGARDING THE SOFTWARE, WEBSITE OR ANY SERVICES PROVIDED BY CLINIPACE UNDER THIS AGREEMENT. FURTHER, CLINIPACE DOES NOT MAKE ANY REPRESENTATIONS OR WARRANTIES REGARDING: (I) THE ACCURACY OR COMPLETENESS OF REDHILL CONTENT [I(II_ THE SECURITY OF THE TEMPO WEBSITE OR (II) THE QUALITY OR CONTINUITY OF THIRD PARTY TELECOMMUNICATIONS SYSTEMS, INFORMATION SYSTEMS OR SERVICES. REDHILL HEREBY ACKNOWLEDGES AND AGREES THAT THE INTERNET IS NOT CONTROLLED, OPERATED, OR OWNED BY A SINGLE ENTITY, AND AS A RESULT, CLINIPACE DOES NOT MAKE ANY REPRESENTATON OR WARRANTY THAT ANY USER SHALL BE ABLE TO ACCESS THE WEBSITE AT ANY PARTICULAR TIME.

(b) Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR CONSEQUENTIAL, INCIDENTIAL OR PUNITIVE LOSS, SPECIAL, OR EXEMPLARY DAMAGES, INCLUDING LOST PROFITS OR LOSS OF USE, EVEN IF THE OTHER PARTY IS NOTIFIED OF THE LIKELIHOOD OF SUCH DAMAGES. CLINIPACE SHALL NOT BE LIABLE TO REDHILL FOR DAMAGES RESULTING FROM A THIRD PARTY ACCESSING THE WEB SERVER OR THE TEMPO WEBSITE. IN ALL EVENTS, CLINIPACE'S LIABILITY HEREUNDER FOR ANY CAUSE WILL IN NO CASE EXCEED USD $2,500,000.00, AND THE EXISTENCE OF MORE THAN ONE CLAIM WILL NOT EXPAND SUCH LIMIT.

(12) Assignments.

Clinipace agrees that the Services to be provided by Clinipace cannot be assigned or transferred by Clinipace without the prior written consent of REDHILL. Notwithstanding the foregoing, either party may assign this Agreement in connection with a merger, acquisition, or sale of all or substantially all of its assets, so long as such surviving entity agrees in writing to be bound by the terms of this Agreement. Clinipace retains the right to use independent contractors in the performance of Services under this Agreement, provided, however, that if Clinipace determines in its sole discretion that any such independent contractor is to perform a significant role in the study, then Clinipace shall receive approval from REDHILL prior to such independent contractor performing Services in such capacity.

(13) Relationship and Status.

Clinipace understands and agrees that, for purposes of this Agreement, Clinipace is acting in the capacity of an independent contractor to REDHILL and not as an employee, agent, partner or joint venturer of REDHILL. REDHILL is not responsible for withholding, and shall not withhold, FICA or taxes of any kind from any payments it owes to Clinipace. Clinipace agrees to comply with all laws related to payment of income or other taxes on Fees paid for the provision of Services hereunder and to indemnify REDHILL therefore. Clinipace does not have authority to represent or act on behalf of REDHILL without prior written consent from REDHILL. Further, as an independent contractor, Clinipace is not eligible to participate in, nor is it eligible for coverage under, any benefit plans of REDHILL, or other programs, employment policies or procedures or workers' compensation insurance of REDHILL. In consideration of REDHILL agreeing to use Clinipace's Services hereunder, REDHILL will be released from and indemnified by Clinipace for any liability arising from the failure to provide such plans, programs, policies, procedures and workers' compensation insurance to Clinipace or any other individuals providing Services or assistance hereunder.

(14) Insurance.

REDHILL agrees that it maintains a commercial general liability insurance policy or other policy covering product liability and personal injury damages and agrees that such policy shall include limits at least equal to $[****]per claim and $[****]in the aggregate where applicable. Clinipace agrees that it shall carry and maintain in force with reputable and financially sound insurers, at all times relevant hereto insurance of the type and minimum coverage limits as follows: 1) commercial general liability with limits of at least $[****]per occurrence and $[****]in the aggregate where applicable; 2) liability attributable to Services rendered hereunder with a limit of at least $[****]in the annual aggregate; and 3) other insurance required by any law or regulation applicable to Clinipace or customary to similar companies in its business and territory. Upon written request, each party will furnish the other party with a certificate of insurance in support of the required coverage(s). Each party will provide the other party with a written notice in the event that any of its insurance coverage is cancelled, terminated or non-renewed.]

(15) Termination.

(a) This Agreement or any Attachment may be terminated by REDHILL, with or without cause, upon sixty (60) days written notice to Clinipace or as otherwise provided in this Agreement. Termination of this Agreement or any Attachment shall not relieve REDHILL of its obligation to pay all Fees that have accrued or are otherwise owed by REDHILL under any Attachment. In the event that REDHILL elects to terminate the Agreement or any Attachment, then upon receipt of such notice of termination, Clinipace agrees to, as soon as commercially reasonable, cease performing all activities related to the Services. Upon termination of this Agreement or any Attachment, Clinipace shall prepare and submit to REDHILL within thirty (30) days a final invoice for Services performed hereunder and an itemized statement of all approved, non-cancelable costs and expenses, which invoice and statement shall be processed and paid by REDHILL pursuant to the section on Fees. In addition, upon such termination, Clinipace shall return to REDHILL all property of REDHILL.

(b) Either party may terminate this Agreement upon written notice if the other party materially breaches this Agreement and fails to cure such breach within thirty (30) days following receipt of written notice specifying the breach in detail, unless such breach is incapable of cure, such as breach of the terms of the Confidentiality provision (defined herein), in which case the non-breaching party may terminate this Agreement and/or any applicable Attachment immediately. The parties shall work together in good faith to resolve any dispute or alleged breach internally by escalating it to higher levels of management prior to resorting to litigation. In the event that, after using good faith efforts to resolve the issues set forth in the termination notice the parties are unable to resolve the issues described in the termination notice within the notice period, then this Agreement and the applicable Attachment shall be terminated effective upon the day immediately following the last day of the notice period. Upon termination, REDHILL will reimburse Clinipace for its reasonable, non-cancelable costs and expenses incurred in the performance of such canceled Services, if any, in accordance with the terms of this Agreement.

(16) Survival Provision.

The provisions of the Agreement under the headings Confidentiality, Publication, Indemnity Agreement, Property Rights, Disclaimer and Limitation of Liabilities, Insurance and Miscellaneous shall survive the termination of this Agreement.

(17) Notices.

Any notice required or permitted to be given hereunder by either party thereunder shall be in writing and shall be deemed given on the date received if delivered personally or by a reputable overnight delivery service, or three (3) days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to Clinipace	If to REDHILL:
Clinipace, Inc.RedHill Biopharma LTD	RedHill Biopharma LTD
3800 Paramount Parkway, Suite 100	21 Ha'arba'a St
Morrisville, NC 27560 USA	64739 Tel-Aviv
Attention: _____	Attention: Gilead Raday
Title:	Title: VP Corporate &Product Development

If REDHILL delivers, ships, or mails materials or documents to Clinipace, or requests that Clinipace deliver, ship, or mail materials or documents to REDHILL or to third parties, then the expense and risk of loss for such deliveries, shipments, or mailings shall be borne by REDHILL, provided that Clinipace followed REDHILL's written instructions for the materials that were delivered, shipped, or mailed. Clinipace disclaims any liability for the actions or omissions of third party delivery services or carriers.

(16) Additional Terms

(a) Unless explicitly stated herein, REDHILL is solely responsible for the conduct of the Studies, and CLINIPACE shall provide various Services defined herein to support REDHILL in the conduct of the Studies.

(b) CLINIPACE shall conduct the Services as outlined herein, and in accordance to the protocol of each Trial, and in accordance with all applicable laws and regulations.

(c) CLINIPACE agrees that for the duration of this Agreement, that it shall notify REDHILL in a timely fashion when CLINIPACE receives information regarding any serious adverse events related to the product use in the Study(s).

(d) CLINIPACE shall report to REDHILL any investigator that is not complying with his/her agreement with REDHILL.

(e) CLINIPACE shall permit REDHILL's representatives to perform, during normal business hours and with reasonable notice and without undue interruption, quality assurance audits of the work performed under this Agreement to assure the Services are being performed in accordance with the applicable protocol(s) and this Agreement. CLINIPACE shall promptly correct any errors or deficiencies discovered during an audit.

(f) REDHILL shall provide a Project Manager who shall be the primary contact with CLINIPACE.

(g) Data shall be collected on the web-based Tempo platform, and entered by clinical site staff, REDHILL Staff or REDHILL coordinators.

(h) CLINIPACE and REDHILL shall work in good faith to establish relevant CLINIPACE SOPs, which shall govern the Study.

(i) All clinical data collected during and related to the Study are the property of REDHILL, and CLINIPACE retains no rights whatsoever in such clinical data.

(17) Miscellaneous Provisions.

(a) This Agreement constitutes the entire agreement between REDHILL and Clinipace with respect to the Services contemplated herein and supersedes all previous negotiations, commitments and writings.

(b) No modifications or amendments hereof shall be effective unless made in writing and signed by authorized representatives of Clinipace and REDHILL.

(c) The provisions of this Agreement are severable, and any judicial determination that any provision(s) is invalid or unenforceable shall not affect the validity or enforceability of any other provision, but rather shall cause this Agreement first to be construed in all respects as if such invalid or unenforceable provision(s) were omitted.

(d) Clinipace and REDHILL agree to execute and deliver such additional instruments and other documents and to use all commercially reasonable efforts to take, or cause to be taken, all actions necessary to consummate the agreements contained herein.

(e) Clinipace agrees to promptly inform REDHILL of any event or change in circumstances which could reasonably affect its ability to perform hereunder in a manner contemplated by the parties.

(f) No failure to exercise any right or to demand performance of any obligation under this Agreement shall be deemed a waiver of such right or obligation.

(g) This Agreement shall be governed by the laws of England. Any disputes shall be submitted to the exclusive jurisdiction of the courts of England.

(h) In the event of a conflict between the terms of this Agreement and any Attachment, the terms of the Attachment shall prevail.

(i) In the event either party shall be delayed or hindered in or prevented from the performance of any act required, hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, wear, Acts of God, inclement weather or other reason or cause beyond that party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay.

IN WITNESS WHEREOF, the parties by their duly authorized representatives have caused this Agreement to be executed effective as of the date first above written.

REDHILL, Inc.:

By: /s/ _____ Date: _____

Name: _____

Title: _____

CLINIPACE, INC.:

By: /s/ _____ Date: _____

Name: _____

Title: _____

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Attachment A-1: Study Work Order

I. RedHill Biopharma Ltd. ("RedHill") and Clinipace, Inc. ("CPWW" or "Clinipace") agree to the following specific description of the project and related tasks and activities ("Services") that the parties anticipate completing in the allocated time, subject to prioritization and timely performance of RedHill Responsibilities (as defined in the MSA) by RedHill and as mutually agreed upon by the parties.

II. Project Assumptions

CPWW will provide Services and staff reasonably necessary to support RedHill's clinical trial, "A randomized placebo controlled phase III study to assess the safety and efficacy of RHB-105 in the treatment of confirmed Helicobacter pylori (H.pylori) infection in non-investigated dyspepsia patients" (the "Study"). The general specifications and assumptions for this Study are included in the table below:

Patient Specifications	
Number of Patients Screened	[****]
Number of Patients Enrolled	[****]
Number of Patients Complete	[****]
Estimated Number of Serious Adverse Events (per subject)	[****]
Site Specifications	
Number of Sites Identified	8.0
Number of Qualification Visits	8.0
Qualification Visit (duration in days)	0.5
Number of Initiation Visits	8.0
Initiation Visit (duration in days)	1.0
Number of Interim Monitoring Visits per Site	3.4
Total number of Interim Monitoring Visits	27.0
Interim Monitoring Visit (duration in days)	1.0
Number of Close-out Visits	8.0
Close-out Visit (duration in days)	1.0
CRF Specifications	
Estimated Unique Pages	15.0
Estimated Total Pages per Patient	30.0
Project Management Specifications	
Number of Kick-off Meetings	1.0
Kick-off Meeting (duration in days)	4.0
Number of Client Project Meetings (face-to-face)	1.0
Number of Client/Clinipace Teleconferences (0.5 hours)	22
Number of Internal Meetings	11.0
SAEs	
Number of SAEs	[****]
Number of Reportable SAEs	[****]
Statistical Analysis	
Number of TLF displays	31

Timeline:

Milestone	Estimated Date	
CPWW Activities Begin	[****]	Pre-Study Activities
Final Protocol/ICF	[****]	
IND Submission	[****]	
Start-up Period Begins	[****]	
Start-up Period Ends	[****]	
Initiation of study activities (upon written confirmation from RHB)	[****]	Study Activities
Enrollment Ends	[****]	
Treatment Period Ends	[****]	
Collection of Final CRFs	[****]	
Query Resolution	[****]	
Database Lock	[****]	
Statistical Analysis	[****]	Post Dosing Activities
Draft Report	[****]	
Final Report	[****]	
CPWW Activities End	[****]	

Initiation of Study Activities (i.e. Enrollment and all ensuing study tasks and services) is conditional upon written approval by RedHill confirming the initiation of the Study Activities following completion of the Pre-Study Activities and positive approval to begin dosing patients from both FDA (IND) and Health Canada.

Enrollment is currently contemplated to begin by [****]. Delays/deferral of the Study Activities prior to their initiation for a period of up to 90 days will not entail any additional costs/fees. Should study enrollment be delayed beyond the 90 days period (i.e. after [****]), RedHill will pay Clinipace [****] until such time as either i) the Study Activities are initiated, or ii) the Work Order is terminated by RedHill. Termination of this Work Order by RedHill prior to initiating Study Activities will be of immediate effect.

III. Schedule of Services

The purpose of this work order is to set forth in more detail the Services that Clinipace shall provide pursuant to the MSA and the terms set forth herein, including but not limited to the obligations set forth in the Schedule of Services (below).

Project-specific Tasks	**Responsibility**			
	N/A	RedHill	CPWW	Joint
Clinical Trial Preparation				
Investigator Brochure Development			☒	
Protocol/Protocol amendment		☒		
eCRF Preparation			☒	
Informed Consent Template Preparation			☒	
Site-Specific Informed Consent Form Review			☒	
Central IRB Selection and Management			☒	
Monitoring Plan Development			☒	

Collection of Site Regulatory Documents (Including site IRB)			☒	
Regulatory Binders to sites			☒	
Regulatory Authority Submission			☒	
Site selection				☒
Central Laboratory Selection (If needed)			☒	
Central Laboratory Management and Payment			☒	
Investigator's Grant Negotiation				☒
Training materials				☒
Project Kick-off Meeting				☒
Investigator's Study Files Structures			☒	
CTM Packaging, Labeling and Distribution		☒		
Monitoring and Trial Management				
Pre-Study visits			☒	
Site Initiation Visits			☒	
Periodic Site Visits (Every 6 to 8 weeks)			☒	
Site Close-out Visits			☒	
Enrollment Status Reports			☒	
SAE reports			☒	
Contact Reports			☒	
Site Management			☒	
Study Reference Manual			☒	
Project Management				
Maintenance of Study Master File			☒	
Schedule Client Meeting / Prepare Minutes			☒	
Study Timelines				☒
Medical Monitoring				
Medical Monitoring			☒	
Medical Review			☒	
Data Safety Monitoring Board Selection			☒	
Data Safety Monitoring Board Management & Meetings			☒	
Pharmacovigilance				
Serious Adverse Event Management			☒	
Regulatory Submission of Adverse Event Reports			☒	
Data Management & Biostatistics				
Database Design Set-up/Modification (included in eCRF design) Refer to Appendix III for Schedule of Events			☒	
Data Management Plan			☒	
Data Coding, AEs, Medications			☒	
Central Laboratory Data Transfer			☒	
Randomization Scheme			☒	
Statistical Analysis Plan			☒	
Prepare Study Tables, Listings and Figures			☒	
Clinical Study Reports				
Provide 2 draft study reports			☒	
Provide 2 Final Study Reports			☒	
Publishing		☒		
Quality Assurance				
GCP Site Audits		☒		
QC Audits of CSRs			☒	
QC Audit of Database			☒	

IV. Professional Fees and Resources

Task	Assumptions	Hours	Total (US$)
PROTOCOL DEVELOPMENT AND AMENDMENTS			**$ [****]**
Protocol Development	Clinipace will review the protocol developed by RedHill Biopharma Ltd. . The estimate is based on two review cycles (administrative changes are not limited to two review cycles)	16	$ [****]
Protocol Amendment(s)	Clinipace will review protocol amendment(s) during the course of this study. We have estimated 1 amendment(s) to the protocol. (Administrative changes/corrections not limited to 1 amendment)	5	$ [****]
REVIEW STUDY MATERIALS			**$ [****]**
Review Study Materials	General review of study materials by Clinipace Project Team.	28	$ [****]
PROTOCOL DISTRIBUTION AND TRANSLATION			**$ [****]**
Distribute Protocol to Sites	Includes IB	8	$ [****]
Distribute Protocol Amendment(s) to Sites	Based on 1 amendment(s).	8	$ [****]
Protocol Translation	Translations will be handled by third party vendors. Includes time to manage the vendors.	9	$ [****]
eCRF DEVELOPMENT			**$ [****]**
Develop eCRF		68	$ [****]
eCRF Completion Guidelines	Clinipace will create the eCRF Completion Guidelines.	11.25	$ [****]
INFORMED CONSENT			**$ [****]**
Develop Informed Consent Form (ICF)	Clinipace will develop the model ICF. RedHill Biopharma Ltd. will review and approve the consent. Based on 1 review cycle.	22	$ [****]
Negotiate changes to template with sites	Clinipace will work with the site(s) on any local changes to the ICF. Clinipace will consult RedHill Biopharma Ltd. on any changes from the site(s).	24	$ [****]
Update ICF - Protocol Amendments	Clinipace will be responsible for updating the ICF based on amendments to the protocol. Based on 1 amendment(s).	16	$ [****]
Translation of Informed Consent	Clinipace will work with the sites to translate the Informed Consent into the appropriate language.	8	$ [****]
INVESTIGATOR SELECTION/PRE-STUDY VISITS			**$ [****]**
Develop Site Recruitment Materials		8	$ [****]
Identify and Recruit Investigators	Clinipace will work to identify 8 investigators willing and able to participate in this trial. Clinipace will provide Sponsor with a list of sites for approval. We have estimated we will need to identify [****] sites to get 8.	[****]	$ [****]

Perform Pre-Study Site Visits - US	4 hours on site, avg. 8 hours travel RT, 6 hours prep and reporting = 18 hours.	[****]	$ [****]
CLINICAL TRIAL AGREEMENTS			**$ [****]**
Negotiate contracts with sites	Clinipace will negotiate and hold site contracts and budgets with each site.	40	$ [****]
Investigator Grants	Clinipace will administer payments to each site. This proposal is based on quarterly payments per site.	9.6	$ [****]
REGULATORY DOCUMENTS			**$ [****]**
Prepare, collect, review appropriate regulatory documents	Clinipace will provide templates to each site including Financial Disclosure Document and 1572, then collect locally required approval documents. This line includes communication with sites to obtain final documents and corrections. Based on 8 sites.	80	$ [****]
Regulatory Binder	Each site will receive a regulatory binder that contains all required documents. This binder will be checked at each monitoring visit.	24	$ [****]
Study Procedures Manual	A study procedures manual will be prepared and distributed to each site. This manual will contain information on lab shipping, monitoring plans, etc.	24	$ [****]
Prepare study aids such as drug logs, etc.		24	$ [****]
Prepare and submit package to sites for submission to ethics committees.		8	$ [****]
Update documentation for IRBs/ECs - Protocol Amendment(s)	Based on 1 amendment(s).	8	$ [****]
Prepare and submit dossier for submission to appropriate Ministry of Health, Track MoH approvals.	RedHill will be responsible for regulatory authority submissions.	0	$ [****]
Communication and preparation of official responses to MoH pending issues.	RedHill will be responsible for regulatory authority submissions.	0	$ [****]
MoH Updates - Protocol Amendment	RedHill will be responsible for regulatory authority submissions.	0	$ [****]
Annual Reviews (EC)	Assume each site will require 1 IRB/IEC renewal(s).	48	$ [****]
Drug Label Review/Translation	RedHill will be responsible for packaging and labeling.	0	$ [****]
TRIAL MASTER FILE			**$ [****]**
Set up Trial Master File		8	$ [****]
Maintain Trial Master File		88	$ [****]
INVESTIGATOR MEETINGS			**$ [****]**
Plan and Manage Investigator Meeting(s)	Clinipace organize a Web-based Investigator Meeting.	40	$ [****]
Prepare meeting binders	Clinipace will create the meeting binder and ship to the sites. Sponsor will approve the contents of the binder. We have included cost for producing 41 binders.	36.5	$ [****]
Prepare Presentations		40	$ [****]
Attend investigator meeting: US	Webinar	48	$ [****]

