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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, 2016

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)

Micha Ben Chorin, Chief Financial Officer
21 Ha'arba'a Street, Tel Aviv 64739, Israel
Tel: 972-3-541-3131; Fax: 972-3-541-3144
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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

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

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

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

None
(Title of Class)

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

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 170,581,594 Ordinary Shares

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

Yes ☐ No ☒

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act 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., a limited liability company incorporated under the laws of the State of Israel, and its direct and indirect subsidiaries. The term "NIS" refers to New Israeli Shekels, the lawful currency of the State of Israel, the terms "dollar", "US$", "$" or "U.S." refer to U.S. dollars, the lawful currency of the United States of America. 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, 2017 ($1 = NIS 3.71). 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 U.S. dollars are translated in this Annual Report into U.S. dollars using exchange rates in effect at the date of the transactions.

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

FORWARD-LOOKING STATEMENTS

Some of the statements under the sections entitled "Item 3. Key Information — Risk Factors," "Item 4. Information on the Company," "Item 5. Operating and Financial Review and Prospects" and elsewhere in this Annual Report may include forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. In some cases, you can identify forward-looking statements by terms including "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," and similar expressions intended to identify forward-looking statements. Forward-looking statements reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties. In addition, the sections of this Annual Report entitled "Item 4. Information on the Company" contain information obtained from independent industry and other sources that we may not have independently validated. 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, Donnatal®, and products that we may sell or market, and the timing of other regulatory filings and approvals;
- the research, manufacturing, preclinical and clinical development, commercialization, and market acceptance of our therapeutic candidates, Donnatal®, and products that we may sell or market;
- our ability to establish and maintain corporate collaborations for our therapeutic candidates, Donnatal®, and products that we may sell or market;
- our ability to acquire products, rights to products or commercialization rights to products approved for marketing in the U.S. or other territories that achieve commercial success;
- our ability to build and maintain our own marketing, sales, and commercialization capabilities, including complying with all applicable laws, regulations and guidelines;
- the interpretation of the properties and characteristics of our therapeutic candidates and of the results obtained with our therapeutic candidates in research, development, manufacturing, preclinical studies or clinical trials;
- the implementation of our business model, ongoing and strategic plans for our business, therapeutic candidates, Donnatal®, and products that we may sell or market;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our therapeutic candidates and our ability to operate our business without infringing upon the intellectual property rights of others;

- estimates of our expenses, future revenues, capital requirements and our need for additional financing;
- parties from whom we acquire rights to our intellectual property defaulting in their obligations towards us;
- the impact of competitive companies and technologies within our industry; and
- the impact of the political and security situation in Israel, the U.S. and other countries in which we may obtain approvals for our products 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 ("IFRS") as issued by the International Accounting Standards Board. We have derived the selected financial data as of December 31, 2016, 2015 and 2014 and for the years ended December 31, 2016, 2015 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, 2013, and 2012 and for the years ended December 31, 2013 and 2012 from our audited financial statements not included in this Annual Report. You should read this selected financial data and other information provided in this Annual Report in conjunction with, and is qualified in its entirety by, our historical financial information including "Item 5. Operating and Financial Review and Prospects" and our financial statements and related notes appearing elsewhere in this Annual Report.

	Year ended December 31				
	2016	2015	2014	2013	2012
	(U.S. Dollars, in thousands, except per share and weighted average shares data)				
Statement of Comprehensive Loss					
Revenues	101	3	7,014	12	16
Cost of Revenue	—	—	1,050	—	—
Research and development expenses, net	25,241	17,771	12,700	8,100	6,455
General, administrative and business development expenses	5,403	4,134	4,011	2,684	2,601
Other (income) expenses	—	100	(100)	—	—
Operating loss	30,543	22,002	10,647	10,772	9,040
Financial income	1,548	1,124	319	158	197
Financial expenses	375	212	383	14	1,483
Financial (income) expenses, net	(1,173)	(912)	64	(144)	1,286
Loss and comprehensive loss	29,370	21,090	10,711	10,628	10,326
Loss per Ordinary Share (in U.S. dollars)					
Basic	0.23	0.19	0.12	0.17	0.20
Diluted	0.24	0.19	0.13	0.17	0.20
Weighted average number of Ordinary Shares used in computing loss per Ordinary Share	128,513,729	110,813,742	86,610,126	62,379,171	52,595,128
Weighted average number of Ordinary Shares used in computing diluted loss per share	128,808,543	111,714,566	87,222,188	62,379,171	52,595,128

	As of December 31 (U.S. Dollars, in thousands)				
	2016	2015	2014	2013	2012
Balance Sheet Data					
Cash and short-term investments	66,154	58,138	22,945	12,113	18,365
Working capital	62,459	54,996	24,299	10,186	17,485
Total assets	74,212	66,828	28,856	14,340	20,096
Total liabilities	11,511	6,751	3,845	2,415	1,078
Accumulated deficit	(89,635)	(61,944)	(42,218)	(33,260)	(23,887)
Equity	62,701	60,077	25,011	11,925	19,018

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 (the "Ordinary Shares") or our American Depositary Shares ("ADSs"). These material risks could adversely impact our results of operations, possibly causing the trading price of our Ordinary Shares and ADSs to decline, and you could lose all or part of your investment.

Risks Related to Our Financial Condition and Capital Requirements

Since our incorporation in 2009, we have focused primarily on the development and acquisition of late clinical-stage therapeutic candidates and have a history of operating losses. We expect to incur additional losses in the future and may never be profitable.

Since our incorporation in 2009, we have focused primarily on the development and acquisition of late clinical-stage therapeutic candidates. All of our therapeutic candidates are in the clinical development stage and none of our therapeutic candidates has been approved for marketing or are being marketed or commercialized in the U.S., although RIZAPORT® has been approved for marketing in Germany but has yet to be marketed. In addition, we were recently granted certain rights to promote, but not sell or distribute, Donnatal® in the U.S. pursuant to an exclusive commercialization agreement (the "Co-Promotion Agreement") with a subsidiary of Concordia International Corp. ("Concordia"). Pursuant to the Co-Promotion Agreement, Concordia maintains all responsibility to receive orders of Donnatal® and distribute Donnatal® in our marketing territories.

Most of our therapeutic candidates will 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, general, administrative and business development expenses in support of our operations. We experienced net losses of approximately $28.9 million in 2016, $21.1 million in 2015 and $10.7 million in 2014. As of December 31, 2016, we had an accumulated deficit of approximately $89.6 million. We may incur significant additional losses as we continue to focus our resources on prioritizing, selecting and advancing our therapeutic candidates, promoting Donnatal® and products that we may sell or market. Our ability to generate any 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 and promote Donnatal® and products we may acquire or for which we may acquire commercialization rights. 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 or sustained revenues.