Project Team Training	We have assumed a 4 hour training session.	16	$ [****]
VENDOR MANAGEMENT			**$** [****]
Central IRB/IEC		14	$ [****]
Central Laboratory			**$** [****]
INITIATION VISITS			**$** [****]
Perform Site Initiation Visits - US	8 hours on-site, avg. 8 hours travel, 6 hours preparation including slides and protocol review, scheduling and reporting per site = 22 hours	[****]	$ [****]
INTERIM MONITORING VISITS			**$** [****]
Develop Monitoring Plan	Clinipace will complete the monitoring plan/guidelines. Clinipace will provide the draft monitoring plan to RedHill Biopharma Ltd. for review and approval. Based on 1 review cycle with RedHill Biopharma Ltd.	12	$ [****]
Perform interim monitoring visits: US	8 hours on-site, 8 hours travel, 6 hours preparation, scheduling and reporting = 22 hours per visit.	594	$ [****]
Remote Monitoring		104	$ [****]
CLOSE-OUT VISITS			**$** [****]
Perform Close-out visits: US	1 day closeout (8 hours) + 8 travel + 6 preparation, scheduling and reporting = 22 hours per visit	[****]	$ [****]
QUERY RESOLUTION			**$** [****]
Query Resolution - Data Lock	Clinipace monitors will assist data management with query resolution at study close in order to expedite database lock.	44.8	$ [****]
SITE MANAGEMENT			**$** [****]
In-house Site Management	This will be done by assigned CRA, to include in-house site management time during active clinical duration. Assume weekly calls to sites during clinical project duration.	208	$ [****]
Lead Clinical Research Associate		102	$ [****]
PROJECT COMMUNICATIONS			**$** [****]
Client Kick-off/Training Meeting	Assume a 4 hour kick-off. Training meeting will be held between the Clinipace and Sponsor teams (via teleconference).	[****]	$ [****]
Enrollment Reports	Clinipace will provide enrollment reports to the sponsor via Tempo.		
Status Reports	Clinipace monthly reports to sponsor, to include screening, enrollment, number of monitoring visits, CRFs harvested; queries outstanding, etc.	44	$ [****]
Teleconferences with Sponsor	Assume monthly calls with sponsor.	73	$ [****]
Provide newsletters	Not requested	0	$ [****]
External Sponsor / Clinipace Face to Face Team Meetings	Anticipate one meeting at the Sponsor attended by the Clinipace Project Director.	18	$ [****]
CRA Study Management	General CRA time for communication with Sponsor and Medical Monitor, file maintenance etc.	104	$ [****]
Internal Team Meetings	Clinipace will hold monthly internal team meetings during the course of this project.	73	$ [****]

PROJECT MANAGEMENT			**$ [****]**
Project Management	General Project Management to include interaction with monitors; review of all documents and general ad hoc sponsor communication	438	$ [****]
Clinical Trial Coordinator - Administrative Support		414	$ [****]
Financial Reporting		44	$ [****]
Return Study Files to Sponsor		16	$ [****]
QUALITY ASSURANCE		0	**$ [****]**
QA Visits	InSymbiosis		
STUDY DRUG			**$ [****]**
Obtain import permits for study drug and supplies; prepare and review import paperwork	InSymbiosis/RedHill	0	$ [****]
Oversee Drug Distribution to Sites from Warehouse	InSymbiosis/RedHill	0	$ [****]
Obtain any necessary export permits for shipping of lab samples to central lab and for return of unused study medication at end of study	Not applicable	0	$ [****]
Drug depot and Central lab contact and local issues management throughout the study	InSymbiosis/RedHill	0	$ [****]
MEDICAL MONITORING			**$ [****]**
Provide medical contact with sites	Clinipace will provide sites with a contact person to answer site questions.	33	$ [****]
Review SAEs		2.5	$ [****]
Review patient eligibility, lab alerts, coding and listings		0.5	$ [****]
DRUG SAFETY/PHARMACOVIGILANCE			**$ [****]**
Create Safety Monitoring Plan	Clinipace will develop the safety plan. Clinipace will provide the draft plan to RedHill Biopharma Ltd. for review and approval. Based on 1 review cycle with RedHill Biopharma Ltd.	16	$ [****]
Set-up SAE Database		57	$ [****]
Document and manage SAEs	Based on [****] SAEs.	20	$ [****]
Follow-up SAEs		5	$ [****]
Report SAEs to regulatory authorities	Based on [****] expedited SAEs.	8	$ [****]
Update all Study Sites of SAEs requiring Expedited Safety Reports/Distribute IND Safety Reports	Clinipace will notify each site of SAEs that require reporting.	4	$ [****]
Write Safety Narratives	Based on 16 narratives.	22	$ [****]
SAE Reconciliation	Based on [****] reconciliations throughout the course of the project.	48	$ [****]
DATA MANAGEMENT			**$ [****]**
STUDY PLATFORM			
Data Management Fees	▪ Includes License Fees, Hosting and Technical Support		$ [****]

Hardware & Systems	▪ 3 servers ▪ Routers/firewall ▪ Tape drive (backup) ▪ Redundancy ▪ Security (IPS, AVS) ▪ Bandwidth		[****]
CRF Revisions			[****]
IMPLEMENTATION			
Clinical Data Capture Module	▪ XML file creation & load ▪ eCRF design ▪ Edit check coding ▪ Data element coding ▪ Workflow configuration ▪ Database development ▪ Testing		$ [****]
Reports			[****]
Randomization			$ [****]
User Administration			[****]
Validation (testing & documentation)			$ [****]
Training Manual			[****]
User training (TTT)			[****]
Printable (PDF) CRFs			[****]
STUDY DATA MANAGEMENT AND SUPPORT			
Data Management Plan			$ [****]
Code book creation			[****]
Data Entry	Not applicable		
Verification	Not applicable		
CRF Tracking	Not applicable		
Coding	Based on 10 codes per patient.		$ [****]
Queries	Based on 10 queries per patient.		$ [****]
Data Imports	Based on 2 data transfers/imports from outside vendors.		$ [****]
Data exports/monthly			[****]
Data export/final			[****]
Data warehousing/archiving			[****]
Administration			$ [****]
STATISTICAL ANALYSIS			**$** [****]
Develop Statistical Analysis Plan	Clinipace will develop the Statistical Analysis Plan. Clinipace will provide the draft analysis plan to RedHill Biopharma Ltd. for review and approval. Based on 1 review cycle with RedHill Biopharma Ltd.	32	$ [****]
Create Randomization Plan		20	$ [****]
Conduct SAS programming and QC of all TLFs	Based on 8 unique tables, 16 non unique tables, 3 unique figures, 6 non unique figures and 20 listings.	114	$ [****]
Prepare Interim Analysis and Report	Not applicable		
Prepare Final Analysis and Report		40	$ [****]
QC All Analysis and Report		15	$ [****]
FINAL REPORT			**$** [****]

Write Clinical Study Report (CSR)	Clinipace will develop the final report for the study. Clinipace will provide the draft report to RedHill Biopharma Ltd. for review and approval. Based on [****] review cycles with RedHill Biopharma Ltd.	134	$ [****]
TOTAL SERVICES		**3992**	**$ [****]**
[****]			$ [****]
SERVICES COSTS GRAND TOTAL		**3,992**	**$ [****]**

V. Payment Terms

2.0 RedHill agrees to pay Clinipace a professional fee of US $ [****] ("Fee") as total payment for the full scope of Services and Tasks. Any task reduced in scope will be credited (on a pro-rata basis in accordance with the actual hours spent) for hours budgeted in the agreement but not performed in full. A down payment of [****] shall be due and payable net 5 days upon Clinipace's receipt of a fully executed copy of this Attachment A-1. From then on, RedHill will be invoiced for the tasks actually performed and milestones reached by Clinipace ("Milestone Invoice"). Each Milestone Invoice shall be itemized in sufficient detail to permit independent auditing and verification that the work covered by such Milestone Invoice has been properly performed and the relevant milestone reached. Once the Study Activities are initiated, as part of the Fee and included therein, and as detailed in the table below, RedHill will pay Clinipace a Quarterly Fee of $ [****], calculated from the date of initiation of Study Activities.

All Invoices, except for the down payment, shall be due within 30 days of invoice. Non-disputed invoices not paid within forty-five (45) days will be subject to a late payment charge of [****] per month until paid in full.

The following table provides a breakup of the Fee into Milestone Payments and Quarterly Payments. The Milestone Payments will be due only upon reaching the said milestone. Quarterly Payments are capped at 4 total payments for a total of $ [****].

Milestone Payments: Pre-IND	$ [****]
Execution of the Agreement	$ [****]
Protocol and ICF Completed	$ [****]
Milestone Payments: Post-IND	$ [****]
Initiation of study activities	$ [****]
Database set-up complete (go live)	$ [****]
First Subject Enrolled	$ [****]
Last Subjects Enrolled [****]	$ [****]
Last CRF Collected	$ [****]
Final CSR	$ [****]
Total Milestone Payments	$ [****]
Quarterly Payments: Beginning Post IND	
Quarterly Payment 1- Invoice due at 3 months post Initiation of Study Activities	$ [****]
Quarterly Payment 2 – Invoice due at 6 months post Initiation of Study Activities	$ [****]
Quarterly Payment 3– Invoice due at 9months post Initiation of Study Activities	$ [****]
Quarterly Payment 4– Invoice due at 12 months post Initiation of Study Activities	$ [****]
Total Monthly Payments	$ [****]
Total	$ [****]

PASS THROUGH COSTS

Clinipace Pass-Through Costs

INDIRECT COSTS	(PASS-THROUGH EXPENSES)	Estimated Cost
/ Ministry of Health and Ethics Committee Fees	Assume 1 initial submission only (no amendments) and 1 annual review(s).	$24,000
CRA AirCards		$1,350
Shipping		$5,500
Phone (Long Distance)		$5,500
Supplies		$3,300
Translation costs	Clinipace will work with the sites and a translation vendor(s) to translate appropriate study documents into local languages. Includes translation into 2 different languages.	$20,000
Plan and Manage Investigator Meeting(s) with meeting planner	Web-based IM - hosting fees	$500
Travel	Includes travel for monitoring visits, client meetings, supervision visits, QA visits.	$52,750
ESTIMATED INDIRECT COSTS TOTAL		**$112,900**

RedHill agrees to reimburse Clinipace for pass through expenses, of the type detailed above and estimated to be approximately US $112,900.00 for the duration of the study. As a prepayment of pass through expenses, US [****] shall be due and payable, upon RedHill written confirmation of the Study enrolment, following approval of the IND/CTA. This will establish a pass-through pay-down account. Clinipace will track the disbursement of pass-through costs from the pass-through pay-down account and will invoice RedHill [****] each time the balance in the pass-through pay-down account drops below [****]. Each such invoice will have annexed to it an updated report of the pass-through pay-down account. Clinipace will track the actual pass-through costs against the estimated budget and will notify REDHILL Clinipace invoices for pass-through expenses shall be payable by RedHill via ACH/WIRE within thirty (30) days after RedHill's receipt of each invoice.

At the end of the project Clinipace will perform a final reconciliation of pass-through costs providing detailed record of each pass-through item in the pass-through pay-down account.

Investigator Grants

Current estimate of Investigator Grants:

Investigator Grants		$ [****]

RedHill agrees to reimburse Clinipace for Investigator Grants, currently estimated to be approximately US $[****]for the duration of the study (up to **$**$ [****]per subject, [****]). It is the combined responsibility of Clinipace and RedHill to negotiate and execute Investigator Agreements. Only Investigator Agreements duly signed by RedHill will serve to establish the actual basis for Investigator Grant payments and reconciliation.

As a prepayment of the Investigator Grants, [****] shall be due and payable, upon initiation of patient enrollment, which is conditional upon pre-approval in writing by RedHill. This will establish a pass-through Investigator-Grants account. Clinipace will track the disbursement of pass-through Investigator-Grants and invoice RedHill US $25,000 each time the balance in the pass-through pay-down account drops below US [****]. Clinipace invoices for pass-through expenses shall be payable by RedHill via WIRE within thirty (30) days after RedHill's receipt of each non-disputed invoice.

At the end of the project Clinipace will perform a final reconciliation of pass-through costs providing detailed record of each pass-through item from the pass-through pay-down account.

As a status update, at least once a month, Clinipace will send RedHill a detailed breakdown of both the accumulated pass-through costs and the Investigators Grants costs so (even if we the amount for invoicing hasn't been reached).

Attachment A-1: Study Work Order

ACH/Wire Instructions:
Beneficiary: Clinipace, Inc.
Account #: [****]
Bank Name: [****]
Bank Address: [****]
USABank Swift: [****]
Bank Routing: [****]

Clinipace FEIN: [****]

Term

The term of this Attachment A-1 shall commence execution of this A-1 and terminate upon the completion of all deliverables, unless terminated sooner in accordance with the terms of the MSA. RedHill and Clinipace agree that the terms and conditions of this Attachment A-1 may be modified in the event that the duration or scope of the Trial is significantly altered to an extent markedly affecting the tasks, but only in accordance with a Change Order agreed by both parties, as defined in the Master Service Agreement.

Signature

Clinipace and RedHill each hereby agree to the terms and conditions of this Attachment A-1, which are subject to the terms and conditions of the Master Services Agreement executed by the parties, effective as of October 28, 2012 (the "MSA"). This Attachment A-1 is hereby incorporated in and made a part of the MSA. Capitalized terms that are not defined herein shall have the meaning given to such terms in the MSA.

CLINIPACE, INC.:		RedHill Biopharma Ltd.:	
By:	/s/	By:	/s/
Name:		Name:	
Title:		Title:	
Date:		Date:	

Exhibit 4.21

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Amendment 1 to Attachment A-1: Study Work Order

I. RedHill Biopharma Ltd. ("RedHill") and Clinipace, Inc. ("CPWW" or "Clinipace") agree to the following specific description of the project and related tasks and activities ("Services") that the parties anticipate completing in the allocated time, subject to prioritization and timely performance of RedHill Responsibilities (as defined in the MSA) by RedHill and as mutually agreed upon by the parties.

RedHill and Clinipace (collectively herein as "Parties") entered into an Attachment A-1 ("Attach A-1", and/or "Attachment A-1") on 29 October 2012, and the Parties desire to amend and replace the Attachment A-1 with this Amendment 1 to Attach A-1 ("Amendment 1").

II. Project Assumptions

CPWW will provide Services and staff reasonably necessary to support RedHill's clinical trial, "A randomized placebo controlled phase III study to assess the safety and efficacy of RHB-105 in the treatment of confirmed Helicobacter pylori (H.pylori) infection in non-investigated dyspepsia patients" (the "Study"). The general specifications and assumptions for this Study are included in the table below:

	Original Contract	Amendment 1
Patient Specifications		
Number of Patients Screened	[****]	[****]
Number of Patients Enrolled	[****]	[****]
Number of Patients Complete	[****]	[****]
Estimated Number of Serious Adverse Events (per subject)	[****]	[****]
Site Specifications		
Number of Sites	8.0	10
Number of Qualification Visits	8.0	6 actuals + 2 projected
Qualification Visit (duration in days)	0.5	0.5
Number of Initiation Visits	8.0	10
Initiation Visit (duration in days)	1.0	1
Number of Interim Monitoring Visits per Site	3.4	3.4
Total number of Interim Monitoring Visits	27.0	35

Interim Monitoring Visit (duration in days)	1.0	1
Number of Close-out Visits	8.0	10
Close-out Visit (duration in days)	1.0	1
CRF Specifications		
Estimated Unique Pages	15.0	45
Estimated Total Pages per Patient	30.0	109
Project Management Specifications		
Number of Kick-off Meetings	1.0	1
Kick-off Meeting (duration in hours)	4.0	4
Number of Client Project Meetings (face-to-face)	1.0	1
Number of Client/Clinipace Teleconferences	22 at 0.5hrs/call/month	30 Calls at 0.5hr/call
Number of Internal Meetings	11.0	16 Calls at 1hr/call Monthly
SAEs		
Number of SAEs	[****]	[****]
Number of Reportable SAEs	[****]	[****]
Statistical Analysis		
Number of TLF displays (Analysis Datasets (ADs) not included and will need to be scoped in once # of ADs are determined in addition to updates to the TFL count)	53	53

Timeline:

Milestone	Estimated Date per Attachment 1		Revised Estimated Dates per Amend 1
CPWW Activities Begin	[****]	Pre-Study	[****]
Final Protocol/ICF	[****]	Activities	[****]
IND Submission	[****]		
Start-up Period Begins	[****]		[****]
Start-up Period Ends	[****]		[****]

Enrollment Begins	[****]	Study Activities	[****]
Enrollment Ends	[****]		[****]
Treatment Period Ends	[****]		[****]
Collection of Final CRFs	[****]		[****]
Query Resolution	[****]		[****]
Database Lock	[****]		[****]
Statistical Analysis	[****]	Post Dosing	[****]
Draft Report	[****]	Activities	[****]
Final Report	[****]		[****]
CPWW Activities End	[****]		[****]

III. Schedule of Services

The purpose of this Amendment 1 to Attachment A-1 is to set forth in more detail the Services that Clinipace shall provide pursuant to the MSA and the terms set forth herein, including but not limited to the obligations set forth in the Schedule of Services (below).

Project-specific Tasks	**Responsibility**			
	N/A	RedHill	CPWW	Joint
Clinical Trial Preparation				
Investigator Brochure Development		☒		
Protocol/Protocol amendment		☒		
eCRF Preparation			☒	
Informed Consent Template Preparation			☒	
Site-Specific Informed Consent Form Review			☒	
Central IRB Selection and Management			☒	
Monitoring Plan Development			☒	
Collection of Site Regulatory Documents (Including site IRB)			☒	
Regulatory Binders to sites			☒	
Regulatory Authority Submission (e.g. FDA, MoH)		☒		
Site selection				☒
Central Laboratory Selection (If needed)		☒		
Central Laboratory Management and Payment		☒		
Investigator's Grant Negotiation				☒
Training materials				☒
Project Kick-off Meeting				☒
Investigator's Study Files Structures			☒	
CTM Packaging, Labeling and Distribution		☒		
Monitoring and Trial Management				
Pre-Study visits			☒	

Site Initiation Visits			☒	
Interim Monitoring Visits (approximately 3.5 per site for 10 sites)			☒	
Site Close-out Visits			☒	
Enrollment Status Reports (none [****] forward)			☒	
SAE reports (none [****] forward)			☒	
Contact Reports (none [****] forward)			☒	
Site Management			☒	
Study Reference Manual			☒	
Project Management				
Maintenance of Study Master File			☒	
Schedule Client Meeting / Prepare Minutes – RedHill to Schedule and prepare minutes (with CPWW review); CPWW to attend				☒
Study Timelines				☒
Medical Monitoring				
Medical Monitoring (maximum of 3 hours/month thru LPO)			☒	
Medical Review (up to [****] - SAEs and [****] - Expedited SAE)			☒	
Data Safety Monitoring Board Selection	**N/A**			
Data Safety Monitoring Board Management & Meetings	**N/A**			
Pharmacovigilance				
Serious Adverse Event Management			☒	
Regulatory Submission of Adverse Event Reports (RedHill to FDA; CPWW to IRBs)				☒
Data Management & Biostatistics				
Database Design Set-up/Modification (included in eCRF design) Refer to Appendix III for Schedule of Events			☒	
Data Management Plan			☒	
Data Coding, AEs, Medications			☒	
Central Laboratory Data Transfer			☒	
Randomization Scheme			☒	
Statistical Analysis Plan			☒	
Prepare Study Tables, Listings and Figures			☒	
Clinical Study Reports				
Provide 2 draft study reports			☒	
Provide Final Study Report			☒	
Publishing		☒		
Quality Assurance				
GCP Site Audits		☒		
QC Audits of CSRs			☒	
QC Audit of Database	**N/A**			

IV. Professional Fees and Resources

Task	Assumptions	Current Contract Total (US$)	Amendment 1 Variance	Revised Contract Total (US$)
PROTOCOL DEVELOPMENT AND AMENDMENTS		**$** [****]	**$** [****]	**$** [****]
Protocol Development	Clinipace MD will review the protocol developed by RedHill. The estimate is based on two review cycles (administrative changes are not limited to two review cycles)	**$** [****]	**$** [****]	**$** [****]
Protocol Amendment(s)	Clinipace MD will review protocol amendment(s) during the course of this study. We have estimated 2 amendment(s) to the protocol. (Administrative changes/corrections not included for Amendment 2 and any forward	**$** [****]	**$** [****]	**$** [****]
REVIEW STUDY MATERIALS		**$** [****]	**$** [****]	**$** [****]
Review Study Materials	General review of study materials by Clinipace Project Team.	**$** [****]	**$** [****]	**$** [****]
PROTOCOL DISTRIBUTION AND TRANSLATION		**$** [****]	**$** [****]	**$** [****]
Distribute Protocol to Sites	Includes IB	**$** [****]	**$** [****]	**$** [****]
Distribute Protocol Amendment(s) to Sites	Based on amendment 1 & 2 for 8 sites.	**$** [****]	**$** [****]	**$** [****]
Protocol Translation	Translations will be handled by third party vendors. Includes time to manage the vendors.	**$** [****]	**$** [****]	**$** [****]
eCRF DEVELOPMENT		**$** [****]	**$** [****]	**$** [****]
Develop eCRF		**$** [****]	**$** [****]	**$** [****]
eCRF Completion Guidelines	Clinipace will create the eCRF Completion Guidelines.	**$** [****]	**$** [****]	**$** [****]
Develop Subject Diary		**$** [****]	**$** [****]	**$** [****]
SODA Form	From PDF to MS Word	**$** [****]	**$** [****]	**$** [****]
INFORMED CONSENT		**$** [****]	**$** [****]	**$** [****]
Develop Informed Consent Form (ICF)	Clinipace will develop the model ICF. RedHill will review and approve the consent. Based on 1 review cycle.	**$** [****]	**$** [****]	**$** [****]
Negotiate changes to template with sites	Clinipace will work with the site(s) on any local changes to the ICF. Clinipace will consult RedHill on any changes from the site(s).	**$** [****]	**$** [****]	**$** [****]

Update ICF - Protocol Amendments	Clinipace will be responsible for updating the ICF based on amendments to the protocol. Based on 1 amendment(s).	$ [****]	$ [****]	$ [****]
Translation of Informed Consent	Clinipace will work with the sites to translate the Informed Consent into the appropriate language.	$ [****]	$ [****]	$ [****]
INVESTIGATOR SELECTION/PRE-STUDY VISITS		$ [****]	$ [****]	$ [****]
Develop Site Recruitment Materials		$ [****]	$ [****]	$ [****]
Identify and Recruit Investigators	Clinipace will work to identify 8 investigators willing and able to participate in this trial. Clinipace will provide Sponsor with a list of sites for approval. We have estimated we will need to identify [****] sites to get [****]. 2 additional sites will be recruited from [****] forward based on established feasibility questionnaire.	$ [****]	$ [****]	$ [****]
Perform Pre-Study Site Visits - US	4 hours on site, avg. 8 hours travel RT, 6 hours prep and reporting = 18 hours. 6 conducted thru [****] with 2 additional projected for new sites	$ [****]	$ [****]	$ [****]
CLINICAL TRIAL AGREEMENTS		$ [****]	$ [****]	$ [****]
Negotiate contracts with sites	Clinipace will negotiate and hold site contracts and budgets with each site.	$ [****]	$ [****]	$ [****]
Investigator Grants	Clinipace will administer payments to each site. This proposal is based on quarterly payments per site.	$ [****]	$ [****]	$ [****]
REGULATORY DOCUMENTS		$ [****]	$ [****]	$ [****]

Prepare, collect, review appropriate regulatory documents	Clinipace will provide templates to each site including Financial Disclosure Document and 1572, then collect locally required approval documents. This line includes communication with sites to obtain final documents and corrections. Based on 8 sites plus 2 sites from [****] forward.	$ [****]	$ [****]	$ [****]
Regulatory Binder	Each site will receive a regulatory binder that contains all required documents. This binder will be checked at each monitoring visit. Total of 10 binders will be distributed.	$ [****]	$ [****]	$ [****]
Study Procedures Manual	A study procedures manual was not developed.	$ [****]	$ [****]	$ [****]
Prepare study aids such as drug logs, etc.		$ [****]	$ [****]	$ [****]
Prepare and submit package to sites for submission to ethics committees.		$ [****]	$ [****]	$ [****]
Update documentation for IRBs/ECs - Protocol Amendment(s)	Based on protocol amendment(s) 1 & 2.	$ [****]	$ [****]	$ [****]
Prepare and submit dossier for submission to appropriate Ministry of Health, Track MoH approvals.	RedHill will be responsible for regulatory authority submissions.	$ [****]	$ [****]	$ [****]
Communication and preparation of official responses to MoH pending issues.	RedHill will be responsible for regulatory authority submissions.	$ [****]	$ [****]	$ [****]
MoH Updates - Protocol Amendment	RedHill will be responsible for regulatory authority submissions.	$ [****]	$ [****]	$ [****]
Annual Reviews (EC)	Assume each site will require 1 IRB/IEC renewal(s).	$ [****]	$ [****]	$ [****]
Drug Label Review/Translation	RedHill will be responsible for packaging and labeling. Clinipace provided review	$ [****]	$ [****]	$ [****]
TRIAL MASTER FILE		$ [****]	$ [****]	$ [****]
Set up Trial Master File		$ [****]	$ [****]	$ [****]
Maintain Trial Master File		$ [****]	$ [****]	$ [****]
INVESTIGATOR MEETINGS		$ [****]	$ [****]	$ [****]
Plan and Manage Investigator Meeting(s)	Clinipace organize a Web-based Investigator Meeting.	$ [****]	$ [****]	$ [****]

Prepare meeting binders	Clinipace will create the meeting binder and ship to the sites. Sponsor will approve the contents of the binder. We have included cost for producing 41 binders.	$ [****]	$ [****]	$ [****]
Prepare Presentations		$ [****]	$ [****]	$ [****]
Attend investigator meeting: US	Webinar	$ [****]	$ [****]	$ [****]
Project Team Training	We have assumed a 4 hour training session.	$ [****]	$ [****]	$ [****]
VENDOR MANAGEMENT		$ [****]	$ [****]	$ [****]
Central IRB/IEC		$ [****]	$ [****]	$ [****]
Central Laboratory		$ [****]	$ [****]	$ [****]
INITIATION VISITS		$ [****]	$ [****]	$ [****]
Perform Site Initiation Visits - US	8 hours on-site, avg. 8 hours travel, 6 hours preparation including slides and protocol review, scheduling and reporting per site = 22 hours Total of 10 SIVs budgeted	$ [****]	$ [****]	$ [****]
INTERIM MONITORING VISITS		$ [****]	$ [****]	$ [****]
Develop Monitoring Plan	Clinipace will complete the monitoring plan/guidelines. Clinipace will provide the draft monitoring plan to RedHill for review and approval. Based on 1 review cycle with RedHill	$ [****]	$ [****]	$ [****]
Perform interim monitoring visits: US	8 hours on-site, 8 hours travel, 6 hours preparation, scheduling and reporting = 22 hours per visit. Total of 35 IMVs included at approximately 3.5 IMVs per site for 10 sites	$ [****]	$ [****]	$ [****]
Extension Visits	Based on 5 total additional days on-site at 8 hours each	$ [****]	$ [****]	$ [****]
Remote Monitoring	7 sites thru [****], 10 sites thereafter thru LPO at an average of 4 hours per site per month	$ [****]	$ [****]	$ [****]
CLOSE-OUT VISITS		$ [****]	$ [****]	$ [****]
Perform Close-out visits: US	1 day closeout (8 hours) + 8 travel + 6 preparation, scheduling and reporting = 22 hours per visit Total of 10 COVs budgeted	$ [****]	$ [****]	$ [****]
QUERY RESOLUTION		$ [****]	$ [****]	$ [****]

Query Resolution - Data Lock	Clinipace monitors will assist data management with query resolution at study close in order to expedite database lock. Redhill responsible for directly communicating with the sites for all query resolution from [****] forward	$ [****]	$ [****]	$ [****]
SITE MANAGEMENT		$ [****]	$ [****]	$ [****]
In-house Site Management	This will be done by assigned CRA, to include in-house site management time during active clinical duration. Assume routine calls to sites during clinical project duration at 1 hour per site per month.	$ [****]	$ [****]	$ [****]
Lead Clinical Research Associate		$ [****]	$ [****]	$ [****]
PROJECT COMMUNICATIONS		$ [****]	$ [****]	$ [****]
Client Kick-off/Training Meeting	Assume a 4 hour kick-off. Training meeting will be held between the Clinipace and Sponsor teams (via teleconference).	$ [****]	$ [****]	$ [****]
Enrollment Reports	Clinipace will provide enrollment reports to the sponsor via Tempo.			
Status Reports	Clinipace monthly reports to sponsor, to include screening, enrollment, number of monitoring visits, CRFs harvested; queries outstanding, etc. All reports to be pulled from Tempo by RedHill from [****] forward	$ [****]	$ [****]	$ [****]
Teleconferences with Sponsor	Assume monthly calls with sponsor. From [****] forward: Monthly Calls thru 3rd month of Close-out (12 total calls) at 1hr/call with attendees: PM, MD, SF, DM, ST, ICRA, & CTC	$ [****]	$ [****]	$ [****]
Provide newsletters	Not requested	$ [****]	$ [****]	$ [****]
External Sponsor / Clinipace Face to Face Team Meetings	Anticipate one meeting at the Sponsor attended by the Clinipace Project Director.	$ [****]	$ [****]	$ [****]

CRA Study Management	General CRA time for communication with internal team as needed, file maintenance etc. thru DBL at 1hr per CRA per week from [****] forward	$ [****]	$ [****]	$ [****]
Internal Team Meetings	Clinipace will hold monthly internal team meetings during the course of this project. From [****] forward: Internal Monthly calls thru 3rd month of Close-out (12 total calls) at 1hr/call with attendees: PM, MD, SF, DM, ST, CRAs, ICRA, & CTC	$ [****]	$ [****]	$ [****]
PROJECT MANAGEMENT		$ [****]	$ [****]	$ [****]
Project Management	General Project Management to include interaction with monitors; review of all documents and general ad hoc sponsor communication thru [****] only	$ [****]	$ [****]	$ [****]
Project Oversight [****] Forward by Lead CRA (LCRA)	General oversight of project to include ad hoc interaction with internal team and ad hoc communications with Sponsor. Maximum of 3 hours/day from [****] forward	$ [****]	$ [****]	$ [****]
Clinical Trial Coordinator - Administrative Support	Limited Project Administrative support (for LCRA) to maximum of 1 hour per day from [****] forward	$ [****]	$ [****]	$ [****]
Financial Reporting		$ [****]	$ [****]	$ [****]
Return Study Files to Sponsor		$ [****]	$ [****]	$ [****]
QUALITY ASSURANCE		$ [****]	$ [****]	$ [****]
QA Visits	InSymbiosis			
STUDY DRUG		$ [****]	$ [****]	$ [****]
Obtain import permits for study drug and supplies; prepare and review import paperwork	InSymbiosis/RedHill	$ [****]	$ [****]	$ [****]
Oversee Drug Distribution to Sites from Warehouse	InSymbiosis/RedHill	$ [****]	$ [****]	$ [****]
Obtain any necessary export permits for shipping of lab samples to central lab and for return of unused study medication at end of study	Not applicable	$ [****]	$ [****]	$ [****]
Drug depot and Central lab contact and local issues management throughout the study	InSymbiosis/RedHill	$ [****]	$ [****]	$ [****]

MEDICAL MONITORING		**$** [****]	**$** [****]	**$** [****]
Medical Monitoring Plan		**$** [****]	**$** [****]	**$** [****]
Provide medical contact with sites	Clinipace will provide sites with a contact person to answer site questions. Capped at 3hrs/month thru Last Patient Out (LPO)	**$** [****]	**$** [****]	**$** [****]
Review SAEs	Total of [****] SAEs	**$** [****]	**$** [****]	**$** [****]
Review patient eligibility, lab alerts, coding and listings		**$** [****]	**$** [****]	**$** [****]
DRUG SAFETY/PHARMACOVIGILANCE		**$** [****]	**$** [****]	**$** [****]
Create Safety Monitoring Plan	Clinipace will develop the safety plan. Clinipace will provide the draft plan to RedHill Biopharma Ltd. for review and approval. Based on 1 review cycle with RedHill Biopharma Ltd.	**$** [****]	**$** [****]	**$** [****]
Set-up SAE Database		**$** [****]	**$** [****]	**$** [****]
Document and manage SAEs	Based on [****] SAEs.	**$** [****]	**$** [****]	**$** [****]
Follow-up SAEs		**$** [****]	**$** [****]	**$** [****]
Report SAEs to regulatory authorities	Based on [****] expedited SAEs to IRBs. RedHill responsible for FDA reporting	**$** [****]	**$** [****]	**$** [****]
Update all Study Sites of SAEs requiring Expedited Safety Reports/Distribute IND Safety Reports	Clinipace will notify each site of SAEs that require reporting.	**$** [****]	**$** [****]	**$** [****]
Write Safety Narratives	Based on [****] narratives.	**$** [****]	**$** [****]	**$** [****]
SAE Reconciliation	Based on [****] reconciliations throughout the course of the project.	**$** [****]	**$** [****]	**$** [****]
DATA MANAGEMENT		**$** [****]	**$** [****]	**$** [****]
STUDY PLATFORM				
Data Management Fees	▪ Includes License Fees, Hosting and Technical Support	**$** [****]	**$** [****]	**$** [****]
Hardware & Systems	▪ 3 servers ▪ Routers/firewall ▪ Tape drive (backup) ▪ Redundancy ▪ Security (IPS, AVS) ▪ Bandwidth	[****]	[****]	[****]
CRF Revisions		[****]	[****]	[****]
IMPLEMENTATION				

Clinical Data Capture Module	▪ XML file creation & load ▪ eCRF programming ▪ Edit check coding ▪ Data element coding ▪ Workflow configuration ▪ Database development ▪ Testing	$ [****]	$ [****]	$ [****]
Reports		[****]		[****]
Randomization		$ [****]	$ [****]	$ [****]
User Administration		[****]		[****]
Validation (testing & documentation)		$ [****]	$ [****]	$ [****]
Training Manual		[****]		[****]
User training (TTT)		[****]		[****]
Printable (PDF) CRFs		[****]		[****]
STUDY DATA MANAGEMENT AND SUPPORT				
Data Management Plan		$ [****]	$ [****]	$ [****]
Code book creation		[****]		[****]
Data Entry	Not applicable			
Verification	Not applicable			
CRF Tracking	Not applicable			
Coding	Based on 10 codes per patient.	$ [****]		$ [****]
Queries	Based on 10 queries per patient.	$ [****]		$ [****]
Data Imports	Based on 2 data transfers/imports from outside vendors.	$ [****]		$ [****]
Data exports/monthly		[****]		[****]
Data export/final		[****]		[****]
Data warehousing/archiving		[****]		[****]
Database Updates	Approved [****] via email	$ [****]	$ [****]	$ [****]
Administration		$ [****]	$ [****]	$ [****]
STATISTICAL ANALYSIS		$ [****]	$ [****]	$ [****]
Develop Statistical Analysis Plan	Clinipace will develop the Statistical Analysis Plan. Clinipace will provide the draft analysis plan to RedHill. for review and approval. Based on 1 review cycle with RedHill	$ [****]	$ [****]	$ [****]
Create Randomization Plan		$ [****]	$ [****]	$ [****]
Conduct SAS programming and QC of all TLFs	Based on 8 unique tables, 16 non unique tables, 3 unique figures, 6 non unique figures and 20 listings.	$ [****]	$ [****]	$ [****]
Analysis Dataset (AD) Programming	Not included in budget.	$ [****]	$ [****]	$ [****]
Prepare Interim Analysis and Report	Not applicable			
Prepare Final Analysis and Report		$ [****]	$ [****]	$ [****]
QC All Analysis and Report		$ [****]	$ [****]	$ [****]
FINAL REPORT		$ [****]	$ [****]	$ [****]

Write Clinical Study Report (CSR)	Clinipace will develop the final report for the study. Clinipace will provide the draft report to RedHill Biopharma Ltd. for review and approval. Based on [****] review cycles with RedHill	$ [****]	$ [****]	$ [****]
TOTAL SERVICES		**$ [****]**	**$ [****]**	**$ [****]**
Discount		$ [****]	$ [****]	$ [****]
SERVICES COSTS GRAND TOTAL		**$ [****]**	**$ [****]**	**$ [****]**

Discount Total in the Original Contract was erroneously calculated in Attachment A-1 and has been adjusted to reflect the correct amount in this Amendment 1 to Attach A-1.

V. Payment Terms

RedHill agrees to pay Clinipace a professional fee of US $[****] ("Fee") as total payment for the full scope of Services and Tasks. Any task reduced in scope will be credited (on a pro-rata basis in accordance with the actual hours spent) for hours budgeted in the agreement but not performed in full. A down payment of [****] was due and paid upon Clinipace's receipt of a fully executed copy of the Attachment A-1. From then on, RedHill was invoiced (as applicable) for the tasks actually performed and milestones reached by Clinipace ("Milestone Invoice"). Each Milestone Invoice shall be itemized in sufficient detail to permit independent auditing and verification that the work covered by such Milestone Invoice has been properly performed and the relevant milestone reached. Upon the initiation of Study Activities, as part of the Fee and included therein, and as detailed in the table below, RedHill was to pay Clinipace a Quarterly Fee of $[****], calculated from the date of initiation of Study Activities thru [****].

All Invoices, except for the down payment, shall be due within 30 days of invoice. Non-disputed invoices not paid within forty-five (45) days will be subject to a late payment charge of 0.5% per month until paid in full.

The following table provides a breakdown of the Fee, as it was set forth in Attachment A-1, into Milestone Payments and Quarterly Payments. The Milestone Payments will be due only upon reaching the said milestone. Quarterly Payments are capped at 4 total payments for a total of $ [****]:

	Current Contract
Milestone Payments: Pre-IND	**$** [****]
Execution of the Agreement **- PAID**	**$** [****]
Protocol and ICF Completed **- PAID**	**$** [****]
Milestone Payments: Post-IND	**$** [****]
Initiation of study activities **- PAID**	**$** [****]
Database set-up complete (go live) **- PAID**	**$** [****]
First Subject Enrolled **- PAID**	**$** [****]
Last Subjects Enrolled ([****] subjects)	**$** [****]
Last CRF Collected	**$** [****]
Final CSR	**$** [****]
Total Milestone Payments	**$** [****]
Quarterly Payments: Beginning Post IND	
Quarterly Payment 1- Invoice due at 3 months post Initiation of Study Activities **- PAID**	**$** [****]
Quarterly Payment 2 – Invoice due at 6 months post Initiation of Study Activities	**$** [****]
Quarterly Payment 3– Invoice due at 9months post Initiation of Study Activities	**$** [****]
Quarterly Payment 4– Invoice due at [****] months post Initiation of Study Activities	**$** [****]
Total Quarterly Payments	**$** [****]
Total Fee per Attachment A-1	**$** [****]

The following table provides a breakdown of the remainder of the Fee, as set forth in this Amendment 1 to Attachment A-1, into Monthly Payments as agreed upon (via email).

Amendment 1 Execution Payment – [****] payable net 15 days from invoice date	**$** [****]
[****] **– due and payable net 30 days from invoice date**	**$** [****]
[****] **– due and payable net 30 days from invoice date**	**$** [****]
[****] **– due and payable net 30 days from invoice date**	**$** [****]
TOTAL PAYMENTS	**$** [****]

Should enrollment go beyond [****], RedHill agrees to pay the following amounts for each month enrollment is extended beyond [****].

	Budget per Month	**Discount**	**Total Less Discount**
Month 5th ([****]) due and payable net 30 days from invoice date	**$** [****]	**$** [****]	**$** [****]
Month 6th ([****]) due and payable net 30 days from invoice date	**$** [****]	**$** [****]	**$** [****]
Month 7th ([****]) onward, due and payable net 30 days from invoice date	**$** [****]	**$** [****]	**$** [****]

Should only 1 of the 2 new sites be activated, a change in scope will be conducted to adjust the Fees accordingly to account for all services not performed for the 2nd site. The maximum reduction in connection with such change in scope as provided in the foregoing sentence shall be for a maximum amount of $[****].

PASS THROUGH COSTS

Clinipace Pass-Through Costs

INDIRECT COSTS	(PASS-THROUGH EXPENSES)	Current Contract Total (US$)	Amendment 1 Variance	Revised Contract Total (US$)
Ministry of Health and Ethics Committee Fees (IRB Fees)	Assume 1 initial submission only (no amendments) and 1 annual review(s).	$24,000	$0	$24,000
CRA AirCards		$1,350	$0	$1,350
Shipping		$5,500	$19,850	$25,350
Phone (Long Distance)		$5,500	$6,617	$12,117
Supplies		$3,300		$3,300
Translation costs	Clinipace will work with the sites and a translation vendor(s) to translate appropriate study documents into local languages. Includes translation into 2 different languages.	$20,000	$0	$20,000
Plan and Manage Investigator Meeting(s) with meeting planner	Web-based IM - hosting fees	$500	$0	$500
Travel	Includes travel for monitoring visits, client meetings, supervision visits, QA visits.	$52,750	$21,700	$73,650
ESTIMATED INDIRECT COSTS TOTAL		**$112,900**	**$48,167**	**$161,067**

RedHill agrees to reimburse Clinipace for pass through expenses, of the type detailed above and estimated to be approximately [****] for the duration of the study. As a prepayment of pass through expenses, [****] was due and paid, upon RedHill written confirmation of the Study enrolment, following approval of the IND/CTA. This established a pass-through pay-down account. Clinipace will track the disbursement of pass-through costs from the pass-through pay-down account and will invoice RedHill each time the balance in the pass-through pay-down account drops below US [****]. Each such invoice will have annexed to it an updated report of the pass-through pay-down account. Clinipace will track the actual pass-through costs against the estimated budget and will notify REDHILL of any overages. Clinipace invoices for pass-through expenses shall be payable by RedHill via ACH/WIRE within thirty (30) days after RedHill's receipt of each invoice.

At the end of the project Clinipace will perform a final reconciliation of pass-through costs providing detailed record of each pass-through item in the pass-through pay-down account.

Investigator Grants

Current estimate of Investigator Grants:

Investigator Grants	**$** [****]

RedHill agrees to reimburse Clinipace for Investigator Grants, currently estimated to be approximately US $ [****] for the duration of the study (up to $ [****] per subject, n=[****]). It is the combined responsibility of Clinipace and RedHill to negotiate and execute Investigator Agreements. Only Investigator Agreements duly signed by RedHill will serve to establish the actual basis for Investigator Grant payments and reconciliation.