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

We have a limited operating history and our operations to date have been limited primarily to acquiring and in-licensing therapeutic candidates, research and development, raising capital and recruiting scientific and management personnel and third-party partners. Except with respect to RHB-106 and related rights, which is out-licensed to Valeant Pharmaceuticals International, Inc. ("Valeant"), and with respect to RIZAPORT®, for which we have received marketing approval in Germany and have entered into exclusive license agreements to commercialize in Spain and South Korea, 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 or commercialization of our therapeutic candidates, the success of products that we may sell or market, the success of promoting Donnatal®, obtain regulatory approvals, reimbursement, achieve market acceptance or favorable pricing for our therapeutic candidates, Donnatal® and products that we may sell or market.

Our current working capital may not be sufficient to complete our research and development with respect to any or all of our therapeutic candidates or to commercialize our products or products to which we have rights, including to promote Donnatal®. We will need to raise additional capital to achieve our strategic objectives of acquiring, in-licensing, developing and commercializing therapeutic candidates, marketing, Donnatal®, and products that we may sell or market, and our failure to raise sufficient capital would significantly impair our ability to fund our operations, develop our therapeutic candidates, and commercialize the products we may sell or market, such as Donnatal®, attract development or commercial partners and retain key personnel.

As of December 31, 2016, we had cash and short-term investments of approximately $66.2 million, and as of December 31, 2015, we had cash and short-term investments of approximately $58.1 million. 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, commercialization of in-licensed or acquired products and raising additional capital through the sale of equity or debt. These amounts are not sufficient to complete the research and development of all of our therapeutic candidates, and we are also not yet certain of the financial impact of our commercialization activities. Accordingly, we may need to raise additional capital in the future.

To date, our business has generated limited revenues. As we plan to continue expending funds in research and development, including clinical trials, as well as to acquire additional products, we will need to raise additional capital in the future through either debt or equity financing or pursuant to development or commercialization agreements with third parties with respect to particular therapeutic candidates. However, we cannot be certain that we will be able to raise capital on commercially reasonable terms or at all, or that our actual cash requirements will not be greater than anticipated. We may have difficulty raising needed capital or securing a development or commercialization partner in the future as a result of, among other factors, our lack of revenues from commercialization of the therapeutic candidates and marketing of Donnatal® and products that we may sell or market, as well as the inherent business risks associated with our company, our therapeutic candidates, Donnatal®, and products that we may sell or market, and present and future market conditions. To the extent we are able to generate revenues from Donnatal®, we may still need to raise capital because the revenues from Donnatal®, if any, may not be sufficient to cover all of our operating expenses and may not be sufficient to cover our commercial operations expenses. 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, marketing of Donnatal®, and products that we may sell or market, any of which may have material adverse effect on our business, financial condition and results of operations. Moreover, to the extent we are able to raise capital through the issuance of debt or equity securities, it could result in substantial dilution to existing shareholders.

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

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

- the number of therapeutic candidates in development;
- the regulatory clarity and path of each of our therapeutic candidates;
- the progress, success and cost of our clinical trials and research and development programs including manufacturing;
- the identification and acquisition of additional therapeutic candidates;

- the costs, timing and outcome of regulatory review and obtaining regulatory clarity and approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of manufacturing, developing and maintaining sales, marketing and distribution channels;
- our ability to successfully commercialize our therapeutic candidates, promote Donnatal®, and products that we may sell or market, including through securing commercialization agreements with third parties and favorable pricing and market share or through securing and maintaining our own commercialization capabilities;
- our ability to successfully commercialize products that we develop or acquire or for which we acquire commercialization rights; 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 or our development or commercialization partners are unable to obtain or maintain the U.S. Food and Drug Administration ("FDA") or other foreign regulatory clearance and approval for our therapeutic candidates or products we may sell or market, we or our commercialization partners will be unable to commercialize our therapeutic candidates or products we may sell or market.

To date, we have not marketed, distributed or sold any therapeutic candidate or product, although we have obtained marketing approval for RIZAPORT® in Germany, and in December 2016, we entered into a Co-Promotion Agreement pursuant to which we were granted certain rights in the U.S. to promote Donnatal® (phenobarbital & belladonna alkyloids), an anticholinergic and barbiturate combination drug product used as adjunctive therapy for irritable bowel syndrome, a condition characterized by abdominal pain, bloating, and diarrhea or constipation. It may also be used as adjunctive therapy for acute enterocolitis and duodenal ulcers.

Donnatal® is a prescription drug included in the Drug Efficacy Study Implementation ("DESI") review program of the FDA. Donnatal® was first commercialized before Congress's 1962 amendment to the Food Drug and Cosmetic Act. The 1962 amendment required evidence of efficacy to be granted FDA approval. At that time, the FDA introduced the DESI program to evaluate the efficacy of drugs approved before 1962. Under DESI, Donnatal® is not an FDA-approved drug, but it is cleared to be marketed and sold until a final determination regarding efficacy is made. To our knowledge at this time and based on our review of docketed correspondence with the FDA, the FDA has not made a final determination as to the efficacy of Donnatal®.

Currently, we have seven therapeutic candidates in various programs and clinical development stages, "RHB-105" for the eradication of *H. pylori* infection; "RHB-104" for the treatment of Crohn's disease and potentially other diseases; "RHB-106" (out-licensed to Valeant) for bowel preparation; BEKINDA® (RHB-102) for acute gastroenteritis and gastritis, irritable bowel syndrome with diarrhea ("IBS-D"), and for the prevention of chemotherapy and radiotherapy-induced nausea and vomiting; YELIVA® (ABC294640), a sphingosine kinase-2 ("SK2") selective inhibitor targeting multiple oncology, inflammatory and gastrointestinal ("GI") indications; "MESUPRON" for targeting GI and other solid tumor cancers; and RIZAPORT® (RHB-103) for the treatment of acute migraine headaches. Our therapeutic candidates are subject to extensive governmental laws, regulations and guidelines relating to development, clinical trials, manufacturing and commercialization of drugs. Other than RIZAPORT® which has received marketing approval to date only in Germany, we may not be able to obtain marketing approval for any of our therapeutic candidates in a timely manner or at all. In addition, although we have certain rights to promote Donnatal® in the U.S., which is currently included in the FDA DESI review program, we cannot guarantee that our co-promotion partner will continue to be allowed to sell or promote Donnatal® in the U.S.