As a prepayment of the Investigator Grants, [****] was due and paid, upon initiation of patient enrollment. This established a pass-through Investigator-Grants account (with the account to be periodically replenished during the Study). Clinipace will track the disbursement of pass-through Investigator-Grants and invoice RedHill each time the balance in the pass-through pay-down account drops below [****]. Clinipace invoices for pass-through expenses shall be payable by RedHill via WIRE within thirty (30) days after RedHill's receipt of each non-disputed invoice.

At the end of the project Clinipace will perform a final reconciliation of pass-through costs providing detailed record of each pass-through item from the pass-through pay-down account.

As a status update, at least once a month, Clinipace will send RedHill a detailed breakdown of both the accumulated pass-through costs and the Investigators Grants costs so (even if we the amount for invoicing hasn't been reached).

REVISED ACH/Wire Instructions:

Beneficiary:	Clinipace, Inc.
Account #:	[****]
Bank Name:	[****]
Bank Address:	[****]
Bank Swift:	[****]
Bank Routing:	[****]
Clinipace FEIN:	[****]

Term

The term of this Amendment 1 to Attachment A-1 shall commence execution of this Amendment 1 to Attachment A-1 and terminate upon the completion of all deliverables, unless terminated sooner in accordance with the terms of the MSA. RedHill and Clinipace agree that the terms and conditions of this Amendment 1 to Attachment A-1 may be modified in the event that the duration or scope of the Trial is significantly altered to an extent markedly affecting the tasks, but only in accordance with a Change Order agreed by both parties, as defined in the Master Service Agreement.

Signature

Clinipace and RedHill each hereby agree to the terms and conditions of this Amendment 1 to Attachment A-1, which are subject to the terms and conditions of the Master Services Agreement executed by the parties, effective as of October 28, 2012 (the "MSA"). This Amendment 1 to Attachment A-1 is hereby incorporated in and made a part of the MSA. Capitalized terms that are not defined herein shall have the meaning given to such terms in the MSA.

CLINIPACE, INC.:		RedHill Biopharma Ltd.:	
By:	/s/	By:	/s/
Name:		Name:	
Title:		Title:	
Date:		Date:	

Exhibit 4.22

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Clinical Trials Global Master Services Agreement

THIS CLINICAL TRIALS GLOBAL MASTER SERVICES AGREEMENT ("the Agreement") is made effective as of the date of the last signature by the parties' authorized representatives (the "Effective Date") by and between Quest Diagnostics Clinical Laboratories, Inc. ("Quest Diagnostics"), with a principal office located at 1201 South Collegeville Road, Collegeville, PA 19426-2998 USA and RedHill Biopharma, Ltd., with a principal office located at 21 Haarba'a St., Tel-Aviv 64739, Israel ("Client"). Quest Diagnostics and Client shall each herein be referred to as a "Party" and together as the "Parties".

Background

Quest Diagnostics provides central laboratory testing and related services ("Services") on a global basis to pharmaceutical, bio-technology, and other companies involved in pharmaceutical and medical research and product development. Client wishes to engage Quest Diagnostics to perform Services, and both parties wish to set forth their respective rights, duties, and obligations in connection therewith.

1. SERVICES

1.1 Provision of Services. Quest Diagnostics shall provide Services in accordance with this Agreement and more specifically, on a project-by-project basis (each a "Study") in the form of a Master Agreement Work Order(s) ("Work Order(s)"), an example of which is attached hereto as Exhibit A. Each Work Order will contain a Global Central Laboratory Worksheet ("CLW"), which describes the nature, scope and timelines for Services being specifically performed for a Study.

1.1.1 Project Manager. Quest Diagnostics will assign a Project Manager to interact on a regular basis with Client, coordinating and monitoring the Services provided by Quest Diagnostics for a Study. Client is responsible for ensuring that all updated versions of the Study protocol or any Study protocol amendments are sent to the Quest Diagnostics Project Manager.

1.2 Affiliates/Referral Laboratories/Subcontractors

1.2.1 Affiliates. "Affiliate" shall mean any entity that directly or indirectly controls, is controlled by or is under common control with a Party through the ownership of a majority of the outstanding voting securities or by contract. For purposes of this provision, the term "control" shall mean the power to either direct or cause the direction of the management of the entity or, in Quest Diagnostics' case, the management of the Services performed under this Agreement. Notwithstanding anything in this Agreement to the contrary, Quest Diagnostics shall have the right to provide Services hereunder through its Affiliates without prior approval of Client. Quest Diagnostics shall remain fully responsible to Client for the performance of such Services. The Parties agree and acknowledge that their respective Affiliates may execute Work Orders under this Agreement. In that event, such Affiliate(s) shall be bound by the terms and conditions of the Agreement and the applicable Work Order and shall be entitled to all of the rights and protections afforded under this Agreement as if they were an original Party to the Agreement. The Parties' Affiliates entering into such Work Orders shall remain responsible for the obligations set forth in any such Work Orders or the Agreement as it relates to the Services or obligations performed under the executed Work Orders by the named Affiliates.

1.2.2 Referral Laboratories. Upon the prior approval of Client, Quest Diagnostics may also provide Services to Client through contractual arrangements with independent laboratories. Quest Diagnostics shall remain fully responsible to Client for the performance of such Services. Client will be invoiced for the fee charged by the referral laboratory and a referral service fee per specimen. Any fee increases imposed by the referral laboratory will be passed through to Client.

1.2.3 Subcontractors. To the extent that Quest Diagnostics engages a third party to provide non-testing services (including, but not limited to, transportation and kit building) under this Agreement, Client agrees that such information shall be contained in the Work Order.

1.3 Specimen Storage Limitations. If requested by Client and agreed by Quest Diagnostics, Quest Diagnostics will hold specimens in storage at the conditions (temperature, etc.) agreed to between the parties for the time period defined by Client in the Study protocol or the CLW. Quest Diagnostics cannot guarantee that the specimens or any specific analyte will remain stable and suitable for testing or that stability data will be available during or after that storage time period. Client should review the stability characteristics of the specimen or analyte with Quest Diagnostics' Scientific Affairs department prior to storage of the samples. If the stability is unknown, the Client must define the specimen type, storage duration, and testing interval of the specimen or analyte. Furthermore, in the event that Client's Study is subject to the laws of the United Kingdom of Great Britain and Northern Ireland, Client represents and warrants to Quest Diagnostics that if Client requests Quest Diagnostics to store any tissue and other specimens covered by the Human Tissue Act 2004 (the "HTA") for any time period beyond the completion of the Study or the period approved by the research ethics committee that reviewed and approved the Study, Client will comply and cause its clinical investigators to comply with any and all consent requirements set forth under the HTA and the applicable codes of practice (including the codes of practice on consent and research) issued by the Human Tissue Authority, including seeking and obtaining appropriate and valid consent from the subjects participating in the Study for such storage of their specimens by Quest Diagnostics.

1.4 Research-Use-Only Tests. Client may, from time to time, request that Quest Diagnostics perform research-use-only tests ("RUO Tests") that have not been cleared or approved by the United States Food and Drug Administration. If Client requests Quest Diagnostics to perform RUO Tests, Client represents and warrants that the Client and all of Client's investigators shall use the results from RUO Tests for research purposes only, and will not use any test results from RUO Tests for diagnostic or clinical purposes.

1.5 Testing/Services Performed by Other Parties. Quest Diagnostics shall have no responsibility for or liability in connection with (a) use of expired supplies by investigators, (b) incorrectly ordered and/or incompatible supplies issued at Client's direction, (c) testing or other services performed, at Client's or an investigator's request, by a third party other than Quest Diagnostics, its Affiliates or its Referral Laboratories, or (d) testing or procedures performed at any investigator site not pursuant to Quest Diagnostics' instructions. Notwithstanding the foregoing, Quest Diagnostics shall be responsible for the shipment of testing kits/supplies sent at Client's direction.

1.6 Cancellation/Revision/Delay

1.6.1 Cancellation. If a Study is cancelled by Client after Quest Diagnostics has been authorized to initiate start-up Services and such Services have been initiated by Quest Diagnostics, Client agrees to reimburse Quest Diagnostics for (i) the project management, data management and logistics set-up fees specified in the Budget, (ii) any applicable fees for Services rendered in accordance with the Budget, including any specimen collection kits that have been prepared or distributed, and (iii) the purchase of any specialized testing reagents and/or supplies.

1.6.2 Revision. If a Study is revised at the request of Client after Study materials have been approved by Client, including but not limited to (i) requisition forms, (ii) investigator manuals, and (iii) specimen collection/transport supplies, Client agrees to pay Quest Diagnostics for Services rendered and costs incurred in the revision or replacement of previously-approved Study materials and supplies, and any costs associated with database changes resulting from Study revision.

1.6.3 Delay. If Client delays the initiation or conduct of a Study, to the extent that specimen collection/transport supplies and/or specialized testing reagents expire, Client agrees to pay Quest Diagnostics for costs incurred to replace expired supplies and/or specialized testing reagents.

2. COMPENSATION

2.1 Billing and Payment Terms. Quest Diagnostics will bill Client for Services once per month. Charges will be billed at the rates agreed to in the applicable Work Order, subject to any adjustments permitted under the Work Order or this Agreement. Services requested by Client that are not included in the applicable Work Order shall be billed at Quest Diagnostics' then-current general fee schedule, subject to any applicable discounts, unless otherwise agreed in writing by Client and Quest Diagnostics. It is a material term of this Agreement that Client shall pay all undisputed amounts within thirty (30) days of the date of an invoice for Services. In addition to any other remedies provided for under this Agreement, Quest Diagnostics reserves the right to charge a late fee of up to [****] on any undisputed amounts outstanding for more than 30 days from Client's receipt of an invoice for Services.

2.2 Upon written notice to Client of non-payment hereunder and failure of Client to cure such non-payment within thirty (30) business days from receipt of such notice, Quest Diagnostics, at its sole option, may suspend further performance of its duties and obligations under the related Work Order until all outstanding undisputed amounts from the related Work Order are fully paid. Any suspension by Quest Diagnostics shall extend any deadlines for performance by Quest Diagnostics of its duties and obligations under the suspended Work Order for a time period equal to the number of days between the date of receipt of Quest Diagnostics' notice of suspension and the date Quest Diagnostics receives full payment of all outstanding undisputed amounts related to the suspended Work Order.

2.3 Invoice and Payment Currency. Invoices shall be sent to the individuals/addresses listed herein or in the applicable Work Order and shall reflect the currency of the budget agreed in the Work Order. Invoices shall be prepared and paid in US dollars according to the official exchange rate on the invoice date. No changes to the invoice or payment currency shall be made through the term of the Study unless both parties agree in writing thirty (30) days in advance of the receipt of the invoice.

2.4 Payments:

2.4.1 Payments shall be made by wire transfer to Quest Diagnostics Clinical Laboratories, Inc., Tax ID Number [****]:

Bank Transfer/Wire Transfer information:

Send to: [****]
Bank address: [****]
USAABA Routing Number: [****]
Account Number: [****]
Swift Number: [****]
Telex Number: [****]*
Please identify the invoice numbers being paid.

2.4.2 Final Invoice. Quest Diagnostics shall complete its invoicing process within ninety (90) days after communication of a database lock. If any samples remain in storage, or if other Services are still to be performed, the parties agree that invoicing shall continue until such samples are removed from Quest Diagnostics' storage facilities, or relevant Services are completed.

2.4.3 Pricing for Supplies. Quest Diagnostics will use commercially-reasonable efforts to maintain pricing levels for supplies for the duration of a particular Study; however, if the cost of supplies increases as a result of circumstances beyond Quest Diagnostics' reasonable control, Quest Diagnostics shall pass the amount of such increase on to inform Client. Quest Diagnostics will notify Client of any such cost change. If approved by the Client, the Parties will then sign an amendment in support of such change prior to implementation.

2.4.4 Courier Service Cost Increases. Courier costs are estimates, and are based upon primary city site locations, unless otherwise noted in the bid submitted by Quest Diagnostics regarding the relevant Work Order. Quest Diagnostics will invoice Client based upon actual costs incurred, which may be increased due to Client's final clinical investigator site locations and availability of courier(s). Client acknowledges that courier costs may fluctuate depending upon final location of Client's clinical investigator sites, and may require a revised budget for the relevant Work Order to reflect Client's final investigator sites selected. If the costs to Quest Diagnostics for courier services increase at any time during the term of the Study, whether due to (i) an increase in the fees charged by Quest Diagnostics commercial couriers,(ii) an increase in the cost of packaging materials used to ship specimens, (iii) a mandatory change in applicable regulations, or (iv) courier services requested on holidays and weekends, Quest Diagnostics shall have the right to increase the courier fees by the same extent as the actual increase in the cost of services. Client agrees to pay for actual courier costs incurred.

2.4.5 Taxes. Client shall pay any sales, use, excise, value-added, goods and services, services, consumption, or other similar tax, if any, imposed by any governmental authority in connection with, or attributable to, Client's receipt of the Services hereunder or in connection with, or attributable to, the issuance of any invoice by Quest Diagnostics to Client for such Services. Quest Diagnostics shall be entitled to invoice Client for any such taxes as may be required by applicable law, and Client shall pay such amounts as invoiced by Quest Diagnostics, unless such amounts are recoverable by Quest Diagnostics under local tax laws or regulations. Client shall not be entitled to deduct any taxes from any payments otherwise due Quest Diagnostics hereunder. In the event that Client is required by applicable law to deduct any taxes from any payments otherwise due Quest Diagnostics hereunder, the price to Client otherwise quoted herein shall be increased to take account of any such taxes so that Quest Diagnostics shall receive the same net amount as if there were not any such taxes. In the event appropriate gross-up is made for any taxes required by applicable law to be deducted by Client from any payments hereunder, Client agrees to provide Quest Diagnostics promptly, but no later than 30 days after the close of the calendar year, with the applicable government certificate demonstrating the payment of such taxes or, if such government certificate is not available, other evidence of the payment of such taxes by Client to the government.

3. TERM AND TERMINATION

3.1 Term. This Agreement shall be effective as of the Effective Date, and shall continue for a period of [****] years unless otherwise terminated as provided herein (the "Term"). Unless specifically provided otherwise in writing by Quest Diagnostics and Client, the terms of this Agreement shall apply to all Services provided by Quest Diagnostics to Client during the Term. At the expiration of the Term, other than for termination in accordance with Section 3.2 below, the Agreement shall continue to apply to all Work Orders remaining in effect after the time of expiration of this Agreement, unless otherwise agreed in writing by the Parties.

3.2 Termination.

3.2.1. For Material Breach. If either party (the "non-breaching party") believes the other party (the "breaching party") is in material breach of any obligations hereunder, the non-breaching party shall have the right to terminate this Agreement or any Work Orders by providing the breaching party with written notice specifying the material breach(es) and indicating clearly its intention to terminate the Agreement or a Work Order thirty (30) days after the breaching party receives such notice. If the breaching party cures such breach within such thirty (30) day period, the non-breaching party's notice shall be void. If the breaching party does not cure such breach within such thirty (30) day period, the Agreement or the relevant Work Order shall terminate at the end of such thirty (30) day period.

3.2.2. Without Cause. Client may terminate this Agreement or any Work Orders by providing the Quest Diagnostics with written notice of termination at least thirty (30) days prior to the effective date of such termination.

3.2.3 Effect of Termination. Unless otherwise provided specifically in (a) this Agreement, such as in Section 3.1 with regard to continuing Work Orders or (b) a separate written document signed by both parties, upon termination or expiration of this Agreement, the parties shall each be released from their obligations hereunder, and this Agreement shall have no further force or effect; provided, however, that Sections 2, 4, 5, 6, 7, 8, 11.5, 11.6, and 11.9 shall survive termination of this Agreement.

4. INTELLECTUAL PROPERTY

4.1 Client Ownership of Data; Inventions. All data, test results, studies and other information generated by Quest Diagnostics in performing the Services (the "Data") shall be the property of the Client. All proprietary, non-public information concerning (a) the study drug and (b) Client's operations (including basic scientific data, prior clinical or laboratory data, formulation information, and research programs supplied by Client to Quest Diagnostics and not in the public domain) ("Client's Confidential Information") shall be considered confidential and shall remain the sole property of Client. Further, except as otherwise provided in Section 4.2 below, all rights to any discovery or invention conceived (or conceived and reduced to practice) in the direct performance of the work conducted under this Agreement (each, an "Invention") shall belong to Client. Quest Diagnostics shall promptly disclose to Client any Invention arising from this Agreement. Quest Diagnostics agrees to assign to Client, upon written request of Client, the sole and exclusive ownership of any Invention hereunder, subject to payment by Client of all expenses incurred by Quest Diagnostics in connection therewith. Quest Diagnostics may assist Client in any further protection or perfection of such Invention to the extent reasonably necessary at a fee to be negotiated and agreed upon by the parties and paid by Client to Quest Diagnostics.

4.2 Quest Diagnostics Intellectual Property. Notwithstanding anything in this Agreement to the contrary, Client and Quest Diagnostics agree that Quest Diagnostics possesses certain intellectual property, including but not limited to inventions, know-how, trade secrets, analytical methods, standard operating procedures, computer technical expertise, software and statistical methodologies originated by Quest Diagnostics prior to or during the Term of this Agreement without benefit of Information provided by Client that is the sole property of Quest Diagnostics ("Quest Diagnostics' Intellectual Property"). Further, to the extent that Quest Diagnostics makes any improvement or addition to Quest Diagnostics' Intellectual Property relating solely to central or diagnostic laboratory analyses and services and/or medical diagnostic assays and methods in the course of performing this Agreement or otherwise, such improvement and/or addition to Quest Diagnostics' Intellectual Property shall be the sole and exclusive property of Quest Diagnostics. Finally, in the course of working with Quest Diagnostics hereunder, Client may become aware of other, non-public information about Quest Diagnostics and its business that Quest Diagnostics considers confidential, which shall be considered confidential and shall remain the sole property of Quest Diagnostics (such information, together with Quest Diagnostics' Intellectual Property, is referred to hereinafter as "Quest Diagnostics Confidential Information").

5. CONFIDENTIALITY OBLIGATIONS

5.1 Protection and Non-use of Confidential Information. Quest Diagnostics and Client each agree to keep in strict confidence and not to disclose Confidential Information of either Party hereto or their Affiliates or subsidiaries to any third party or use such Confidential Information for any purpose other than for the performance of this Agreement without the prior written consent of the other Party hereto. Each Party may disclose the other Party's Confidential Information to its subsidiaries, employees and agents performing any of that Party's obligations or Services hereunder who have a need to know such Confidential Information and are bound by obligations of confidentiality and non-use equal to or greater than those contained herein. Each Party agrees to provide the other Party's Confidential Information with a reasonable level of protection from disclosure (but in no event less than that accorded its own Confidential Information), and to take all reasonable precautions to prevent the unauthorized disclosure to any third party of the Confidential Information that it receives hereunder. The above notwithstanding, the receiving Party's obligations of confidence and non-use with respect to the Confidential Information disclosed hereunder shall not include:

(a) Information that at the time of disclosure to the receiving Party is in the public domain, or that thereafter becomes part of the public domain through no fault of the receiving Party;

(b) Information that is known to the receiving Party prior to the time of disclosure to the receiving Party, as evidenced by its contemporaneous written records;

(c) Information that has been or is disclosed to the receiving Party in good faith by a third party who was not, or is not, under any obligation to keep the Information confidential;

(d) Information that is independently developed by or on behalf of the receiving Party, without reliance on the Information received hereunder; or

(e) Information that is required to be disclosed by law, provided that the receiving Party gives the disclosing Party prompt notice of such required disclosure.

5.2 Term of Confidentiality. The obligations of confidentiality and non-use set forth herein shall remain in effect for a period of [****] years after the last date on which Confidential Information is disclosed by one Party to the other hereunder, or termination of this Agreement, whichever date occurs last.

6. INDEMNIFICATION/LIMITATION OF LIABILITY/INSURANCE

6.1 Indemnification

6.1.1 Indemnification by Quest Diagnostics. Quest Diagnostics agrees to defend, indemnify and hold Client, and its officers, directors, employees, members, agents, successors and assigns harmless from claims, demands, costs, expenses (including reasonable attorneys' fees) and liabilities or losses (hereinafter referred to individually as a "Claim" and collectively as "Claims") that may be asserted against Client arising out of or in connection with: (a) any breach of this Agreement by Quest Diagnostics or (b) the negligence (including acts or omissions) or willfully wrong acts or omissions of Quest Diagnostics, its employees, or agents in connection with this Agreement. Notwithstanding the foregoing, this indemnification and hold harmless provision shall not apply to the extent that any Claim is (A) based upon any negligent or willfully wrong act or omission of Client, its employees, or agents or (B) compromised because Client has failed to give notice of the existence of any Claim or otherwise failed to comply with the provisions of Section 6.1.3 below.

6.1.2 Indemnification by Client. Client agrees to defend, indemnify and hold Quest Diagnostics, its Affiliates, and its officers, directors, employees, members, agents, successors and assigns harmless from any and all Claims asserted against Quest Diagnostics to the extent that such Claim or Claims directly and solely result from the compound, substance, device, or drug ("Product") that is under investigation by Client, including without limitation (a) any Study protocols and specifications of the Client relating to tests or testing methods to be used by Quest Diagnostics in connection with the Services, (b) the manufacture, distribution, sale or use in any manner of Client's Product, (c) any breach of this agreement by Client, or (d) the negligent or willful misconduct of the Client. Notwithstanding the foregoing, this indemnification and hold harmless provision shall not apply to the extent that any Claim asserted against Quest Diagnostics is (A) based upon any negligent or willfully wrong act or omission of Quest Diagnostics, its employees, or agents, or (B) compromised because Quest Diagnostics has failed to give notice of the existence of any Claim or otherwise failed to comply with the provisions of Section 6.1.3 below.

6.1.3 Notification. A Party seeking indemnification (the "Indemnified Party") agrees to promptly notify the other Party (the "Indemnifying Party"), in writing, of any Claim asserted against the Indemnified Party, and shall promptly deliver to the Indemnifying Party a true copy of any such Claim including, but not limited to, a true copy of any summons or other process, pleading or notice issued in any suit or other proceeding to assert or enforce any such Claim. The Indemnifying Party shall control the investigation, trial and defense of such Claim (including all negotiations to effect settlement) and any appeal arising therefrom, and shall have full authority to settle all economic aspects of the Claim on behalf of the Indemnified Party. The Indemnified Party shall have the right to approve all non-economic aspects (if any) of the settlement before it becomes final, such approval to be provided promptly and not to be withheld unreasonably, and shall employ or engage attorneys of its own choice. By way of example, non-economic aspects of a settlement might include admissions of fault or guilt, or agreement to imposition of an obligation or restriction such as an injunction. The Indemnified Party may, at its own cost, participate in such investigation, trial and defense of such Claim and any appeal arising therefrom. The Indemnified Party shall provide full cooperation to the Indemnifying Party at all times until the Claim is resolved completely, including (without limitation) providing the Indemnifying Party with all available information concerning the Claim.

6.2 Limitation of Liability. NEITHER PARTY HERETO SHALL BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, PUNITIVE OR SPECIAL DAMAGES OF ANY KIND (INCLUDING, BUT NOT LIMITED TO, LOST PROFITS) ARISING OUT OF OR RELATING TO THIS AGREEMENT. THIS LIMITATION OF LIABILITY SHALL NOT APPLY IN RESPECT OF THE PARTIES INDEMNIFICATION OBLIGATIONS REGARDING THIRD-PARTY CLAIMS

6.3 Insurance. The Client is responsible for maintaining, at its own expense and throughout the term of this Agreement, programs of insurance or self-insurance as it deems appropriate to protect its liabilities and contractual obligations.

Quest Diagnostics shall maintain liability insurance with a reputable and locally licensed risk carrier with a financial rating of A or better by S&P or AM Best, to adequately cover its obligations and liability under this Agreement, and in no event less than the minimum amount of insurance required by applicable law, including for its professional liability / E&O, and shall provide a certificate of insurance showing that such insurance is in place. Notwithstanding anything to the contrary contained herein, Quest Diagnostics may utilize self insurance for all or any portion of the minimum limits of insurance required to be carried. Coverage for professional liability / E&O should be in an amount of not less than $[****] USD per occurrence. Such coverage shall be in force during the Provision of the Services and for the greater of the expiration of the applicable statute of limitations where the Services under the Agreement are being performed or [****] years after the completion of such Services. Quest Diagnostics undertakes to notify Client of the expiration, termination, non-renewal of the policy or any material adverse condition added mid-term or on renewal. The policy shall contain a cross-liability provision.

However, failure of either Party to have insurance coverage, inability to obtain insurance coverage, or any inadequacy of insurance coverage of such Party shall not relieve such Party of any part of its liabilities under this Agreement.

7. DISPUTES/CHOICE OF LAW

7.1 Disputes

7.1.1 Choice of Law/Forum Selection. This Agreement shall be construed and enforced in accordance with English Law. Jurisdiction and venue for litigation of any dispute, controversy or claim arising out of, or in connection with, this Agreement shall be in the English courts. Each of the parties hereby expressly submits to the personal jurisdiction of the foregoing courts located in England, and waives any objection or defense based on personal jurisdiction or venue that might otherwise be asserted to proceedings in such courts. Except as specifically provided herein, in any litigation, each party shall bear its own fees and expenses, including attorneys' fees.

7.1.2 Waiver of Jury Trial - Both parties hereby irrevocably waive, to the fullest extent permitted by law, all right to trial by jury in any action, proceeding or counterclaim (whether in contract, statute, tort (including negligence) or otherwise) relating to or arising from this Agreement.

8. REGULATORY COMPLIANCE

8.1 Compliance with Applicable Laws

8.1.1 General. Each of the Parties represents and warrants to the other Party that it will comply with all laws, rules and regulations applicable to this Agreement ("Applicable Laws"), including, but not limited to, applicable privacy and security regulations and GCP (Good Clinical Practice). Failure by either Party to comply with any Applicable Laws shall be considered a material breach of this Agreement.

8.1.2 Data Retention.

a) Quest Diagnostics will follow all applicable guidelines (including, but not limited to, all applicable Food and Drug Administration ("FDA") guidelines), laws and regulations with regard to the storage and disposal of clinical trials records.

b) Records. All Study-specific paper information used by Quest Diagnostics shall be retained for fifteen (15) years following Study completion. All such documents in Quest Diagnostics possession after fifteen (15) years shall be subject to a confidential document destruction process. If Client requests any of these records to be retrieved by Quest Diagnostics, retrieval and shipping charges will be the sole responsibility of Client.

c) Client-Specific Requirements. Client will advise Quest Diagnostics in writing of any data retention requirements that exceed the standards described in 8.1.2 (b) above. Quest Diagnostics will use reasonable efforts to accommodate such requirements for an additional charge.

8.1.3 IATA Dangerous Goods Regulations:

8.1.3.1 Shipment of infectious substances. Client represents and warrants that unless it has specifically informed Quest Diagnostics otherwise on the Central Laboratory Worksheet, no shipments sent by Client shall contain risk group 4 pathogens (Category A pathogens as defined in the IATA Dangerous Goods Regulations). Client acknowledges that under the IATA Dangerous Goods Regulations (i) risk group 4 Category A pathogens should not be transported as Biological substance, category B specimens formerly known as diagnostic specimens and (ii) the shipper, not Quest Diagnostics, is responsible for classifying the shipment properly.

8.1.3.2 Shipment of other Dangerous Goods. The shipment of other dangerous goods, such as certain chemicals and dry ice, ("Dangerous Goods") is subject to local, national, and international laws and regulations. The person placing the Dangerous Goods in the shipping package is responsible for ensuring that the package, when shipped, meets the requirements of all applicable regulations and any local laws (including any training requirements). Any information provided by Quest Diagnostics in its Central Laboratory Worksheet, Investigator instructions, Investigator meetings, or otherwise, is not intended to be, and should not be considered as, training in the handling of dangerous goods.

9. **AUDIT.** During the term of this Agreement and at reasonable times and upon reasonable advance notice, Client may, at Client's sole cost and expense and in accordance with applicable security policies and procedures of Quest Diagnostics, visit Quest Diagnostics facilities to conduct quality assurance audits in connection with the work being performed under this Agreement. Third-party auditors will be required to sign Quest Diagnostics' standard Confidentiality Agreement at the time of their visit to any Quest Diagnostics facility. Client shall advise Quest Diagnostics in writing, of any special or unusual record keeping needs for a Study and Quest Diagnostics will use reasonable efforts to accommodate Client's requirements. Additional charges may apply for any requirements in excess of Quest Diagnostics usual record keeping process.

10. **ASSIGNMENT OF RIGHTS.** Except as provided specifically in the Agreement, neither Party may assign this Agreement or any right or interest hereunder without the prior written consent of the other Party. Any attempted assignment in violation hereof shall be void. Either Party may assign the Agreement to a successor entity to whom such Party transfers or assigns all or substantially all of its assets or transfers a controlling interest in the Party, or to its parent corporation (if any). The assigning Party shall provide written notice to the other Party of such assignment. Unless otherwise agreed in writing, the assigning Party shall remain financially liable to the non-assigning Party for any non-performance by the assignee under the Agreement.

11. **MISCELLANEOUS**

11.1 **Independent Contractor.** Quest Diagnostics is performing the Services as an independent contractor, and not as an employee, agent, partner of, or joint venturer with Client. Neither Party has any authority to bind or act on behalf of the other except as specifically stated herein. Furthermore, in the event that Client's Study is subject to the laws of the United Kingdom of Great Britain and Northern Ireland, Client represents and warrants to Quest Diagnostics that Client will comply with the additional consent requirements listed in Section 1.3 of this Agreement.

11.2 **Informed Consent**. Unless otherwise specified in this Agreement or an Exhibit, the parties agree that Quest Diagnostics shall not be required to obtain any required patient consents pertaining to its Services performed hereunder, including without limitation testing of DNA or genetic material. Client and Client's clinical investigators are responsible for obtaining informed consent for all subjects participating in the Study and for ensuring that the informed consent and Study protocol allow for the performance of all Services to be ordered by Client and its investigators and provided by Quest Diagnostics under this Agreement. Client shall inform Quest Diagnostics promptly if informed consent is withdrawn to ensure that no further Services are performed on specimens covered by such informed consent.

11.3 **Entire Agreement.** This Agreement contains the entire understanding between the Parties hereto with respect to the subject matter hereof and supersedes any and all prior agreements, understandings and arrangements between the Parties relating to the subject matter hereof. No amendment, change, modification or alteration of the terms and conditions hereof shall be binding unless set forth in written form and signed by all the Parties hereto. To the extent there are any inconsistencies between the terms of this Agreement and those of any Work Orders, the terms of this Agreement shall control unless otherwise specifically stated in the Work Order.

11.4. **Manner of Notice.** All notices permitted under the terms of this Agreement shall be deemed to have been given if delivered personally, or when sent by registered letter or overnight commercial courier to the respective registered addresses of each Party as indicated below:

If to Client:
RedHill Biopharma Ltd.
21 Ha'arba'a st.
Tel-aviv 64739, Israel
Attention: Ori Shilo, VP Finance and Operation

With a copy to:
RedHill BioPharma contact specified on work order

If to Quest Diagnostics:
Quest Diagnostics Clinical Trials
1201 South Collegeville Road
Collegeville, PA 19426
Attention: Contract Analyst

With a copy to:
Quest Diagnostics Incorporated
3 Giralda Farms
Madison, NJ 07940
Attention: Legal Department, Clinical Trials

11.5 Publication. Neither Party will make any press release or other public disclosure regarding this Agreement or the transactions contemplated hereby without the other Party's express prior written consent (which shall not be unreasonably withheld, conditioned or delayed except as provided in this Section). The Party that wishes to make the press release or public disclosure shall provide a draft of the publication to the other Party at least fifteen (15) days before the intended date of publication, during which time the other Party will review and comment on the draft publication and request any changes that relate to the reviewing Party's information and the Party making the publication will make such changes. Notwithstanding the above, if the publication is required under applicable law or stock exchange requirement or by any governmental agency or regulatory authority, then the Party required to make the press release or public disclosure shall provide the draft publication at least three (3) business days before the intended date of publication, during which time the other Party will review and comment on the draft publication as to the form, nature, and extent of the press release or public disclosure and request any changes that relate to the reviewing Party's information and the Party making the publication will make such changes prior to issuing the press release or making the public disclosure.

11.6 No Waiver. The failure of either Party to exercise or enforce any right conferred upon it hereunder shall not be a waiver of any such right and shall not prevent the exercise or performance thereof at any time or times thereafter; nor shall a waiver of any right hereunder at any given time, including rights to any payments, be deemed a waiver thereof for any other time.

11.7 Force Majeure. No Party to this Agreement shall be liable for failure to perform any duty or obligation that such Party may have under this Agreement where such failure has been occasioned by any act of God, fire, strike, inevitable accident, war or any cause outside the reasonable control of the Party who had the duty to perform; provided, however, that the non-performing Party shall give prompt notice to the other Party of the reason for its non-performance and its reasonable best estimate of when performance would begin again. The non-performing Party shall promptly begin to perform again after the intervening event has concluded.

11.8 Severability. If any provision of this Agreement is held to be illegal, invalid, or unenforceable by a court of competent jurisdiction, the Parties shall, if possible, agree on a legal, valid and enforceable substitute provision which is as similar in effect to the deleted provision as possible. The remaining portion of this Agreement not declared illegal, invalid or unenforceable shall, in any event, remain valid and effective for the term remaining unless the provision found illegal, invalid or unenforceable goes to the essence of this Agreement.

11.9 Debarment. Quest Diagnostics certifies that no person employed or engaged by Quest Diagnostics to perform any Services has been debarred under Section 306 of the United States Federal Food, Drug, and Cosmetic Act. To the extent that Quest Diagnostics becomes debarred or receives notice that any debarment proceedings have been initiated, Quest Diagnostics shall provide Client with written notice thereof.

11.10 Export Control. It is understood and agreed by the parties that Quest Diagnostics shall not provide Services or support to any entity or individual located in any of the countries identified in the then-current (a) list of countries subject to embargo as identified by the Department of Commerce's Bureau of Industry and Security pursuant to the federal Export Administration Regulations and/or (b) list of sanction programs of the Treasury Department's Office of Foreign Assets Control pursuant to 31 CFR Parts 500 et seq. (the "Prohibited Countries"). Furthermore, Client represents, covenants and warrants that neither Client nor its participating investigators shall submit specimens or samples pursuant to this Agreement for Services or support by Quest Diagnostics that originate from any of the Prohibited Countries. In the event that Quest Diagnostics detects or becomes aware that Client or Client's investigators submitted a specimen/sample from any of the Prohibited Countries to Quest Diagnostics or if it is discovered that Client or any of Client's investigators are located in one of the Prohibited Countries, Quest Diagnostics shall have the right to immediately terminate this Agreement.

IN WITNESS WHEREOF, Client and Quest Diagnostics have duly executed this Agreement on the first day above written.

REDHILL BIOPHARMA LIMITED	**QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC.**
/s/	/s/ Christopher Fikry
Signature	Signature
Name printed	Christopher Fikry, M.D.
Title:	Vice President, Clinical Trials
Date:	Date:

EXHIBIT A

MASTER AGREEMENT WORK ORDER (example)
PROTOCOL #

RedHill Biopharma Limited
21 Ha'arba'a St.
Tel-Aviv Israel 64739

Protocol Name:

1) Contact information:
RedHill Biopharma Contact:
Quest Diagnostics Project Manager:

2) Work Order Term: Effective Date: End Date:
The term of this work order may be extended an amendment signed by both parties.

3) The Estimated Central Laboratory Budget dated is attached as Attachment #1 and is incorporated herein by reference.

The estimated Study Value is

4) Affiliates and Subcontractors: In accordance with the Agreement, the following Quest Diagnostics affiliates and subcontractors shall be utilized for services hereunder:

Affiliate/Subcontractor Name	Service Provided

5) Invoices:

Electronic Invoices shall be sent to: E-mail address:
Attention:
Phone number:

6) Fee Increases. Fees for testing performed at a Quest Diagnostics laboratory shall not increase for the term of this work order. After the conclusion of such term, Quest Diagnostics may increase fees for its Services provided hereunder and annually thereafter to offset any increased costs of operations by providing thirty (30) days written notice to Client. Any such increase shall not exceed the annual inflation rate during the previous twelve-month period ending on the last day of the month immediately preceding the effective date of the increase, as measured (i) i[****], by the increase in the Retail Price Index for the [****], and (ii) in the United States, by the increase in the Consumer Price Index for All Urban Consumers (CPI-U): U. S. City Average, Medical care.

The fees and services quoted in this Work Order and its attachments and all other terms and conditions for the performance of services for this clinical protocol shall be in accordance with the Clinical Trials Global Master Services Agreement (effective XEFFECTIVE DATE) between Quest Diagnostics Clinical Laboratories, Inc. (Quest Diagnostics) and RedHill Biopharma Limited (CLIENT).

REDHILL BIOPHARMA LIMITED	**QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC.**
/s/	/s/ Christopher Fikry
Signature	Christopher Fikry Vice President Clinical Trials
Name printed	
Title:	
Date:	Date:

Attachment #1
Estimated Central Laboratory Budget
Proposal Version X Dated XX
(xx pages incorporated herein)

Attachment #2
Global Central Laboratory Worksheet Version X Dated XDATE

[CHOOSE ONE at the time the Work Order is drafted]

The Global Central Laboratory Worksheet describes the nature, scope and timelines for Services being specifically performed for a Study. The Global Central Laboratory Worksheet is attached hereto and incorporated into this Work Order by reference.

Changes to the Global Central Laboratory Worksheet will be made independent to the contracting process, except in those instances where changes to the Global Central Laboratory Worksheet affect the Central Laboratory Budget and/or timelines of Services. In those instances an amendment will be executed between the Parties identifying the changes in the Central Laboratory Budget and/or timelines.

Or

The Global Central Laboratory Worksheet ("CLW") is not attached to this Work Order. Quest Diagnostics will prepare and obtain Client's approval of this document. Upon Client's signature of the CLW, it will become a part of this Work Order.

CONFIDENTIAL

CLINICAL TRIALS GLOBAL MASTER SERVICES AGREEMENT AMENDMENT NO. 1

This Amendment No. 1 is made effective as of the date last signed below ("Amendment No. 1 Effective Date") by and between RedHill Biopharma, Ltd. ("Client") and Quest Diagnostics Clinical Laboratories, In This Amendment No. 1 amends the Clinical Trials Global Master Services Agreement dated 27-December-2012 to which both Client and Quest Diagnostics are parties (the "Agreement").

1. The purpose of this Amendment No. 1 is to replace Sections 4.1 and 4.2 of the Agreement with the following language:

4.1. Client Ownership of Data; Inventions. All data, test results, studies and other information generated by Quest Diagnostics in performing the Services (the "Data") shall be the property of the Client. All proprietary, non-public information concerning (a) the study drug and (b) Client's operations (including basic scientific data, prior clinical or laboratory data, formulation information, and research programs supplied by Client to Quest Diagnostics and not in the public domain) ("Client's Confidential Information") shall be considered confidential and shall remain the sole property of Client. Further, except as otherwise provided in Section 4.2 below, all rights to any discovery or invention conceived (or conceived and reduced to practice) in the direct performance of the work conducted under this Agreement (each, an "Invention") shall belong to Client. Quest Diagnostics shall promptly disclose to Client any Invention arising from this Agreement. Quest Diagnostics agrees to assign to Client, and hereby does assign to Client, the sole and exclusive ownership of and the entire right, title and interest in any Invention hereunder. Client agrees to reimburse Quest Diagnostics for any patent application drafting costs incurred by Quest Diagnostics in connection with any Invention assigned to Client arising from this Agreement. Quest Diagnostics may assist Client in any further protection or perfection of such Invention to the extent reasonably necessary at a fee to be negotiated and agreed upon by the parties and paid by Client to Quest Diagnostics.

4.2 Quest Diagnostics Intellectual Property. Notwithstanding anything in this Agreement to the contrary, Client and Quest Diagnostics agree that Quest Diagnostics possesses certain intellectual property, including but not limited to inventions, know-how, trade secrets, analytical methods, standard operating procedures, computer technical expertise, software and statistical methodologies originated by Quest Diagnostics prior to or during the Term of this Agreement without benefit of Information provided by Client that is the sole property of Quest Diagnostics ("Quest Diagnostics' Intellectual Property"). Further, to the extent that Quest Diagnostics makes any improvement or addition to Quest Diagnostics' Intellectual Property relating solely to central or diagnostic laboratory analyses and services and/or medical diagnostic assays and methods in the course of performing this Agreement or otherwise, such improvement and/or addition to Quest Diagnostics' Intellectual Property shall be the sole and exclusive property of Quest Diagnostics and Quest Diagnostics shall grant and hereby grants to Client an irrevocable, perpetual, worldwide, non-exclusive, royalty-free, sublicensable, and transferable license to such improvement or addition to Quest Diagnostics' Intellectual Property. For clarity, any improvement or addition to Quest Diagnostics' Intellectual Property utilizing, incorporating, or including any Confidential Information of Client shall be considered an Invention under Section 4.1 owned exclusively by Client, and Quest Diagnostics hereby does assign to Client the sole and exclusive ownership of and the entire right, title and interest in any such improvement, addition or Invention utilizing, incorporating or including any Confidential Information of Client. Finally, in the course of working

with Quest Diagnostics hereunder, Client may become aware of other, non-public information about Quest Diagnostics and its business that Quest Diagnostics considers confidential, which shall be considered confidential and shall remain the sole property of Quest Diagnostics (such information, together with Quest Diagnostics' Intellectual Property, is referred to hereinafter as "Quest Diagnostics Confidential Information").

2. All other terms and conditions of the Agreement shall remain in full force and effect. In the event of any conflict between the terms of the Agreement and this Amendment No. 1, the terms of this Amendment No. 1 shall control.

5. The parties hereto agree to be bound by this Amendment No. 1 as of the Effective Date by their authorized signature below.

REDHILL BIOPHARMA LTD.	**QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC.**
Authorized Signature	Authorized Signature
Dror Ben-Asher	CHRISTOPHER FILEY
Name Printed	Name Printed
CEO	VP, CLINICAL TRIALS
Title	Title
June 19, 2014	6/20/14
Date	Date

THE SYMBOL "[****]" DENOTES PLACES WHERE PORTIONS OF THIS DOCUMENT HAVE BEEN OMITTED PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. SUCH MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Confidential

MASTER AGREEMENT WORK ORDER
PROTOCOL # RHB-104-01 (MAP Testing and Other Analysis)

RedHlll Blopharma Limited
21 Ha'arba'a St
Tel-Aviv Israel 64739

Protocol Name: A Phase Ill Randomized, Double Blind, Placebo-controlled, Multicenter, Parallel Group Study to Assess the Efficacy and Safety of Fixed-dose Combination RHB-104 in Subjects with Moderately to Severely Active Crohn's Disease

1) Contact jnformatlon :
RedHill Blopharma Contact: Patrick Mclean
Quest Diagnostics Project Manager: Mariana Klinger

2) Work Order Term: Effective Date: 10-Oct-2013 [****]
The term of this work order may be extended an amendment signed by both parties.