Any material delay in obtaining or maintaining, or the failure to obtain or maintain, required regulatory clearances and approvals will increase our costs and materially adversely affect our ability to generate future revenues. Any regulatory clearance or approval to market a therapeutic candidate, Donnatal® or products that we may sell or market may be subject to limitations on the indicated uses for marketing or may impose restrictive conditions of use, including cautionary information, thereby limiting the size of the market for the therapeutic candidate, Donnatal®, or products that we may sell or market. We also are, and will be, subject to numerous regulatory requirements from both the FDA and other foreign regulatory authorities that govern the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. Moreover, clearance or approval by one regulatory authority does not ensure clearance or 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, Donnatal®, and products that we may sell or market. Additionally, the FDA or other foreign regulatory authorities may change its clearance or approval policies or adopt new laws, regulations or guidelines in a manner that materially delays or impairs our ability to obtain the necessary regulatory clearances or approvals or our ability to commercialize our therapeutic candidates, promote Donnatal® and products that we may sell or market.

We or our commercialization partners are subject to risks related to the regulatory environment with respect to Donnatal®.

Currently, we will promote Donnatal®. Donnatal® is a pre-1962 drug that is not FDA-approved, but it is currently cleared to be marketed and sold in the U.S. as it is included in the FDA DESI review program.

Based on our review of docketed correspondence with the FDA, our co-promotion partner, Concordia, is currently a party to the unresolved Notice of Opportunity Hearing for anticholinergic and barbiturate combination drug products. We make no assurances that the FDA will not seek to begin a hearing process to remove Donnatal® from the market, commence proceedings to remove Donnatal® from the market, or otherwise remove Donnatal® from the market at any time. If this were to happen, it could have a material adverse effect on our reputation, business, financial condition, and results of operations.

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 or our development or commercialization partners will not be able to commercialize our therapeutic candidates and products we may sell or market without completing such trials, even products that may have already been cleared or approved for marketing.

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

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

- delays in securing clinical investigators or trial sites for the clinical trials;
- delays in receiving import or other government approvals to ensure appropriate drug supply;
- delays in obtaining institutional review board (IRB) and other regulatory approvals to commence or continue 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 or studies in connection with therapeutic candidates in development as well as for products that have already been cleared and approved for marketing;
- 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 or restrictive uses, including the inclusion of warnings and contraindications, which could significantly limit the marketability and profitability of a therapeutic candidate;
- the clinical trials may be delayed or not completed due to the failure to recruit suitable candidates or if there is a lower rate of suitable candidates than anticipated or if there is a delay in recruiting suitable candidates; and
- changes to the current regulatory requirements related to clinical trials which can delay, hinder or lead to unexpected costs in connection with our receiving the applicable regulatory clearances or 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 of our current or future therapeutic candidates does not produce favorable results, our ability to obtain regulatory approval for the therapeutic candidate may be adversely impacted, which could have a material adverse effect on our business, financial condition and results of operations.

If we are unable to establish collaborations for our therapeutic candidates or products we may sell or market, or otherwise not be able raise substantial additional capital, we will likely need to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our therapeutic candidates and products that we may sell or market, such as Donnatal®, will require additional cash to fund expenses. As such, our strategy includes either selectively partnering or collaborating with multiple pharmaceutical and biotechnology companies to assist us in furthering development or potential commercialization of our therapeutic candidates, promoting Donnatal® and products that we may sell or market, in whole or in part, in some or all jurisdictions or through securing our own commercialization capabilities. Although we are currently aware of potential new third-party partners for the development or commercialization of our therapeutic candidates, marketing of Donnatal®, and development or commercialization of products that we may sell or market, we may not be successful in entering into collaborations with third parties on acceptable terms, or at all. In addition, if we fail to negotiate and maintain suitable development, commercialization or promotion agreements or otherwise raise substantial additional capital to secure our own commercialization capabilities, we may have to limit the size or scope of our activities or we may have to delay one or more of our development or commercialization programs. Any failure to enter into development or commercialization agreements with respect to the development, marketing and commercialization of any therapeutic candidate or failure to develop, market and commercialize such therapeutic candidate independently may 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-licensing of RHB-106 and RIZAPORT®. We do not control third parties with whom we have or may have collaborative arrangements, and we rely on such third parties to achieve results which may be significant to us. In addition, any future collaborative arrangements may place the development or commercialization of our therapeutic candidates, marketing of Donnatal®, or development or commercialization of products that we may sell or market, 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 such third parties to achieve results which may be significant to us. To date, we have out-licensed one of our therapeutic candidates, RHB-106, and related rights to Valeant and have entered into exclusive license agreements with Grupo JUSTE, S.A.Q.F. (now Exeltis Healthcare, S.L.) and Pharmatronic Co. to commercialize RIZAPORT® in Spain and South Korea, respectively. We do not control Valeant, Exeltis Healthcare, S.L. or Pharmatronic Co., but we rely on Valeant to clinically develop and commercialize RHB-106 and related rights and rely on Exeltis Healthcare, S.L. and Pharmatronic Co. to obtain regulatory approvals and commercialize RIZAPORT® in Spain and South Korea, respectively. In addition, with respect to Donnatal®, pursuant to the Co-Promotion Agreement, we rely on Concordia as the party responsible for, among others, the manufacture, supply, and other operating responsibilities for Donnatal® in all territories in the U.S.

Relying upon collaborative arrangements to develop and commercialize our therapeutic candidates, such as RHB-106 and RIZAPORT®, and products that we may sell or market, and Donnatal®, subjects us to a number of risks, including but not limited to the following:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our therapeutic candidates, Donnatal®, or products that we may to sell or market;
- 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, making it difficult for them to fulfill their obligations to us, including payment obligations, or they may experience changes in business focus;
- our collaborators' partners may fail to secure adequate commercial supplies of our therapeutic candidates upon or after obtaining marketing approval, if at all, Donnatal®, or of products that we may sell or market;
- our collaborators' partners may have a shortage of qualified personnel;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator's business or business strategy may adversely affect a collaborator's willingness or ability to complete its obligations under any arrangement;
- under certain circumstances, a collaborator could move forward with a competing therapeutic candidate or product 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 or may limit or terminate our rights to promote Donnatal® in the U.S. or products we may sell or market.