3) The Estimated Central l.aboratorv Budget dated is attached as Attachment #1 and is incorporated herein by reference.

The estimated Study Value is $ [****]

See Exhibit A with the expected budget for the study. The actual cost will be based on the actual work that will be done by Quest during the study based on the cost per item in Exhibit A.

RedHlll has the right to request Quest to change the couriers utilized for the shipment in Exhibit A with other couriers required by RedHill. If such courier is not currently under a subcontract with Quest Diagnostics, then RedHill shall contract with the courier and provide the shipping information to Quest Diagnostics for shipments and RedHill shall be accountable for any such shipments.

4) Affiliates and Subcontractors: In accordance with the Agreement, the following Quest Diagnostics affiliates and subcontractors shall be utilized for services hereunder:

Affiliate/Subcontractor Name	Service Provided
Quest [****]	Testing and related services
[****]	Testing and related services
[****]	[****]
[****]	[****]

5) Invoices:
Electronic Invoices shall be sent to: E-mail address: [****]
Attention: [****]
Phone number: [****]

CC: [****]

6) Fee Increases. Fees for testing performed at a Quest Diagnostics laboratory shall not increase for the term of this work order. After the conclusion of such term, Quest Diagnostics may increase fees for its Services provided hereunder and annually thereafter to offset any increased costs of operations by providing thirty (30) days written notice to the Client. Any such increase shall not exceed the annual inflation rate during the previous twelve-month period ending on the last day of the month immediately preceding the effective date of the increase, as measured (i) [****] and (ii) in the United States, by the increase in the Consumer Price Index for All Urban Consumers (CPI-U): U. S. City Average, Medical care.

6) For this Work Order only the following language shall apply in support of shipping charges to and from the [****].

The current Work Order budget reflects the total costs for shipping specimens to and from [****] ("[****] Specimen Shipping Charges") for services provided by [****]. RedHill Biopharma shall pay the [****] Specimen Shipping Charges monthly as invoiced by Quest Diagnostics. Beginning with the April 2014 invoice, Quest Diagnostics will issue RedHill Biopharma a credit (in a separate invoice) in an amount equal to [****] Specimen Shipping Charges that have been invoiced in the prior six (6) months for shipping specimens to and from [****] ("[****]Shipping Credit"). Successive Specimen Shipping Credits shall continue every six (6) months of the duration of the study.

At the conclusion of the study, a final credit will be applied for any remaining months that did not receive the [****] Specimen Shipping Credit.

The fees and services quoted in this Work Order and its attachments and all other terms and conditions for the performance of services for this clinical protocol shall be in accordance with the Clinical Trials Global Master Services Agreement (effective 22-Dec-2012) between Quest Diagnostics Clinical Laboratories, Inc. (Quest Diagnostics) and RedHill Biopharma Limited (CLIENT).

REDHILL BIOPHARMA, LIMITED	QUEST DIAGNOSTICS CLINICAL LABORATORIES, INC.
Signature	Signature
Name printed 01-; 56,10 | Dror Ben-Asher	Name printed Tony R. Brown
Title: Deputy CEO | CEO	Title: Global Controller
May 12, 2014 | May 12, 2014	13- May - 2014
Date	Date

APPROVED BR CONTRACT ANALYST

Attachment #1
Estimated Central Laboratory Budget

RHB10-01(CR)(Bid1
vl2).pdf

Budget Version 12 Dated 14-Oct-2013
(23 pages incorporated herein)

CONFIDENTIAL

Quest Diagnostics Clinical Trials
Central Laboratory Services Budget

RedHill Biopharma Limited
RHB-104-01 (CR) v12
Version 12
14-Oct-13

Prepared for: [****]

by: [****]

Tel: [****]

Email: [****]

Tel: [****]
Fax: [****]
Email: [****]

14-Oct-13

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) v12**

Dear Patrick :

Thank you for the opportunity to submit a revised budget for your study. This budget includes the following changes.

- **version 12: Updated patients:visits distribution based on info dated 9-October [****]**

Quest Diagnostics Clinical Trials 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
Quest Diagnostics Clinical Trials

Assumptions
Protocol: RHB-104-01 (CR) v12

Assumptions:

Global Phase III trial- Israel and US/Canada

RHB-104 therapy requires a diagnostic for infection with Mycobacterium avium paratuberculosis in patients with Crohn's Disease

3 countries, [****] sites respectively
[****] screened, [****] baseline to visit [****], and [****] respectively
Canada-US region: [****]
Grand total of [****]
Grand total of [****]

We assume Quest Diagnostics to supply each site with [****].

Recommended couriers:
Israel- [****]
Canada - [****]
US- [****]
Quest [****]
Courier mapping- [****]
Sites to [****]
Sites to [****]
Sites to [****]
Sites to [****]
Quest [****]
Courier mapping- [****]
Sites to [****]
Sites [****]
Sites to [****]
Sites to [****]

Transportation budget: Quest Diagnostics does offer a cost-effective solution [****]

Warning: Please note that Quest Diagnostics refuse to do [****].

Inbound budget (shipments from sites to Quest Diagnostics): [****]

Worst case scenario: we assume [****] be revised in accordance to validation data.
PK [****]

HIV Western Blot-[****]

Disclaimer:
[****]

Stored specimen:
For bidding purpose, we assume average storage [****].
Disclaimer: RHB to confirm if QDCT has to include into this budget the fact that [****].

[****] services -
Note that we have included $25 towards handling charges on top of the [****]

Week-end shipments from sites [****]
EWP(extreme weather packaging)- [****].

Quote for Services

Change In Scope History
Protocol: RHB-104-01 (CR) v12

Category	Updated Study Value	Previous Study Value *	Difference
Laboratory Testing	[****]	[****]	[****]
Supplies	[****]	[****]	[****]
Additional Pass-Through Services	[****]	[****]	[****]
Study Management	[****]	[****]	[****]
Storage & Services	[****]	[****]	[****]
Inbound Transportation	[****]	[****]	[****]
Batched Inbound	[****]	[****]	[****]
Outbound Transportation	[****]	[****]	[****]
Outbound Transportation - Shipping Containers	[****]	[****]	[****]
Estimated Central Laboratory Budget:	**[****]**	**[****]**	**[****]**

* Budget taken from RedHill Biopharma Limited: RHB-104-01 (CR) version 11

RedHill Biopharma Limited

Quote for Services

Budget Summary
Protocol: RHB-104-01 (CR) v12

Study Duration:	[****]	Total Investigators:	[****]
		Total Countries:	[****]
		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	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
	Study Set-up Fees	[****]	[****]	[****]
				[****]
Average Cost Per Patient-Visit	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
	Study Set-up Fees	[****]		
		[****]	[****]	[****]
Average Cost Per Patient	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
	Study Set-up Fees	[****]		
		[****]	[****]	[****]

Detailed Budget Summary

Laboratory Testing	Region	Billing Amount	Conversion Rate	Estimated Total Amount
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
[****]				[****]
Supplies	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
[****]				[****]
Additional Pass-Through Services	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
[****]				[****]
Storage	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
[****]				[****]
Study Management	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
	Study Set-up Fees	[****]	[****]	[****]
[****]				[****]
Inbound Transportation	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]

	Israel	[****]	[****]	[****]
[****]				[****]
Outbound Transportation	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
[****]				[****]
Shipping Container Transportation	**Region**	**[****]**	**[****]**	**[****]**
	USA, Canada	[****]	[****]	[****]
	Israel	[****]	[****]	[****]
[****]				[****]

RedHill Biopharma Limited

Quote for Services

Detail Summary
Protocol: RHB-104-01 (CR) v12

Laboratory Testing	Region	Time Points	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]

[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
Laboratory Testing Total							[****]

Supplies	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]

[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
Supplies Total							[****]

Additional Pass-Through Services	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
Additional Pass-Through Services Total							[****]

Storage	Region	Aliquots	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]

[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada	[****]	[****]	[****]	[****]	[****]	[****]

Storage	Region	Aliquots	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	Israel	[****]	[****]	[****]	[****]	[****]	[****]
Storage Total							[****]

Study Management	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Study Set-up Fees		[****]	[****]	[****]	[****]	[****]
[****]	Study Set-up Fees		[****]	[****]	[****]	[****]	[****]
[****]	Study Set-up Fees		[****]	[****]	[****]	[****]	[****]
[****]	Study Set-up Fees		[****]	[****]	[****]	[****]	[****]
Study Management Total							[****]

Inbound Transportation	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
Inbound Transportation Total							[****]

Outbound Transportation	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
Outbound Transportation Total							[****]

Shipping Container Transportation	Region	Unit	Quantity	Billing Currency Unit Price	Billing Amount	Conversion Rate	Estimated Total Amount
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	USA, Canada		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
[****]	Israel		[****]	[****]	[****]	[****]	[****]
Shipping Container Transportation Total							[****]

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Quote for Services

Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category	Name	Screening	Baseline	V2	V3	V4	V5	V6	V7	V8
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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RedHill Biopharma Limited

Quote for Services

Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category	Name	Screening	Baseline	V2	V3	V4	V5	V6	V7	V8
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category	Name	Screening	Baseline	V2	V3	V4	V5	V6	V7	V8
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category		Screening	Baseline	V2	V3	V4	V5	V6	V7	V8
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category	Name	V9	V10	V11	V12	V13	V14	Biopsy Processing ([****])	Sample processing – [****] tubes ([****])	Sample processing – [****] tubes ([****])	Susceptibility Testing ([****])
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
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[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

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Quote for Services

Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category	Name	V9	V10	V11	V12	V13	V14	Biopsy Processing ([****])	Sample processing – [****] tubes ([****])	Sample processing – [****] tubes ([****])	Susceptibility Testing ([****])
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

RedHill Biopharma Limited

Quote for Services

Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category	Name	V9	V10	V11	V12	V13	V14	Biopsy Processing ([****])	Sample processing – [****] tubes ([****])	Sample processing – [****] tubes ([****])	Susceptibility Testing ([****])
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

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Quote for Services

Test Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Category		V9	V10	V11	V12	V13	V14	Biopsy Processing ([****])	Sample processing – [****] tubes ([****])	Sample processing – [****] tubes ([****])	Susceptibility Testing ([****])
	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
[****]	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
	[****]		[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

RedHill Biopharma Limited

Quote for Services

Patient Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Country	Sites	Screening	Baseline	V2	V3	V4	V5	V6	V7	V8	V9	V10	V11	V12
Calculated Totals:	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
Canada(Toronto)	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
United States(New York)	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]
Israel(Tel Aviv)	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]	[****]

Quote for Services

Patient Visit Schedule
All Locations
Protocol: RHB-104-01 (CR) v12

Country	Sites	V13	V14	Biopsy Processing ([****])	Sample processing – [****] tubes ([****])	Sample processing – [****] tubes ([****])	Susceptibility Testing ([****])
Calculated Totals:	[****]	[****]	[****]	[****]	[****]	[****]	[****]
Canada(Toronto)	[****]	[****]	[****]	[****]	[****]	[****]	[****]
United States(New York)	[****]	[****]	[****]	[****]	[****]	[****]	[****]
Israel(Tel Aviv)	[****]	[****]	[****]	[****]	[****]	[****]	[****]

Quote for Services

End Notes
Protocol: RHB-104-01 (CR) v12

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 Quest Diagnostics Clinical Trials' Year 2011 Fee Schedule.

[2LT] Referral test to be performed by UCF. 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] The sample testing fees include the receipt of samples into a Quest Diagnostics-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.

[5LT] 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) Quest Diagnostics-US proprietary courier.

[6LT] It is Quest Diagnostics Clinical Trials' (Quest) 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 Quest practice to not provide glass slides and to not require the sites to make PBS slides . The performance by Quest 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.

[7LT] 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.

[8LT] CBC and Peripheral blood smear pricing are based on assumptions received at the point of preparing this quotation. Quest Diagnostics 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.

[1SL] Quest Diagnostics Clinical Trials will determine the price for a 40+ Visit Specific Kit(VSP) once all tubes and details of kit components have been finalized with the sponsor.

Global Summary - Supplies (ST)

[1ST] The "In" fee includes receipt, preparation, storage and entry of specimens into Quest Diagnostics Clinical Trials storage facility and computer system.

[2ST] The "Monthly Maintenance" fee includes inventory, storage, temperature monitoring and continuous security coverage at Quest Diagnostics Clinical Trials 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 Quest 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 Quest, which lays out detailed specifications for the set-up and management of the study. Quest 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 Quest Diagnostics 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] Quest Diagnostics 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] Quest Diagnostics Clinical Trials 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.

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.

1IT The inbound specimen transportation fees are based on typical volumetric weight, and vary by city. Quest Diagnostics Clinical Trials 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. Quest Diagnostics' must also receive Client's approval of Quest Diagnostics' verification report (without changes) at least 2 days prior to shipment.

2OT Please note that Quest Diagnostics Clinical Trials 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 Quest Diagnostics' 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 Quest Diagnostics 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. Quest Diagnostics Clinical Trials 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.

Attachment #2
Global Central Laboratory Worksheet

The Global Central Laboratory Worksheet describes the nature, scope and timelines for Services being specifically performed for a Study. The Global Central Laboratory Worksheet ("CLW") is not attached to this Work Order. Quest Diagnostics will prepare and obtain Client's approval of this document. Upon Client's signature of the CLW and any changes of scope, it will become a part of this Work Order.

Exhibit 4.25

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
(Quest Diagnostics Clinical Trials)

Protocol: RHB-104-01	**Requester:** Patrick McLean	
Proposed date of Implementation:	**Project Manager(s):** Lillard, Martha KLINGLER, MARIANA	**Date of Request:** **Request Reference** 8/8/2013

Original Specifications (if applicable):

MAP [****]

US and Canada ONLY

[****] to be sent in to [****]. One for [****] and one for [****]. [****] will be generated. One will go to [****] and the other will be [****]. Any [****].

[****] will be collected and shipped [****]. [****] it will then follow the [****]. The remaining [****], will be [****].

MAP [****]

[****] will be collected and shipped to [****]. [****] will be followed.

Change in Specifications/New Specifications:

1 . Add Collection time to the MAP PCR requisition and Colonoscopy requisition

2. Pull all blood MAP PCR testing on to one requisition

3. All [****]. Using the [****].

MAP Blood

US/Canada sites:

MAP [****]**:** Visits: [****]

Will collect [****] and ship directly to [****]. [****] will use the [****]. [****] will then [****], so that the [****]. [****] will combine the [****]

into the following

[****] - sent to [****] from [****] to be placed into [****]; UCF will place approx [****] into [****].

[****] - to be sent to [****] will place approx [****] into the [****].

[****] will use to [****] and *will* do the following:

(1) [****] that will remain [****]

(1) [****] that will remain [****]

(1) [****] - to be sent to [****]. **Results for the** [****] **will be** [****] **will be performed on ALL samples received for** [****]**, as well as the** [****]**. Details of this to be provided at a later date.**

MAP [****]**:** Visits: [****]

Will collect [****] with a copy of [****]. [****] will use the [****]. [****] will then [****], so that the [****]. [****] will combine the [****]. [****]into the following:

[****] - sent to [****] from [****] to be placed into [****][****] will place approx [****] into the [****]

[****] - to be sent to [****]; [****] will place approx [****] into the tube.

MAP [****]
Israel sites:

MAP [****]**:** Visits: [****]

Will collect [****] with a copy of [****]. [****] will combine the [****]. [****]into the following:

[****] - sent to [****]to be placed into [****]; [****] will place approx [****] into the tube

[****] - to be sent to [****];[****] will place approx t [****] into the tube

[****] will be sent to [****].[****].[****] will place approx [****].[****] will use to culture - [****] and will do the following:

(1) [****] that will remain [****].

(1) [****] that will remain [****].

(1) [****] - to be sent to [****] - Sent [****] every [****]

Results for [****] **will be performed on** [****]**. Details of this to be provided at a later date.**

MAP [****] **PCR:** Visits: [****]

Will collect [****] directly to [****] with a copy of our [****].[****] will [****]. The [****] will then be [****] into the following:

[****] - sent to [****] to be placed into [****];[****] will place approx [****] into the tube

[****] - to be sent to Valencia [****];[****] will place approx [****] into the tube

MAP [****]

[****]:[****] visits

[****]. It will contain [****]. This will be shipped [****].[****] will use the [****].[****] will then [****], so that the [****].[****].[****].

(1) [****] that will remain [****].

(1) [****] that will remain [****].

(2) [****] - to be sent to [****]

[****] - Sent [****] to [****] every [****]

Results for [****] will be performed on [****]. Details of this to be provided at a later date.

MAP [****]

[****] sites:

Will collect [****]. It will contain [****]. This will be [****].[****] will transfer [****]. This will then be [****].[****] will use the [****].[****] will then Scan [****], so that the [****].[****] will be transferred to a [****].[****].

(I) [****] that will remain [****].

(1) [****] that will remain [****].

(3) [****] that will remain [****].
[****] - Sent [****] to [****] every [****]

Results for [****] will be performed on [****]. Details of this to be provided at a later date.

Note: [****] needs to provide [****].[****] will also need to provide [****].

DNA Extraction details:

All - DNA Extraction - [****]

[****] will be received for DNA [****] will be divided into the following:

[****]
[****]
[****]
[****]

Please see details of changes :

☒ **Requisition(s) including Starter/Reorder Forms**

☒ 1-5 (No charge)

☒ **Investigator Manual**

☒ Insert updated reqwsition(s) (No charge)

☒ Specimen collection (No charge)

☒ **Supplies**

☒ Visit specific style(s) (No charge)

☒ **Database**

☒ Addition of 1-10 storage order units (No charge)

☒ Addition of 1 - 10 storage custom items (No charge)

☒ **Miscellaneous**

☒ Admin fee (No charge)

Total Amendment Fee: $ 0.00

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: REZA FATHI

Signature: Reza Fathi Date: 8/9/2013

REDHILL BIOPHARMA LTD

Change Specification Form

(Quest Diagnostics Clinical Trials)

Protocol: RHB- 104-01		**Requester:** Clara Fehnnann
Proposed date of Implementation: 2 weeks from approval	**Project Manager(s):** Lillard, Martha KLINGLER. MARIANA	**Date of Request:** 02-0ct- 13 **Request Reference -Title:** US-6859

Original Specifications (if applicable):

No specification of type of tissue. normal or inflamed, the colonoscopy sample to be stored and then shipped to 3rd party vendor.

Change in Specifications/New Specifications:

Type of tissue, [****], to be preprinted on the label for the colonoscopy sample to be stored and then shipped to 3rd party vendor.

Please see details of changes :

- ☒ **Management Fees**
  - ☒ Administration fee
- ☒ **Requisition(s) including Starter/Reorder Forms**
  - ☒ Forms (Requisitions/Starter pack/Reorder) : update 1-3

Total Amendment Fee: $ 1720.2 for account 64160601

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: _____ Date: 10/14/2013

REDHILL BIOPHARMA LTD

Change Specification Form

(Quest Diagnostics Clinical Trials)

Protocol: RHB- 104-01		**Requester:** Ira Kalfus
Proposed date of Implementation: 3 weeks from approval	**Project Manager(s):** Lillard, Martha KLINGLER. MARIANA	**Date of Request:** 16-Oct-13 **Request Reference -Title:** US-6884
Original Specifications (if applicable): [****].		
Change in Specifications/New Specifications: [****]. Updates to Manual and supplies need to be made.		

Please see details of changes :

- ☒ **Investigator Manual**
  - ☒ Update/create 1-3 different specimen collection procedures
- ☒ **Management Fees**
  - ☒ Administration fee
- ☒ **Requisition(s) including Starter/Reorder Forms**
  - ☒ Forms (Requisitions/Starter pack/Reorder) : update 1-3
- ☒ **Supplies**
  - ☒ Update/Create 1-3 visit specific style(s)

Total Amendment Fee: $ 2436.9 for account 64160601

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: Reza Fathi

Signature:  Date: **10/21/2013**

REDHILL BIOPHARMA LTD

Change Specification Form

(Quest Diagnostics Clinical Trials)

Protocol: RHB- 104-01		**Requester:** Clara Fehrmann
Proposed date of Implementation: 6 weeks from approval	**Project Manager(s):** Lillard, Martha KLINGLER. MARIANA	**Date of Request:** 20-Dec-13 **Request Reference -Title:** US-7030

Original Specifications (if applicable):

For the RHB-104 [****] Samples:
1) For the [****] are used.
2) For the [****] a minimum of [****]
3) [****].

For the RHB-104 [****] Samples:
1) [****] samples to be [****].
2) The [****] samples to be [****].

Change in Specifications/New Specifications:

For the RHB-104 [****] Samples:
1) For the [****] we will [****] the sample in [****].
2) For the [****] will be [****] to a [****].
3) [****] samples will have [****].
4) [****] for samples to be spun [****].

For the RHB-104 [****] Samples:
1) [****] to be placed on [****].[****]. Procedures to be detailed in [****].
2) [****].

Please see details of changes :

☒ **Database**

☒ Update/create 1-10 demographic items (ie collection time, patient demographics)

☒ Update/create of 1 - *5* Storage Items (inc specemins)

☒ **Investigator Manual**

☒ Insert updated requisition(s)

☒ Update laminated pictograms

☒ Update reporting section image

☒ Update/create 1-3 different specimen collection procedures

☒ **Management Fees**

☒ Administration fee

☒ **Requisition(s) including Starter/Reorder Forms**

☒ Forms (Requisitions/Starter pack/Reorder) : update 1-3

☒ **Supplies**

☒ Update/Create 1-3 visit specific style(s)

Total Amendment Fee: $ 3,471.6 for account 64160601

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: Ofi Shiffo

Signature: _____ Date: Dec. 23, 2013

Dtor Ben-Asher

Dec. 23, 2013

REDHILL BIOPHARMA LTD

Change Specification Form

(Quest Diagnostics Clinical Trials)

Protocol: RHB- 104-01		**Requester:** Clara Fehrmann
Proposed date of Implementation: 5 weeks from approval	**Project Manager(s):** Lillard, Martha KLINGLER. MARIANA	**Date of Request:** 25-Mar-14 **Request Reference -Title:** US-7374

Original Specifications (if applicable):

1) [****]
2) [****]
3) [****]

Change in Specifications/New Specifications:

1) [****].
2) [****].
3) [****].

Please see details of changes :

x Database

- ☒ Update/create 1-10 toxicity/flagging/alerts items
- ☒ Update/create 1-10 visit(s)

☒ **Investigator Manual**

- ☒ Update/create 1-3 different specimen collection procedures

☒ **Management Fees**

- ☒ Administration fee

☒ **Requisition(s) including Starter/Reorder Forms**

- ☒ Forms (Requisitions/Starter pack/Reorder) : update 1-3

☒ **Supplies**

- ☒ Update/Create 1-3 visit specific style(s)

Total Amendment Fee: $ 3090.3 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: _____ Date: 30/3/2014

REDHILL BIOPHARMA LTD

Change Specification Form

(Quest Diagnostics Clinical Trials)

Protocol: RHB- 104-01		**Requester:** Clara Fehrmann
Proposed date of Implementation: 4 weeks from approval	**Project Manager(s):** Lillard, Martha KLINGLER. MARIANA	**Date of Request:** 26-Jun-14 **Request Reference -Title:** US-7719

Original Specifications (if applicable):

Sites in the US 22. Site number is one letter and two digits. Subject number is site number- two digits

Change in Specifications/New Specifications:

[****]. For remaining countries site has option to use other available option for their region. For all countries the kit will include collection instructions. Ifsubject is not returning to the site for those 3 visits the site must give the subject the kit.

Please see details of changes :

- ☒ **Database**
  - ☒ Addition of investigator site (Per site) (X 78)
  - ☒ Update/create 1-10 visit(s)
- ☒ **Data Management**
  - ☒ Change/Addition in Output format/File/mapping /Adhoc Data transfers (per hour)
- ☒ **Investigator Manual**
  - ☒ Insert updated requisition(s)
  - ☒ Update/create 1-3 different specimen collection procedures
- ☒ **Management Fees**
  - ☒ Administration fee
- ☒ **Requisition(s) including Starter/Reorder Forms**
  - ☒ Forms (Requisitions/Starter pack/Reorder) : update 1-3
- ☒ **Supplies**
  - ☒ Update/Create 1-3 visit specific style(s)

Total Amendment Fee: $ 4830.7 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: D. Ben-Asher

Signature: _____ Date: 7/7/14

7-7-14 July 7/14

REDHILL BIOPHARMA LTD

Change Specification Form

(Quest Diagnostics Clinical Trials)

Protocol: RHB- 104-01		**Requester:** Patric McLean
Proposed date of Implementation: 3 weeks from approval	**Project Manager(s):** Lillard, Martha KLINGLER. MARIANA	**Date of Request:** 04-Jun-14 **Request Reference -Title:** US-7699
Original Specifications (if applicable): N/A		
Change in Specifications/New Specifications: Addition of [****] sites in [****] and [****] sites in [****]. Each site will have [****] for a final number of [****] in [****] and [****] in [****].		

Please see details of changes :

- ☒ **Database**
  - ☒ Addition of investigator site (Per site) (X 15)
- ☒ **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
- ☒ **Supplies**
  - ☒ Update/Create 1-3 visit specific style(s)

Total Amendment Fee: $ 2995.45 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 incu rred as a result of these changes.

-

Comments

Reviewer's Name:
Signature: _____ Date: July 14, 2014

July 14, 2014

REDHILL BIOPHARMA LTD

Change Specification Form

(Quest Diagnostics Clinical Trials)

Protocol: RHB- 104-01		**Requester:** Clara Fehrmann
Proposed date of Implementation: 6-8 weeks from approval	**Project Manager(s):** Lillard, Martha KLINGLER. MARIANA	**Date of Request:** 08-Dec-14 **Request Reference -Title:** US-8343

Original Specifications (if applicable):
Original visit names:

Change in Specifications/New Specifications:

New visit names in database will only state the week number, the names on the requisitions will also state old visit as listed below

Original visit names to be updated:

[****]

Addition of [****]. [****] will not be a [****]. Adding [****]. Once all [****] any [****] related to the following [****]:
[****].

These [****] will be [****]. [****] will be [****] to [****].

[****]

Addition of [****] in [****] to the study.

Please see details of changes :

- ☒ **Database**
  - ☒ Addition of investigator site (Per site) (X 12)
  - ☒ Update/create 1-10 visit(s)
- ☒ **Data Management**
  - ☒ Change/Addition in Output format/File/mapping *I*Adhoc Data transfers {per hour)
- ☒ **Investigator Manual**
  - ☒ Insert updated requisition(s)
  - ☒ Update/create 1 -3 different specimen collection procedures
- ☒ **Management Fees**
  - ☒ Administration fee
- ☒ **Requisition(s) including Starter/Reorder Forms**
  - ☒ Forms (Requisitions/Starter pack/Reorder) : update 1-3 (X 22)
- ☒ **Supplies**
  - ☒ Update/Create 1-3 visit specific style(s)

Total Amendment Fee: $ 12350.35 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: Dr. Shiv Uti Mahmood Ahmad

Signature: _____ Date: Dec. 18, 2016

Confidential

RedHill Biopharma Ltd.
(the "Company")

OPTION PLAN (2010)

Originally Adopted by the Board of Directors on February 4, 2010,
As been amended from time to time, and
As most recently amended by the Board of Directors on May 2, 2013

TABLE OF CONTENTS

1. Preamble.
2. Administration of the Plan.
3. [Reserved]
4. Option Exercise Prices.
5. Exclusivity of the Plan.
6. Grant of the Options to the Trustee; Voting of Shares.
7. Option or Share Purchase Agreement; Termination of Employment.
8. Acceleration of an Option; Liquidation.
9. Term of Options; Exercise.
10. Taxation.
11. Dividends.
12. Rights and/or Benefits arising out of the Employee/Employer Relationship and the Absence of an Obligation to Employ.
13. Adjustments Upon Changes in Capitalization.
14. Term, Termination and Amendment.
15. Effectiveness of the Plan; Approvals.
16. Release of the Trustee and the Attorney from Liability.
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APPENDICES

Appendix A: Employee's Notice to the Trustee as to Exercise of the Option (Section 9.2).

Appendix B: Notice to the Company of Exercise of the Option by the Trustee (Section 9.2).

1. **PREAMBLE**

1.1 This plan, as amended from time to time, shall be known as the RedHill Biopharma Ltd. Option Plan (2010)" (the **"Plan"**). The purpose and intent of the Plan is to provide incentives to employees, directors and/or service providers including advisors of the Company and/or of subsidiaries and/or affiliated companies of the Company (each a **"RelatedCompany"** and collectively, **"Related Companies"**) by providing them with the opportunity to purchase ordinary shares and/or American Depositary Shares of the Company, as determined pursuant to the Plan, and such other securities as may be substituted for such shares pursuant to this plan (any of the foregoing "**Shares**").

1.2 The Plan is intended to enable the Company to grant options under various and different tax regimes, including, without limitation: (i) pursuant and subject to Section 102 of the Israeli Income Tax Ordinance (New Version), 1961 (the "**Income Tax Ordinance**") or any provision which may amend or replace it and any regulations, rules, orders or procedures promulgated thereunder (collectively, "**Section 102**") and to designate them as either grants made through a trustee or not through a trustee; (ii) pursuant and subject to Section 3(i) of the Income Tax Ordinance; (iii) as "incentive stock options" within the meaning of Section 422 of the United States Internal Revenue Code of 1986, as amended ("**Incentive Stock Options**" and the "**Code**", respectively); (iv) as options to U.S. residents, which would not qualify as Incentive Stock Options ("**Non-Qualified Stock Options**"); (v) to grantees in jurisdictions other than Israel and the United States; and (vi) as restricted shares.
The Company, however, does not warrant that the Plan will be recognized by the income tax authorities in any jurisdiction or that future changes will not be made to the provisions of applicable laws, or rules or regulations which are promulgated from time to time thereunder, or that any exemption or benefit currently available, whether pursuant to Section 102 or otherwise, will not be abolished.

1.3 The Board of Directors of the Company (the "**Board**") shall have the authority to make any requisite adjustments in the Plan and determine the relevant terms in any Agreement (as defined in Section 7 below) in order to comply with the requirements of any relevant tax regime. Furthermore, should any provision of Section 102 be amended, such amendment shall be deemed included in the Plan with respect to options granted in the context of Section 102. Where a conflict arises between any section of the Plan, the Agreement or their application, and the provisions of any relevant tax law, rule or regulation, whether relied upon for tax relief or otherwise, the Board in its sole discretion shall determine the necessary changes to be made to the Plan and its determination regarding this matter shall be final and binding.

1.4 The Plan contemplates the grant of option awards by the Company both as a private company and as a company whose securities are publicly-traded. In the event the Company's securities should be registered for trading on the Tel Aviv Stock Exchange, the New York Stock Exchange, any other stock exchange or an electronic quotation system, whether in Israel, the USA or elsewhere, the options allotted in accordance with the Plan may be made conditional to any requirement or instruction of the stock exchange authorities or of any other relevant authority acting pursuant to applicable law as shall exist from time to time. In such case, by means of a Board resolution, the Plan and the Agreements prepared pursuant hereto, may be amended as necessary to meet such requirements. In the event of a contradiction between any such amendment and the Plan's provisions, the amendment shall prevail.

2. **ADMINISTRATION OF THE PLAN**

2.1 The Plan shall be administered by the Board and/or by any committee of the Board so designated by the Board. Any subsequent references herein to the Board shall also mean any such committee, if appointed and, unless the powers of the committee have been specifically limited by law or otherwise, such committee shall have all of the powers of the Board granted herein. Without derogating from the generality of the foregoing, the Board shall have the authority to designate grants made pursuant to Section 102 as either grants made through a trustee or not through a trustee and to determine (and from time to time change, subject to Section 102) the tax route applicable to options granted through a trustee pursuant to Section 102 (e.g., the capital gains route or the employment income route) and to make any other elections with respect to the Plan pursuant to applicable law. Subject to Sections 4 and 15, the Board shall have plenary authority to determine the terms and conditions of all options (which need not be identical), including, without limitation, whether the options will be exercisable into ordinary shares of the Company or into American Depositary Shares, the purchase price of the Shares covered by each option, the identity of those to whom, and the time or times at which, options shall be granted, the number of Shares to be subject to each option, whether an option shall be granted pursuant to Section 102 or otherwise and when an option can be exercised and whether in whole or in installments. Subject to Section 15, the Board shall have plenary authority to construe and interpret the Plan, to prescribe, amend and rescind the rules and regulations relating to it and to make all other determinations deemed necessary or advisable for the administration of the Plan. All determinations and decisions of the Board pursuant to the provisions of the Plan and all related orders and resolutions of the Board shall be final, conclusive and binding on all persons, including the Company, its shareholders, grantees and their estates and beneficiaries.

2.2 Any directive or notice signed by a member of the Board shall constitute conclusive proof and authority for every act or decision of the Company.

2.3 No director or officer of the Company shall be personally liable or obligated to any grantee as a result of any decision made and/or action taken with respect to the Plan or its execution.

3. [Reserved]

4. **OPTION EXERCISE PRICES**

The consideration to be paid by a grantee for each Share purchased by exercising an option (the **"Option Exercise Price"**) shall be as determined by the Board on the date of grant, provided that the Option Exercise Price shall not be less than the nominal value of the Shares subject to the option, and if on the date of grant the Company's Shares are listed on any established stock exchange or a national market or quotation system, then except as otherwise determined by the Board, the Option Exercise Price shall not be less than the closing price on the date of grant on the Tel Aviv Stock Exchange. The Option Exercise Price shall be denominated in the currency of the primary economic environment of, either the Company or the grantee (that is the functional currency of the Company or the currency in which the grantee is paid) as determined by the Company.

The Board may, in its discretion, grant to the holder of an outstanding option, in exchange for the surrender and cancellation of such option, a new option having an Option Exercise Price lower than provided in the option so surrendered and canceled, and containing such other terms and conditions as the Board may prescribe in accordance with the provisions of this Plan provided that such new Option Exercise Price shall not be less than the nominal value of the Shares subject to the new option.

5. **EXCLUSIVITY OF THE PLAN**

Unless otherwise determined by the Board in any particular instance as part of the Agreement, each grantee hereunder will be required to declare and agree that all prior agreements, arrangements and/or understandings with respect to options to purchase Shares of the Company which have not actually been granted prior to execution of the Agreement shall be null and void and that only the provisions of the Plan and/or the Agreement shall apply.

Notwithstanding the above, the adoption of this Plan, by itself, shall not be construed as amending, modifying or rescinding any incentive arrangement previously approved by the Board or as creating any limitations on the power of the Board to adopt such other incentive arrangements as it may deem desirable, including, without limitation, the granting of options otherwise than under this Plan, and such arrangements may be either applicable generally or only in specific cases.

6. **GRANT OF THE OPTIONS TO THE TRUSTEE; VOTING OF SHARES**

6.1 The Board shall appoint a trustee for the purposes of this Plan, which trustee shall be approved, with respect to grants designated as grants made through a trustee pursuant to Section 102, in accordance with Section 102 (the "**Trustee**"). The Trustee shall have all the powers provided by law, Section 102 and the Plan and shall act pursuant to the provisions thereof, as they shall apply from time to time. The Company shall pay the Trustee a fee as shall be agreed between the Trustee and the Company.

6.2 Unless otherwise determined by the Board, all option awards shall be issued by the Company in the name of the Trustee and the Share certificates representing any Shares issued pursuant to options exercised hereunder, and any and all other or additional rights deriving in connection therewith, if any, such as, but not limited to, bonus Shares (Share dividends) ("**Additional Rights**"), shall be issued by the Company in the name of the Trustee in trust for the designated grantee and shall be deposited with the Trustee, held by him or her and registered in his or her name in the register of members of the Company for such period as determined by the Board but, in the case of grants designated as grants made through a trustee pursuant to Section 102, not less than the period required, or approved, with respect thereto pursuant to Section 102, as shall be in effect from time to time (the "**Required Holding Period**").

Furthermore, and without derogating from the aforesaid or any other provision hereof, with respect to options granted which were designated as made through a trustee pursuant to Section 102: (i) they may not be sold until the end of the Required Holding Period, unless otherwise allowed or determined by the Israeli tax authorities; and (ii) all Additional Rights will be subject to the same tax route applicable to the original option.

6.3 Options granted and designated as grants made through a trustee pursuant to Section 102 will be held by the Trustee and registered in his name in trust for the designated grantee, for not less than the Required Holding Period.

6.4 Options granted hereunder shall not confer upon the holder thereof any of the rights of a shareholder of the Company with respect to the Shares subject to such options until such Shares are issued and registered in the name of the holder upon exercise of the options.

6.5 For as long as any Shares are held by the Trustee or registered in his name or for as long as the certificates representing any Shares are held by the Trustee, the Trustee alone shall be entitled to receive every notice to which a shareholder is entitled, or to demand any information, and any financial and/or other report to which a shareholder is entitled from the Company, and only he or whomever he shall designate pursuant to the Proxy and Power of Attorney referred to and as defined in Section 10.2 below (the **"Attorney"**), shall be entitled to exercise every other right of the shareholders vis-a-vis the Company including the right to participate in and to vote at all shareholders' meetings. No grantee shall be entitled to exercise any of these rights as shareholder nor make any demand or request of the Trustee and/or of the Attorney in this regard.

6.6 Shares registered in the Trustee's name shall be represented at all meetings of shareholders of the Company and shall be voted by the Trustee or the Attorney in the same manner, proportionately, as the other shareholders of the Company voting on such matter.

6.7 Nothing in the foregoing provisions shall derogate from the power of the Board to grant options to the Trustee otherwise than under the provisions of Section 102 or to grant options to grantees directly otherwise than through the Trustee or on terms which differ from those specified above or to approve the transfer of Shares from the Trustee to the name of any grantee(s) upon such conditions as shall be determined by the Board.

7. OPTION AGREEMENT; TERMINATION OF EMPLOYMENT

Unless otherwise determined by the Board, every grantee shall be required to sign grant letter or other documents as shall be determined by the Board, in the form approved by the Board (the "**Agreement"**).

The Agreement shall specify the type of option award granted and whether it constitutes an option pursuant to Section 102, and if so, under which regime, an option pursuant to Section 3(i) of the Income Tax Ordinance, an Incentive Stock Option, a Non-Qualified Stock Option or otherwise. The Agreement need not be identical with respect to each grantee. The following terms, however, shall apply to all options, unless expressly otherwise decided in respect of a particular option:

7.1 The Option Exercise Price shall be paid by the grantee to the Company no later than the date of exercise of the option unless otherwise determined in the Agreement.

7.2 The grantee shall have no right of first refusal to purchase Shares of the Company which may be offered for sale by shareholders of the Company, and shall have no pre-emptive rights to purchase Shares which are being allotted or shall in the future be allotted by the Company, to the extent any such rights otherwise exist.

7.3 The option and/or the right to the option are personal and except insofar as is specified in this Plan, and, where applicable, subject to Section 102, may not be transferred, assigned, pledged, withheld, attached or otherwise charged either voluntarily or pursuant to any law, except by way of transfer pursuant to the laws of inheritance, and no power of attorney or deed of transfer, whether the same has immediate effect or shall take effect on a future date, shall be given with respect thereto. During the lifetime of the grantee the option may only be exercised by the designated grantee or, if granted to the Trustee, by the Trustee on behalf of the designated grantee. A note as to the provisions of this sub-section or a legend may appear on any document which grants the option and in particular in the Agreement, and also on any Share certificate.

7.4 The right to exercise the option is granted to the Trustee on behalf of the grantee. Unless otherwise provided in the Agreement, vesting shall be in installments, gradually over a period of four (4) years from the date of grant of the option or such other period or periods as determined by the Board. Unless otherwise determined, at the conclusion of each period for the exercise of the option as determined in the Agreement ("**Vesting Periods**"), the option may, from time to time, be exercised in relation to part or all the Shares allocated for that period in such manner that at the end of each year following the granting of the option the Trustee shall, in the absence of a contrary determination in the Agreement, be entitled to exercise on behalf of the grantee and at his or her request up to one third (1/4) of the Shares subject to the option.

In addition, during each of the Vesting Periods, the option may be exercised in relation to all or part of the Shares allocated for any previous Vesting Period in which the option was not fully exercised, provided, subject to the provisions of Section 7.6 hereof, that at the time of the exercise of the option the grantee has continued to be employed by or to serve as a director of or provide services to, the Company or a Related Company on a continual basis from the date of the grant thereof until the date of their exercise. After the end of the Vesting Periods and during the balance of the option period, the option may be exercised, from time to time, in relation to all or part of the Shares which have not at that time been exercised and which remain subject to the option, subject to the provisions of Section 7.6 hereof and to any condition in the Agreement, if such exists, which provides a minimum number of Shares with respect to which the option may be exercised and any provision which determines the number of times that the Trustee may send the Company notice of exercise on behalf of the grantee in respect of the option. The Board shall be entitled at any time to shorten the vesting schedule or any Vesting Period.

7.5 The Board may determine at its sole discretion, that any grantee shall be entitled to receive the options, through the Trustee, pursuant to the provisions of this Plan or, subject to the provisions of Section 102 as relevant, directly in the name of the grantee, immediately upon execution of the Agreement or on such other date or dates as the Company has undertaken towards such grantee. In the event that a grantee is exempt from the Vesting Periods (pursuant to the provisions of Section 7.4), the Board shall be entitled, subject to the provisions of Section 102 as relevant, to determine that where the grantee does not comply with the conditions determined by the Board or ceases to be an employee of the Company or a Related Company, the Trustee, the Company or a Related Company shall have the right to repurchase the Shares from the grantee for nominal or any other consideration paid by the grantee or as otherwise determined by the Board at the time of grant. The Board may set additional conditions to this right of repurchase, including the provision of appropriate arrangements for the monies which shall be available to the Trustee or a Related Company or others for the purpose of the repurchase and may set conditions with respect to the voting rights of the grantee, rights of first refusal or pre-emptive rights to purchase Shares in the Company, to the extent such rights exist, the grantees right to receive reports or information from the Company, and the grantee's right to a dividend in respect of Shares which are subject to a right of reacquisition as aforesaid. For as long as the foregoing conditions of the Board (including a minimum period of employment as a condition for the lapse of the right to reacquisition) have not been complied with, the grantee shall not be entitled to sell or charge or transfer in any other manner the Shares which are subject to the right of reacquisition. As security for the compliance with this undertaking the Share certificate will be deposited with the Trustee who will release the same to the grantee only after the grantee becomes entitled to the Shares and the same are not subject to any other restrictive condition.