In addition, our reliance upon Concordia in connection with our promoting of Donnatal® pursuant to the Co-Promotion Agreement subjects us to a number of additional risks, including but not limited to, the following:

- we do not control Concordia's communications with the FDA, and the FDA may determine to withdraw Donnatal® from the market due to any action or inaction taken by Concordia (see "– We or our development or commercialization partners may be subject to product withdrawal requests by the FDA or other foreign regulatory authorities for Donnatal® or products which we may sell or market.");
- we rely on Concordia to manufacture Donnatal® through third-party manufacturers with the requisite quality and manufacturing standards as required under applicable laws and regulations, and we also rely on Concordia to supply Donnatal®, which may result in us having Donnatal® in insufficient quantities or on timelines to achieve adequate or successful promotion and sale of Donnatal® in the U.S.;
- Concordia may increase or decrease the price of Donnatal® to a level that could adversely affect the sales or revenues of Donnatal®;
- we rely on Concordia for most decisions relating to the marketing of Donnatal®, and any action or inaction taken by Concordia may adversely affect the sales of Donnatal®;
- Concordia may not be successful in maintaining or expanding reimbursement from government or third-party payors, such as insurance companies, health maintenance organizations and other health plan administrators, which may adversely affect the sales of Donnatal®; and
- Concordia may terminate the Co-Promotion Agreement with after an agreed upon period for reasons set forth in the Co-Promotion Agreement.

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

Donnatal® or products which we may sell or market may be withdrawn from the market at any time due to product withdrawal requests by the FDA or other foreign regulatory authorities.

Products we acquire or to which we acquire commercialization rights may be subject to withdrawal requests by the FDA or other foreign regulatory authorities for various reasons. For instance, certain products, such as Donnatal®, may be subject to regulatory review due to their classification as a DESI product which the FDA has the right to determine as ineffective and impose limitations or request withdrawal of the product from the market. Donnatal® is currently subject to the FDA's DESI proceedings, to determine its effectiveness and the right to continue to be marketed in the U.S. and there is no assurance as to the outcome of such proceedings. To our knowledge at this time and based on our review of docketed correspondence with the FDA, the FDA has not made a final determination as to the efficacy of Donnatal®. In addition,

the process and timing of any FDA DESI proceedings with respect to Donnatal® are unclear. Historically, the FDA has generally permitted products to stay on the market during these proceedings, although there is no assurance as to the time of commencement of such proceedings or whether the FDA will in fact grant such permission to any future DESI-related proceedings, including for Donnatal®. Regulatory authorities in other jurisdictions may have similar procedures that may subject any product we may sell or market to limitations or withdrawal requests. In addition, the FDA or other foreign regulatory authorities may determine that the chemistry, manufacturing and controls ("CMC") of marketed products that we develop, acquire or to which we acquire commercialization rights, such as Donnatal®, is unsatisfactory due to the manufacturing standards of the products. If either of these or any regulatory action is taken, Donnatal® or any product we sell or market could be withdrawn from the market at any time. In addition, we could suffer from delays in further commercialization of any product we sell or market.

We may not be successful in acquiring products or companies that own the rights to, or otherwise acquire commercialization rights to, products cleared or approved for marketing in the U.S. or elsewhere that achieve commercial success or in building our own marketing and commercialization capabilities.

Part of our strategy is to identify and acquire rights to products that have been cleared or approved for marketing in the U.S. or elsewhere, in particular, those with a therapeutic focus on GI, inflammation or cancer. Specifically, we seek to acquire rights to products that are already commercialized, which would enable us to commercialize such products independently and build our own marketing and commercialization capabilities. We recently entered into a Co-Promotion Agreement with Concordia pursuant to which we were granted certain rights to promote Donnatal® in the U.S., which is our first agreement to commercialize a product being marketed in the U.S., However, there can be no assurance as to our ability to identify and acquire rights to any additional products, in particular those with a therapeutic focus on GI, inflammation or cancer. If we are not successful in acquiring any products or in promoting Donnatal®, we may not be able to build or maintain our own marketing and commercialization capabilities. This may limit our ability to commercialize products on our own and may require us to contract with third-party development or commercialization partners which may not be on commercially favorable terms. Additionally, these efforts to establish commercial capabilities could be found more costly than our forecast and have an adverse effect on our business, financial condition and results of operations.

In addition, there can be no assurance that we will accurately or consistently identify products approved for marketing that will achieve commercial success or that we will be able to successfully commercialize.

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

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

We have no history of independently commercializing therapeutic candidates or marketed products and may have difficulty promoting Donnatal® or commercializing any product on our own.

We have no prior experience in commercializing therapeutic candidates or marketed products on our own, which may materially increase marketing and sales expenses or cause us to be ineffective in these efforts. We recently entered into a Co-Promotion Agreement with Concordia pursuant to which we were granted certain rights to promote Donnatal® in the U.S. There can be no assurance we will successfully commercialize our therapeutic candidates or promote Donnatal® or any products we may sell or market.

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

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

We currently do not have the ability to independently conduct clinical trials and related non-clinical studies for our therapeutic candidates, and we rely on third parties, such as contract research organizations, medical institutions, contract laboratories, development and commercialization partners, clinical investigators and independent study monitors to perform these functions. Our reliance on these third parties for research and development activities reduces our control over these activities. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. Although we have, in the ordinary course of business, entered into agreements with such third parties, other than with respect to RHB-106 and related rights, which we have out-licensed to Valeant, we continue to be responsible for confirming that each of our clinical trials and related non-clinical studies 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 ("GCP"), 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, and regulatory authorities in other jurisdictions may have similar responsibilities and requirements. Our reliance on third parties does not relieve us of these responsibilities and requirements. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be required to replace them or perform such functions independently. Although we believe that there are a number of other third-party contractors we could engage to continue these activities, it may result in a delay of the affected trial and additional costs. Accordingly, we may be materially delayed in obtaining regulatory approvals for our therapeutic candidates and may be materially delayed in our efforts to successfully commercialize our therapeutic candidates for targeted diseases.

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

If third parties do not manufacture our therapeutic candidates or do not manufacture and sell any products we may sell or market in sufficient quantities, in the required timeframe, and at an acceptable cost and quality, clinical development and commercialization of our therapeutic candidates or promotion of products we may sell or market would be delayed and sales of any product we may sell or market may be adversely affected.

We do not currently own or operate manufacturing facilities. We rely, and expect to continue to rely, on third parties to manufacture clinical and commercial quantities of our therapeutic candidates and products that we may sell or market. For RIZAPORT®, we rely on IntelGenx Corp. to supply and provide sufficient quantities in the required timeframe for registration and sales in Spain and South Korea, and for Donnatal®, we rely on Concordia, which has a manufacturing agreement with a third party to provide sufficient quantities of Donnatal® in the required timeframe. 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 and any products that we may sell or market may adversely affect our future operations and our ability to develop therapeutic candidates and commercialize any therapeutic candidates and any products that we may sell or market 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 or our development or commercialization partners' manufacturers do not perform as agreed or expected, we or our partners 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, and such additional costs and delays may adversely impact our ability to obtain regulatory clearances and approvals to commercialize our therapeutic candidates or any product we may sell or market, or make such commercialization or marketing economically unfeasible.

We rely on third parties to manufacture and supply us with high quality active pharmaceutical ingredients ("APIs") 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 development, manufacture and supply of our APIs that are used to formulate our therapeutic candidates and products we may sell or 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 clearances or approvals for our therapeutic candidates or products that we may sell or market or in conducting clinical trials of our therapeutic candidates and incur additional costs or experience an adverse effect on our sale of any product we may sell or market.

For example, our supplier of raw materials for RIZAPORT® has been sending updates to the FDA regarding progress of corrective actions in regard to compliance issues at its manufacturing facility and subsequently invited the FDA for re-inspection, which are independent of us and not specific to RIZAPORT®. Although we were informed that the supplier recently resolved these compliance issues and although we have been working to ensure continued supply of the necessary raw materials for RIZAPORT® from an alternative supplier, our ability to obtain FDA approval for RIZAPORT® may be delayed until we are able to successfully manufacture new batches with new API secured from a compliant source.

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

If we are not able to find stable, affordable, high quality, or reliable supplies of our APIs, we may not be able to produce enough supplies of our therapeutic candidates or products we may sell or market, which could have a material adverse effect on our business, financial condition or results of operations.

We anticipate continued reliance on third-party manufacturers if we are successful in obtaining marketing approval from the FDA and other regulatory agencies for any of our therapeutic candidates and reliance on third-party manufacturers for any products that we may sell or market, including Donnatal®.

To date, our therapeutic candidates have been manufactured in relatively small quantities for preclinical testing and clinical trials as well as for other regulatory purposes by third-party manufacturers. If the FDA or other regulatory agencies approve any of our therapeutic candidates for commercial sale, we expect that we would continue to rely, at least initially, on third-party manufacturers to produce commercial quantities of our approved therapeutic candidates. In addition, we expect that we will rely, at least initially, on third-party manufacturers to produce commercial quantities of Donnatal ® or any product that we may sell or market. These manufacturers may not be able to successfully increase or maintain the manufacturing capacity for any of our approved therapeutic candidates, Donnatal® or any product we may sell or market, 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 the third-party manufacturers are unable to successfully increase or maintain the manufacturing capacity for a therapeutic candidate or for products that we may sell or market, or we are unable to establish our own manufacturing capabilities or secure replacement third-party manufacturers, the commercial launch of any approved products may be delayed or there may be a shortage in supply which could have a material adverse effect on our business, financial condition or results of operations.

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

We and our third-party manufacturers are, and will be, required to adhere to laws, regulations and guidelines of the FDA and other foreign regulatory authorities setting forth current good manufacturing practices ("cGMP"). These laws, regulations and guidelines cover all aspects of the manufacturing, testing, quality control and recordkeeping relating to our therapeutic candidates and any products we may sell or market, including Donnatal®. We and our third-party manufacturers may not be able to comply with applicable laws, regulations and guidelines. We and our third-party manufacturers are and will be subject to unannounced inspections by the FDA, state regulators and similar foreign regulatory authorities outside the U.S. Our failure, or the failure of our third-party manufacturers, to comply with applicable laws, regulations and guidelines could result in the imposition of sanctions on us, including fines, injunctions,

civil penalties, failure of regulatory authorities to grant marketing approval of our therapeutic candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of our therapeutic candidates and commercially marketed products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect regulatory approval and supplies of our therapeutic candidates and commercially marketed products, and materially and adversely affect our reputation, business, financial condition and results of operations.

Our therapeutic candidates, Donnatal®, and any product we may sell or market, even if all regulatory clearances and approvals are obtained, 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 clearances and approvals, and our reputation, business, financial condition and results of operations may be materially and adversely affected.

Even if our therapeutic candidates, Donnatal®, and products we may sell or market receive regulatory approval, we and our commercialization partners, as applicable, will be subject to ongoing reporting obligations with respect to our therapeutic candidates, Donnatal®, and any product we may sell or market, including pharmacovigilance, and the manufacturing operations of our therapeutic candidates, Donnatal®, and any product we may sell or market will be subject to continuing regulatory review, including inspections by the FDA and other foreign regulatory authorities. The results of any ongoing review may result in withdrawal from the market of a therapeutic candidate, Donnatal®, or another product we may sell or market, interruption of manufacturing operations or imposition of labeling or marketing limitations for such therapeutic candidate or product. Since many more patients are exposed to drugs following their marketing clearance or approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the therapeutic candidate or any product we may sell or market, including Donnatal®. As we develop our therapeutic candidates or commercialize our products, we may also periodically discuss with the FDA and other regulatory authorities certain clinical, regulatory and manufacturing matters and, our views may, at times, differ from those of the FDA and other regulatory authorities. For example, the FDA may seek to regulate our therapeutic candidates or any product we may sell or market that consist of two or more active ingredients as combination drugs under its Combination Drug Policy. The Combination Drug Policy requires that we demonstrate that each active ingredient in a drug product contributes to the product's claimed effect. If the FDA raises questions regarding whether available data and information provided to the FDA demonstrate the contribution of each active ingredient in such combination drug products, we may be required to provide additional information, which may require us to conduct additional preclinical studies or clinical trials. If we are required to conduct additional clinical trials or other testing of our therapeutic candidates, Donnatal® or any product we may sell or market, we may face substantial additional expenses, be delayed in obtaining marketing approval or may never obtain marketing approval for such therapeutic candidate or product we may sell or market, including Donnatal®. In addition, Donnatal® is currently subject to the FDA's DESI proceedings to determine its effectiveness and the right to continue to be marketed in the U.S., and there is no assurance as to the outcome of such proceedings. To our knowledge at this time and based on our review of docketed correspondence with the FDA, the FDA has not made a final determination as to the efficacy of Donnatal®. See "– We or our development or commercialization partners may be subject to product withdrawal requests by the FDA or other foreign regulatory authorities for Donnatal® or products which we may sell or market."

In addition, third-party manufacturers and the manufacturing facilities that we and our development or commercialization partners use to manufacture any therapeutic candidate and any products that we may sell or market, including Donnatal®, will be subject to periodic review and inspection by the FDA and may be subject to similar review by other regulatory authorities. Later discovery of previously unknown problems with any therapeutic candidate or product we may sell or market, including Donnatal®, 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, marketed product, manufacturer or manufacturing process;
- warning letters from the FDA or other foreign regulatory authorities;
- withdrawal of the therapeutic candidate or marketed product from the market;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications that we or our development or commercialization partners submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our therapeutic candidates or products that we may sell or market;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and

- adverse publicity.

If we or our commercialization partners, suppliers, third-party contractors or clinical investigators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we and our development or commercialization partners may lose marketing clearance or approval for any of our therapeutic candidates if any of our therapeutic candidates are approved, and we may lose marketing clearance or approval of any products already cleared or approved for marketing in any jurisdiction, resulting in decreased or lost revenue from such therapeutic candidates and products and could also result and other civil or criminal sanctions, including fines and penalties.

Modifications to our therapeutic candidates, or to any product that we may sell or market, may require new regulatory clearances or approvals or may require us or our development or commercialization partners, as applicable, to recall or cease marketing of these therapeutic candidates or products until clearances or approvals are obtained.

Modifications to our therapeutic candidates and any products we may sell or market, after they have been cleared or approved for marketing, if at all, 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 regulatory authorities require pharmaceutical product 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 regulatory authorities. However, the FDA or other regulatory authorities can review a manufacturer's decision and may disagree. The FDA or other regulatory authorities may also on their own initiative determine that a new clearance or approval is required. If the FDA or other regulatory authorities require new clearances or approvals of any pharmaceutical product for which we or our partners, including development or commercialization partners previously received marketing approval, we or our partners, including development or commercialization partners may be required to recall and stop marketing such marketed product, which could require us or our partners, including development or commercialization partners to redesign the marketed product and may cause a material adverse effect on our reputation, business, financial condition and results of operations.

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

Our seven therapeutic candidates were all acquired or licensed by us from third parties. We evaluate internally and with external consultants each therapeutic candidate. However, there can be no assurance as to our ability to accurately or consistently identify therapeutic candidates that are likely to achieve commercial success, specifically therapeutic candidates that have been approved for marketing in the U.S. or elsewhere. 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 in-license or acquisition opportunities.

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

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

We acquired our rights to three of our therapeutic candidates, RHB-105, RHB-104 and RHB-106, from a third party pursuant to an asset and purchase agreement. In addition, we in-licensed our rights to four other therapeutic candidates,

BEKINDA®, YELIVA®, MESUPRON and RIZAPORT® pursuant to license agreements in which we received exclusive perpetual licenses to certain patent rights and know-how related to these therapeutic candidates. We have also obtained certain rights to promote Donnatal® in the U.S. under our Co-Promotion Agreement. 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 and marketed products. 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 or commercializing our therapeutic candidates 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. for RIZAPORT® requires us to renegotiate certain provisions of the agreement in the event the agreed-to budget is exceeded by a certain amount. In the event we are required to renegotiate this agreement, there is no guarantee that we will agree upon new terms promptly, or at all, which could delay the development or commercialization of RIZAPORT®.

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

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

The loss of the services of members of senior management or other key personnel could delay or otherwise adversely impact the successful completion of our planned clinical trials or the commercialization of our therapeutic candidates and any product we may sell or market, including Donnatal® 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, Reza Fathi, Ph.D., our Senior Vice President for Research and Development, Gilead Raday, our Chief Operating Officer, Adi Frish, our Senior Vice President for Business Development and Licensing, Guy Goldberg, our Chief Business Officer, and Micha Ben Chorin, our Chief Financial Officer. 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, sales, 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, as part of our plan to promote Donnatal® and potentially products we may develop, we will need to build and expand and maintain our marketing and sales capabilities. While we attempt to provide competitive compensation packages to attract and retain key personnel, many of our competitors are likely to have greater resources and more experience than we have, making it difficult for us to compete successfully for key personnel. If we cannot attract and retain sufficiently qualified suitable employees on acceptable terms, we may not be able to develop and commercialize competitive therapeutic candidates. Further, any failure to effectively integrate new personnel could materially prevent us from successfully growing our company.

We face several risks associated with international business.

We operate our business in multiple international jurisdictions. Such operations could be materially affected by changes in foreign exchange rates, capital and exchange controls, expropriation and other restrictive government actions, changes in intellectual property legal protections and remedies, trade regulations and procedures and actions affecting approval, production, pricing, and marketing of, reimbursement for and access to, our therapeutic candidates and products we may sell or market, including Donnatal®, as well as by political unrest, unstable governments and legal systems and inter-

governmental disputes. Any of these changes could have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Industry

Even if our therapeutic candidates or any product we may sell or market, receive, have received regulatory clearance or approval or do not require regulatory clearance or approval, they may not become commercially viable products.

Except for RIZAPORT®, which has been approved for marketing in Germany but has yet to be marketed, none of our therapeutic candidates or products have been cleared or approved for marketing, and except for Donnatal®, for which we were granted certain rights to promote Donnatal® in the U.S., none is currently being marketed or commercialized in any jurisdiction. Even if any of our therapeutic candidates or any product we may sell or market receive, have received or do not require regulatory clearance or approval, it may not become a commercially viable product. For example, even if we or our development or commercialization partners receive regulatory clearance or approval to market a therapeutic candidate, or have received regulatory clearance or approval to sell or market any product, the clearance or approval may be subject to limitations on the indicated uses or subject to labeling or marketing restrictions which could materially and adversely affect their marketability and profitability. 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 or any product that we may sell or market, 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 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 development or commercialization partners have not received licenses;
- incompatibility with other therapeutic candidates or marketed 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, if at all;
- ineffective marketing, sales and distribution activities and 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 generate sufficient revenues from the sale or marketing of a product in view of the economic arrangements that we have with commercialization or other partners;
- changes to labels, indications or other regulatory requirements as they relate to the commercialization of our products;
- inability to establish collaborations with third-party development or commercialization partners on acceptable terms, or at all, and our inability or unwillingness for cost or other reasons to commercialize the therapeutic candidates or any product we may sell or market on our own; and
- timing of market introduction of competitive products.

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

The market for our therapeutic candidates and for any product we may sell or market is rapidly changing and competitive, and new drug delivery mechanisms, drug delivery technologies, new drugs, treatments and products 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, developing and marketing products

designed to address the indications for which we are currently developing therapeutic candidates or may develop therapeutic candidates in the future or for which we may sell or market products. 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 or products that we may sell or market. 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 and products we may sell or market 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 and products we may sell or market. In addition, Donnatal® and products we may sell or market may compete with products for market share, and generic drugs or products that treat the same indications as Donnatal® or products we may sell or market can have an adverse effect on our revenues by reducing our market share or requiring us to reduce the price of the products we market.

Technological competition from, and commercial capabilities of, 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, therapeutic candidates or products we may sell or market, even if commercialized. Many of our targeted diseases and conditions can also be treated by other medications or drug delivery technologies. These treatments may be widely accepted in medical communities and have a longer history of use, among other possible advantages. The established use of these competitive drugs may limit the potential for our therapeutic candidates to receive widespread acceptance if commercialized and may limit the potential for widespread acceptance of promoting Donnatal® and for products we may sell or market.

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

On March 23, 2010, President Obama signed the "Patient Protection and Affordable Care Act" (P.L. 111-148) and on March 30, 2010, the President signed the "Health Care and Education Reconciliation Act" (P.L. 111-152), collectively commonly referred to as the "Healthcare Reform Law." The Healthcare Reform Law included a number of new rules regarding health insurance, the provision of health care, and conditions to reimbursement for healthcare services provided to Medicare and Medicaid patients. Through the law making process, substantial changes have been and continue to be made to the current system for paying for healthcare in the U.S., including changes made in order to extend medical benefits to tens of millions of Americans who lacked insurance coverage and to contain healthcare costs. Extending coverage to a large population could substantially change the structure of the health insurance system and the methodology for reimbursing medical services and drugs. This legislation is one of the most comprehensive and significant reforms ever experienced by the U.S. in the healthcare industry and has significantly changed the way healthcare is financed by both governmental and private insurers. This legislation has impacted the scope of healthcare insurance and incentives for consumers and insurance companies, among others. Additionally, the Healthcare Reform Law's provisions are designed to encourage providers to find cost savings in their clinical operations. Pharmaceuticals represent a significant portion of the cost of providing care. Through modified reimbursement rates and other incentives, the U.S. government is requiring that providers identify the most cost-effective services, supplies and pharmaceuticals. This environment has caused changes in the purchasing habits of providers and resulted in specific attention to the pricing negotiation, product selection and utilization review surrounding pharmaceuticals. To the extent that our therapeutic candidates may at some point be reimbursable by U.S. federal government programs, this attention may result in our therapeutic candidates and products we may sell or market being chosen less frequently or the pricing being substantially lowered. Some of the provisions of the Healthcare Reform Law have not yet been fully implemented and the effect of the legislation is difficult to predict. At this stage, we are unable to estimate the full extent of the direct or indirect impact of the Healthcare Reform Law on us.

These structural changes could entail further modifications to the existing system of private payors and government programs (such as Medicare, Medicaid and state children's health insurance programs), creation of government-sponsored

healthcare insurance sources, or some combination of both, as well as other changes. Restructuring the coverage of medical care in the U.S. could impact the reimbursement for prescribed drugs and pharmaceuticals, such as those we and our development or commercialization partners are currently developing or those that we may sell or market. If reimbursement for approved therapeutic candidates or any product we may sell or market, if any, is substantially reduced in the future, or rebate obligations associated with them are substantially increased, it could have a material adverse effect on our business, financial condition and results of operations.

Extending medical benefits to those who currently lack coverage will likely result in substantial cost to the U.S. federal government, which may force significant additional changes to the healthcare system in the U.S. Much of the funding for expanded healthcare coverage may be sought through cost savings. While some of these savings may come from realizing greater efficiencies in delivering care, improving the effectiveness of preventive care and enhancing the overall quality of care, much of the cost savings may come from reducing the cost of care and increased enforcement activities. Cost of care could be reduced by decreasing the level of reimbursement for medical services or products (including those therapeutic candidates currently being developed by us or our development or commercialization partners or any product we may sell or market, including Donnatal®), 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 or any product we may sell or market, including Donnatal®, or for which we receive marketing approval in the future, could have a material adverse effect on our business, financial condition and results of operations.

Several states and private entities initially mounted legal challenges to the Healthcare Reform Law, and they continue to litigate various aspects of the legislation. On July 26, 2012, the U.S. Supreme Court generally upheld the provisions of the Healthcare Reform Law at issue as constitutional. However, the U.S. 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 number of individuals covered by their respective state Medicaid programs. Some states have determined that they will not expand their Medicaid programs and will develop other cost-saving and coverage measures to provide care to currently uninsured individuals. Many of these efforts to date have included the institution of Medicaid-managed care programs. The manner in which these cost-saving and coverage measures are implemented could have a material adverse effect on our business, financial condition and results of operations. Further, the healthcare regulatory environment has seen significant changes in recent years and is still in flux. Legislative initiatives to modify, limit, or repeal the Healthcare Reform Law and judicial challenges continue, including a recent executive order issued by the U.S. President directing government agencies and departments to minimize the economic burden of the Healthcare Reform Law to the extent permitted by law, and may increase in light of the change in administrations following the presidential election. We cannot predict the impact on our business of future legal challenges to the Healthcare Reform Law or other changes to the current laws and regulations.

If third-party payors do not adequately reimburse customers for any of our therapeutic candidates that are approved for marketing or for products that we may sell or market, including Donnatal® they might not be purchased or used, and our revenues and profits will not increase and they may decrease.

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

- 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 or for any product that we may sell or market from any government or other third-party payor is a time-consuming and costly process that could require us or our development or commercialization partners to provide supporting scientific, clinical and cost-effectiveness data for the use of our therapeutic candidates or any product that we may sell or market to each payor. Even when a payor determines that a therapeutic candidate or any product that we may sell or market 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 or the use of any product that we may sell or market 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 products or services, and may reflect budgetary constraints or imperfections in Medicare, Medicaid or other data used to calculate these rates. In particular, reimbursement for the use of Donnatal® is not available from Medicare and Medicaid, and reimbursement from other third-party payors may be limited for Donnatal® due to its status as a DESI product.

In the U.S., there have been, and we expect that there will continue to be, federal and state proposals to constrain expenditures for medical products and services, which may affect payments for our therapeutic candidates or for any product that we may sell or market in the U.S. In addition, there is a growing emphasis on comparative effectiveness research, both by private payors and by government agencies. To the extent other drugs or therapies are found to be more effective than our products, payors may elect to cover such therapies in lieu of our products or reimburse our products at a lower rate. 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, or for any product that we may sell or market. This could materially and adversely impact our business, financial condition and results of operations by reducing our ability to generate revenue, raise capital, obtain additional collaborators and market. At this stage, we are unable to estimate the extent of the direct or indirect impact of any such federal and state proposals.

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

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

Upon our marketing of products in the U.S., we will become subject to additional healthcare regulation and enforcement by the federal government and the states in which we conduct or will conduct our business. The laws that may affect our ability to operate include, but are not limited to, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under government healthcare programs such as the Medicare and Medicaid programs;
- the federal Anti-Inducement Law (also known as the Civil Monetary Penalties Law), which prohibits a person from offering or transferring remuneration to a Medicare or State healthcare program beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State healthcare program;
- the Ethics in Patient Referrals Act of 1989, commonly referred to as the Stark Law, which prohibits physicians from referring Medicare or Medicaid patients for certain designated health services where that physician or family member has a financial relationship with the entity providing the designated health service, unless an exception applies;
- federal false claims laws that prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent;
- the so-called federal "Sunshine Act", which requires pharmaceutical and medical device companies to monitor and report certain financial relationships with physicians and other healthcare providers to the Centers for Medicare and Medicaid Services for disclosure to the public;
- the federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

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

Most recently, there has been a trend in federal and state legislation aimed at requiring pharmaceutical companies to disclose information about their production and marketing costs, and ultimately lowering costs for drug products. Several states have introduced bills that would require disclosure of certain pricing information for prescription drugs that have no threshold amount or are above a certain annual wholesale acquisition cost, and in June 2016 Vermont became the first state to pass legislation requiring certain drug companies to disclose information relating to justification of certain price increases. The U.S. Congress has also introduced bills targeting prescription drug price transparency.

Any such implementation of legislation requiring publication of drug costs could materially and adversely impact our business, financial condition and results of operations by promoting a reduction in drug prices. As such, patients may choose to use other low-cost, established drugs or therapies.

The scope and enforcement of these laws are uncertain and subject to change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. We cannot predict the impact on our business, financial condition nor results of operations of any changes in these laws. Federal or state regulatory authorities may challenge our current or future activities under these laws. Any such challenge could have a material adverse effect on our reputation, business, financial condition and results of operations. Any state or federal regulatory review of us, regardless of the outcome, would be costly and time-consuming.

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

The clinical trials that we conduct, and the testing, manufacturing, marketing and commercial sale and use or misuse of our therapeutic candidates and any products we may sell or market, involve and will involve an inherent risk that significant liability claims may be asserted against us or our development or commercial partners. We currently have a product liability policy that includes coverage for our clinical trials and intend to obtain product liability insurance that covers our co-promotion of Donnatal®. Should we decide to seek additional insurance against such risks before 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 or litigation costs, especially in the case of wrongful death claims. Product liability claims or other claims related to our therapeutic candidates and any products we may sell or market, regardless of merit or 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 therapeutic candidates or products we may sell or market. A product liability claim could also significantly harm our reputation and the market price of our shares and delay market acceptance of our therapeutic candidates and decrease demand for any products that we sell or market, including Donnatal®.

Global economic conditions may make it more difficult for us to commercialize our therapeutic candidates and any products that we may sell or market.

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

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 or commercialization partners' research and clinical development activities, as well as the manufacture of materials and therapeutic candidates and any products that we may sell or market, we and our development or commercialization partners are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens and waste. We and our development 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 development or commercialization partners to obtain patent protection for our therapeutic candidates and any products that we may sell or market, maintain the confidentiality of our trade secrets and know-how, operate without infringing on the proprietary rights of others and prevent others from infringing on 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, and we plan to try to do the same with products we may acquire, sell or market in the future, where this is possible.

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 development or commercialization partners may not provide us with any competitive advantages, may be held invalid or unenforceable as a result of legal challenges by third parties or could be circumvented. Ownership of the patent rights we in-license from our development or commercialization partners or the patent rights to the products already approved for marketing that we acquire or for which we acquire commercialization rights may be challenged, and as a result, the rights we in-license and the rights to products we acquire may turn out not to be exclusive or we may not actually have rights under the patents despite receiving representations from a development or commercialization partner. Our competitors may also independently develop drug delivery technologies or products similar to ours or design around or otherwise circumvent patents issued to, or licensed by, us. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third

parties may not result in patents being issued. If these patents are issued, they may not provide us with proprietary protection or competitive advantages. The degree of future protection to be afforded by our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

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

After the completion of development and registration of our patents, third parties may still manufacture or market products in infringement of our patent-protected rights. Such manufacture or market of products 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 or any product we may sell or market, including Donnatal®, thereby reducing our potential profits.

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

In addition, in some cases we may rely on our licensors to conduct patent prosecution, patent maintenance or patent defense on our behalf. Therefore, our ability to ensure that these patents are properly prosecuted, maintained, or defended may be limited, which may adversely affect our rights in our therapeutic candidates and potential approved for marketing products. Any failure by our licensors or development or commercialization partners to properly conduct patent prosecution, patent maintenance, patent enforcement, or patent defense could materially harm our ability to obtain suitable patent protection covering our therapeutic candidates or products or ensure freedom to commercialize the products in view of third-party patent rights, thereby materially reducing our potential profits.

In addition, Donnatal®, for which we were granted certain rights to promote Donnatal® in the U.S, is not protected by patents. If the FDA proceedings related to Donnatal® designed to determine its effectiveness will be ongoing, only products that receive a New Drug Application ("NDA") from the FDA, DESI products and those actively participating in the hearing process of the FDA may be marketed. However, other competing products may freely enter the market, and we and our partners may not have sufficient intellectual property rights in Donnatal® to protect it from such competition. See "Item 3. Key Information – D. Risk Factors – Risks Related to Our Business and Regulatory Matters – We or our development or commercialization partners may be subject to product withdrawal requests by the FDA or other foreign regulatory authorities for Donnatal® or products which we may sell or market."

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 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 and any products we may sell or market.

The development, manufacture, use, offer for sale, sale or importation of our therapeutic candidates or any products that we may sell or market 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 an 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 or any products we may sell or market 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 and any products that we may sell or market 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 have a material adverse effect on our business, financial condition and results of operations.

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 become a party to other patent litigation or proceedings before regulatory agencies, including interference or re-examination proceedings filed with the U.S. Patent and Trademark Office or opposition proceedings in other foreign patent offices regarding intellectual property rights with respect to our therapeutic candidates or any products that we may sell or market, as well as other disputes regarding intellectual property rights with development or commercialization partners, or others with whom we have contractual or other business relationships. Post-issuance oppositions are not uncommon, and we and/or our development 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 ADSs

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 "Item 10. Additional Information – 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 – U.S. Federal Income Tax Considerations – 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 Tel Aviv Stock Exchange ("TASE") and our ADSs on the NASDAQ Capital Market 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 ADSs on the NASDAQ Capital Market have fluctuated in the past, and we expect they will continue to do so. The market price of our Ordinary Shares and ADSs are and will be subject to a number of factors, including but not limited to:

- announcements of technological innovations or new therapeutic candidates or new products approved for marketing 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 or market;
- the volatility of market prices for shares of biotechnology companies generally;
- success or failure of research and development projects;
- departure of or major events adversely affecting 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 proceedings and decisions;
- developments by our development 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 or ADSs and result in substantial losses by our investors.

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

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

All of our outstanding Ordinary Shares are registered and available for sale in Israel. In addition, as of February 22, 2017, we had options to purchase 20,275,548 Ordinary Shares