7.6 Termination of Employment

7.6.1 If a grantee ceases to be an employee, director or service provider (or, if relevant, an employee of a service provider) of the Company or a Related Company, other than: (i) by reason of death, disability (as determined by the Board in its absolute discretion) or retirement as provided in Section 7.6.3 below; or (ii) for Cause (as defined in Section 8.2 below) (at which time the option shall terminate immediately upon the earlier of such cessation or notice of cessation); the option shall remain exercisable for a period of ninety (90) days following the earlier of such cessation or notice of cessation (but only to the extent exercisable at termination of employment and not beyond the scheduled expiration date), unless the Agreement provides otherwise.

7.6.2 If the employment or the director or service-provider relationship of a grantee is terminated by reason of death, disability (as determined by the Board in its absolute discretion) or retirement after age 60 with the approval of the Board, the option shall remain exercisable for a period of twenty four (24) months following such termination (but only to the extent exercisable at termination of employment and not beyond the scheduled expiration date).

7.6.34 The Board may determine whether any given leave of absence constitutes a termination of employment. Options awarded under this Plan shall not be affected by any change of employment so long as the grantee continues to be an employee, director or service-provider, as applicable, of the Company or a Related Company.

7.6.4 Notwithstanding the foregoing, the Board may in its absolute discretion, extend the period of exercise of the option by a grantee or grantees for such time as it shall determine either with or without conditions.

8. **ACCELERATION OF AN OPTION; LIQUIDATION**

8.1 Acceleration in the Event of Sale of Assets, Certain Mergers. In the event of: (i) a sale of all or substantially all of the assets of the Company; or (ii) a consolidation or merger of the Company in which the Company is not the continuing or surviving corporation and the continuing or surviving corporation (or, if such transaction is effected through a subsidiary, the parent of such continuing or surviving corporation), does not assume the option or substitute it with an appropriate option in the continuing or surviving corporation (or in the parent as aforesaid), then, notwithstanding any contrary Vesting Periods in any Agreement or in this Plan, and unless in each case: (A) the applicable Agreement provides otherwise; or (B) the Board determines otherwise, all of the outstanding options held by or for the benefit of any grantee whose vesting dates fall within the first twelve (12) months thereafter shall be accelerated and become vested and exercisable immediately prior to the consummation or closing of such proposed action.

8.2 Acceleration in the Event of a Significant Event. If a "Significant Event", as defined below, shall occur, and the employment of a grantee with the Company or a Related Company is terminated by the Company or a Related Company within twelve (12) months thereafter, other than for "Cause" as defined below; and unless: (i) the applicable Agreement provides otherwise; or (ii) the Board determines otherwise, all of the outstanding options held by or for the benefit of any grantee whose vesting dates fall within the first twelve (12) months thereafter shall be accelerated and become immediately vested and exercisable.

Each of the following shall be a "**Significant Event**": a consolidation or merger of the Company with or into another corporation in which the Company is the continuing or surviving corporation or in which, if the Company is not the continuing or surviving corporation, the continuing or surviving corporation (or, if such transaction is effected through a subsidiary, the parent of such continuing or surviving corporation) assumes the option or substitutes it with an appropriate option in the surviving corporation (or in the parent as aforesaid).

The term "**Cause**" shall mean, for the purposes hereof, conviction (whether following trial, by plea of guilty or failure to contest prosecution) in a criminal proceeding of (i) a misdemeanor involving fraud, false statements or misleading omissions, embezzlement, bribery, forgery or extortion; or (ii) a felony; or (iii) an equivalent charge to those in (i) and (ii) above in jurisdictions which do not use those designations.

8.3 Liquidation; Merger. Unless otherwise determined by the Board, in the event of: (i) the proposed liquidation or dissolution of the Company; or (ii) a consolidation or merger as described in Section 8.1 (ii) above; all outstanding options (including, without limitation, any options accelerated pursuant to Section 8.1 above) will terminate and expire immediately upon to the consummation or closing of such proposed action. Without derogating from any other right or authority of the Board hereunder, the Board may, in connection with any proposed liquidation or dissolution, or in connection with any merger or consolidation as aforesaid, determine any other date and time upon which any outstanding option will terminate and may also provide for the acceleration and vesting of, and right to exercise, any option which would not otherwise be exercisable.

9. TERM OF OPTIONS; EXERCISE

9.1 The term of each option shall be for such period as the Board shall determine, but not more than ten (10) years from the date of grant thereof or such shorter period as is prescribed in Section 7.6 or 8.3 hereof or, with respect to Incentive Stock Options, as prescribed in Section 4 above.

9.2 A grantee who desires that the Trustee exercise an option granted to the Trustee on his or her behalf shall so instruct the Trustee in writing in the form annexed hereto as **Appendix A** or in such other form as shall be approved by the Board from time to time. The notice shall be accompanied by, or specify the arrangements for, payment of the full Option Exercise Price of such Shares as provided in the Agreement. The Company may require as a condition to the exercise of an option that the grantee pay or otherwise make arrangements to the Company's satisfaction, for the payment of the tax and other obligatory payments applicable to him or her (including all sums payable arising out of or in connection with the Company's obligation to deduct tax and other obligatory payments at source) pursuant to applicable law and the provisions of the Plan. The Company may also require that the grantee provide or make such representations and agreements as to grantee's investment intent and such other matters as the Company may deem necessary, advisable or appropriate at such time. Upon receipt of all the requisite documents, approvals and payments from the grantee, including sufficient proof of payment or other arrangement with respect to the payment of any applicable taxes in form satisfactory to the Company and the Trustee, the Trustee shall deliver a notice to the Company in the form annexed hereto as **Appendix B** or in such other form as shall be approved by the Board from time to time, whereupon the Company shall allot the Shares in the name of the Trustee.

9.3 A grantee who desires to exercise an option granted directly to him or her (and not through the Trustee) shall so notify the Company in writing in such form as shall be prescribed by the Board from time to time. As a condition for the exercise of the option, the grantee shall pay or otherwise make arrangements, to the Company's and Trustee's satisfaction, for the payment of the tax and other obligatory payments applicable to him or her (including all sums payable by the Company arising out of its obligation to deduct tax and other obligatory payments at source) pursuant to applicable law and the provisions of the Plan. Upon receipt of all the requisite documents, approvals and payments from the grantee, including sufficient proof of payment or other arrangement with respect to the payment of any applicable taxes in form satisfactory to the Company and the Trustee, the Company shall allot the Shares in the name of the grantee.

9.4 Without limiting the foregoing, the Board may, with the consent of the grantee, from time to time cancel all or any portion of any option then subject to exercise, and the Company's obligation in respect of such option may be discharged by: (i) payment to the grantee or to the Trustee on behalf of the grantee of an amount in cash equal to the excess, if any, of the Fair Market Value (as defined below) of the relevant Shares at the date of such cancellation subject to the portion of the option so canceled over the aggregate Option Exercise Price of such Shares; (ii) the issuance or transfer to the grantee or to the Trustee on behalf of the grantee of Shares of the Company with a Fair Market Value at the date of such transfer equal to any such excess; or (iii) a combination of cash and Shares with a combined value equal to any such excess, all as determined by the Board in its sole discretion.

For purposes hereof, the "**Fair Market Value**" of the Ordinary Shares shall mean, as of any date, the last reported sale price, on that date, of the Ordinary Shares of the Company on the principal securities exchange on which such Shares are then traded, or, in the event that no sales of such Shares took place on such date, the last reported sale price of such Shares on such principal securities exchange on the most recent prior date on which a sale of Shares took place; provided, however, that if such Shares are not publicly traded on the date as of which Fair Market Value is to be determined, "Fair Market Value" of the Ordinary Shares shall mean the value as determined in good faith by the Board.

Without derogating from the above, solely for the purpose of determining the tax liability pursuant to Section 102(b)(3) of the Income Tax Ordinance, if at the date of grant the Company's Shares are listed on any established stock exchange or a national market or quotation system, the Fair Market Value of an Ordinary Share at the date of grant shall be determined in accordance with the average value of the Company's Shares during the thirty (30) trading days preceding the Date of Grant, or in the thirty (30) trading days following the date of registration for trading, as the case may be.

9.5 Exercise of options will not be permitted on the effective date for distribution of bonus Shares, rights offering, distribution of a dividend, capital consolidation, capital split or capital reduction (all of the above will be: "**Effective Date**" and "**Company Event**", respectively).

If the Ex Date of a Company Event precedes the Effective Date of a Company Event, the exercise of options will not be permitted on the Ex Date as mentioned.

Ex Date - the first trading day, in which the securities are traded without the right to any payment under a Company Events.

10. **TAXATION**

10.1 General

The grantee shall be liable for all taxes, duties, fines and other payments which may be imposed by the tax authorities (whether in Israel or abroad) and for every obligatory payment of whatever source (including, but not limited to, social security, health tax, etc., as may be applicable) in respect of the options (including, without limitation, upon the grant of the options, the exercise of the options, or the registration of the Shares in the grantee's name) or dividends or any other benefit in respect thereof and/or for all charges which shall accrue to the grantee, the Company, any Related Company and/or to the Trustee in connection with the Plan, the options, or any act or omission by the grantee or the Company in connection therewith or pursuant to any determination by the applicable tax or other authorities, including, without limitation, any such payments required to be made by the Company as the result of any sale by the grantee of Shares which were designated as made through a trustee pursuant to Section 102 prior to the end of the Required Holding Period. Notwithstanding the foregoing, if the Company elects the "employment income" route for options granted through a trustee pursuant to Section 102, the Company or the Related Company, as applicable, shall pay, at its expense, any social security payments payable by the employer with respect to options so granted to the extent required as a result of such choice.

10.2 Deduction at Source

The Company (including any Related Company) and/or the Trustee shall have the right to withhold or to require the grantee to pay an amount in cash or to retain or sell without notice Ordinary Shares in value sufficient to cover any tax or obligatory payment required by any governmental or administrative authority to be withheld or otherwise deducted and paid with respect to the options or the Ordinary Shares subject thereto (including, without limitation, upon their grant, exercise, issuance or sale or the registration of the Ordinary Shares in the grantee's name) or with respect to dividends or any other benefits in respect thereof ("**Withholding Tax**"), and to make payment (or to reimburse itself or himself for payment made) to the appropriate tax or other authority of an amount in cash equal to the amount of such Withholding Tax. Notwithstanding the foregoing, the grantee shall be entitled to satisfy the obligation to pay any Withholding Tax, in whole or in part, by providing the Company and/or the Trustee with funds sufficient to enable the Company and/or the Trustee to pay such Withholding Tax.

10.3 Certificate of Authorization of Assessing Officer

The Company (including any Related Company) or the Trustee shall at any time be entitled to apply to the Assessing Officer, and in the case of a grantee abroad, to any foreign tax authority, and to any other governmental or administrative authority for receipt of their certificate of authorization as to the amount of tax or other obligatory payments which the Company or any Related Company or the grantee or the Trustee is to pay to the tax or other authorities resulting from granting the options, or regarding any other question with respect to the application of the Plan.

10.4 Security for Payment of Taxes

Without derogating from the above, the Company (including any Related Company) and/or the Trustee shall have the right to require that any grantee provide guarantees or other security to the Company's satisfaction to guarantee the payment of any taxes or other obligatory payments which may be payable as a result of or in connection with the grant of an option, the exercise thereof, the registration of any options in the grantee's name (including any sum payable arising out of or in connection with the Company's obligations to deduct tax and other obligatory payments at source); and, with respect to options granted pursuant to Section 102 which were not designated as made through a trustee, if the grantee's employment with the Company or any Related Company is terminated for any reason, the grantee will be obligated to provide the Company with a guarantee or other security to its satisfaction and at its discretion, to cover any tax obligations which may arise thereafter in connection with the disposition of the Shares.

11. **DIVIDENDS**

The Ordinary Shares issued as a result of the exercise of the options shall participate equally with the Company's other Ordinary Shares in every cash dividend that shall be declared and distributed subject to the following provisions:

11.1 A cash dividend shall be distributed only to persons registered in the register of members as shareholders on the record date fixed for the distribution of the dividend.

11.2 A dividend with regard to Shares that are registered in the name of the Trustee shall be paid to the Trustee, subject to any lawful deduction of tax, whether such rate is at the usual rate applicable to a dividend or at a higher rate. The Trustee shall transfer the dividend to the grantees in accordance with instructions that he shall receive from the Company. Alternatively, the Company shall be entitled to pay the dividend directly to the grantee subject to the deduction of the applicable tax.

11.3 Without derogating from the provisions of Sections 10.2 and 11.2 hereof, the Company or the Trustee shall be entitled to set off and deduct at source from any dividend any sum that the grantee owes to the Company (including any Related Company) or the Trustee, whether under the Plan or otherwise, and/or any sum that the grantee owes to the tax or other authorities.

12. RIGHTS AND/OR BENEFITS ARISING OUT OF THE EMPLOYEE/ EMPLOYER RELATIONSHIP AND THE ABSENCE OF AN OBLIGATION TO EMPLOY

12.1 No income or gain which shall be credited to or which purports to be credited to the grantee as a result of the Plan, shall in any manner be taken into account in the calculation of the basis of the grantee's entitlements from the Company or any Related Company or in the calculation of any social welfare right or other rights or benefits arising out of the employee/employer relationship. If, pursuant to any law, the Company or any Related Company, shall be obliged for the purposes of calculation of the said items to take into account income or gain actually or theoretically credited to the grantee, the grantee shall indemnify the Company or any Related Company, against any expense caused to it in this regard.

12.2 Nothing in the Plan shall be interpreted as obliging the Company or any Related Company to employ the grantee and nothing in the Plan or any option granted pursuant thereto shall confer upon any grantee any right to continue in the employment of the Company or any Related Company or restrict the right of the Company or any Related Company to terminate such employment at any time. The grantee shall have no claim whatsoever against the Company or any Related Company as a result of the termination of his or her employment, including, without limitation, any claim that such termination causes any options to expire and/or prevents the grantee from exercising the options and/or from receiving or retaining any Shares pursuant to any agreement between him or her and the Company, or results in any loss due to an imposition, or earlier than anticipated imposition, of tax or other liability pursuant to applicable law.

13. ADJUSTMENTS

Upon the occurrence of any of the following described events, a Grantee's rights to purchase Shares under the Plan shall be adjusted as hereinafter provided:

13.1 In the event that the Company distributes a **cash dividend**, the effective date for the distribution thereof, will take place after the date of the allocation of the Options to the Trustee for a Grantee, but before the exercise or expiry of the Options, the exercise price shall be decreased in respect of each Option by the amount of the dividend per Share. For the avoidance of doubt, under no circumstances will the exercise price be decreased to a price which is less then the nominal value of an ordinary share of the Company.

13.2 In the event that the Company distributes **bonus Shares**, the effective date for the distribution of which takes place after the date of the allocation of the Options to the Trustee for the Grantee, but before the exercise or expiry of the Options, the number of Shares to which the Grantee is entitled upon the exercise of the Options shall increase by the number of the Shares that the Grantee would have been entitled to as bonus Shares, had he exercised the Options prior to the effective date for the distribution of the bonus Shares. The exercise price of each Option shall not vary as a result of the increase in the number of Shares to which the Grantee is entitled in the wake of the distribution of bonus Shares.

13.3 If rights to acquire any securities whatsoever are offered to Company shareholders by way of **rights**, the Company shall act with a view that the number of Shares that each Grantee is entitled to upon the exercise of the Options will be adjusted multiplying it by the Benefit Ratio.

Benefit Ratio - the closing price of the stock exchange on the Last trading day before the Ex Date divided by the base price of the ex-rights stock.

13.4 In any event of **division or consolidation** of the Company's share capital, or any other corporate capitalization event of a significantly similar nature, the Company shall effect such changes or adjustments as are required to prevent dilution or increase in a Grantee's rights, pursuant to the Plan with respect to the number and class of the Shares in relation to the Options not yet exercised by the Grantee and/or the exercise price of each Option.

13.5 In any event of a **merger**, spin-off and/or any other structural change, Options which have been granted under this Plan, shall be replaced by, or converted to, an alternative option in the Company after such structural change, all at the absolute discretion of the Company's Board.

14. TERM, TERMINATION AND AMENDMENT

Unless the Plan shall theretofore have been terminated as hereinafter provided, the Plan shall terminate on, and no option shall be granted after, the tenth anniversary of the date the Plan is adopted by the Board. The Board may at any time terminate, modify or amend the Plan in such respects as it shall deem advisable. Options granted prior to termination of the Plan may, subject to the terms of the Plan and any Agreement, be exercised thereafter. No amendment or modification of the Plan may, without the consent of the grantee to whom any option shall theretofore have been granted, adversely affect the rights of such grantee under such option.

15. EFFECTIVENESS OF THE PLAN; APPROVALS

The Plan shall become effective as of the date determined by the Board. Notwithstanding the foregoing and Sections 3 and 15 above, in the event that approval of the Plan or any modification or amendment thereto by the shareholders of the Company is required under applicable law or pursuant to applicable stock exchange rules or regulations, such approval shall, to the extent possible, be obtained within the time required under the applicable law, rule or regulation. If such shareholder approval is required in connection with the application of specified tax treatments, the Company shall make reasonable efforts to obtain such approval within the required time.

16. RELEASE OF THE TRUSTEE AND THE ATTORNEY FROM LIABILITY

In no event shall the Trustee or the Attorney be liable to any grantee under the Plan, or to a purchaser of Shares from any grantee with respect to any act which has been or will be carried out in relation to the Plan, its execution and any matter connected thereto or arising therefrom. The grantee will be required to covenant upon signing the Agreement that he or she will not make any claim against the Trustee or the Attorney in any manner whatsoever and on any ground whatsoever and that he or she will expressly agree that if the Trustee or the Attorney are sued by them, then the Trustee or the Attorney shall be entitled by virtue of this Section alone to apply to the court for dismissal of the action against them with costs.

17. **GOVERNING LAWS**

The Plan and all instruments issued thereunder shall be governed by and construed in accordance with the laws of the State of Israel, subject to the provisions of the Code with respect to Incentive Stock Options and, in the event of any ambiguity or conflict, the provisions hereof shall be so construed and applied as to give effect to the intention that any Incentive Stock Option granted will qualify as such under Section 422 of the Code.

* * *

RedHill Biopharma Ltd.

Appendix A
to
RedHill Biopharma Ltd.'s Option Plan (2010), as amended
(Section 9.2)

NOTICE OF EXERCISE

Date: _____

To: Meitav Dash Trusts Ltd. (the "**Trustee**") , By Fax: 972-3-6960255

To: RedHill Biopharma Ltd. ("**RedHill**"), Fax: 972-3-5413144 or Email: uri@redhillbio.com

Dear Sir/Madam:

Re: **Notice of Exercise**

I hereby wish to inform you that it is my desire to exercise _____ options ("**Options**") out of the _____ options which were granted on my name on _____ [Date] under the RedHill Biopharma Ltd. Option Plan (2010), as amended ("**Plan**"), and tenders herewith payment of the purchase price for such shares in full.

The exercise price of said Options is USD _____ per share, all in accordance with the Plan and the Israeli Securities Law of 1968 or any state securities laws.

The total amount for the exercise of the Options of USD _____ was paid to RedHill by me on the date of _____. I am aware that the exercise of the Options will be done only after RedHill will transfer to you written confirmation that the exercise amount was paid in full.

I am aware that all the shares will be allotted to you, registered in your name and that you will hold all the share certificates representing such shares. Likewise, I am aware of and agree to all the other provisions of the Plan and applicable laws.

Yours sincerely,

Signature: _____

Name: _____

The receipt of this form by the Trustee must be verified by phone (No. 972-3-7903444).

RedHill Biopharma Ltd.

Appendix B
to
RedHill Biopharma Ltd.'s Employee Option Plan (2010), as amended
(Section 9.2)

NOTICE OF EXERCISE

Date: _____

To: RedHill Biopharma Ltd.

Dear Sirs:

Re: **Notice of Exercise**

Please be advised that on the date of _____ we received instruction from _____ (the "**Grantee**") to exercise _____ options ("**Options**") out of the _____ options which were granted in his/her name on _____ [Date] under the RedHill Biopharma Ltd. Option Plan (2010), as amended ("**Plan**").

The exercise price of said Options is USD _____ per share, all in accordance with the Plan and the Israeli Securities Law of 1968 or any state securities laws.

The total amount for the exercise of the Options of USD _____ should have been paid to you in full by the Grantee. Upon reception of a written confirmation from you that you received this amount in full, we will exercise the Options for shares and register these shares under our name.

Attached to this notice is the exercise notice sent to us by the Grantee.

Yours sincerely,

Meitav Dash Trusts Ltd.

Signature: _____

Name: _____

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, 2015

/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, 2015

/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, 2014 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, 2015

/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) and the Registration Statement on Form S-8 (file No. 333-188286) of RedHill Biopharma Ltd. (the "Company"), of our report dated February 25, 2015, relating to the financial statements of the Company, which appears in this Form 20-F.

Tel-Aviv, Israel
February 25, 2015

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited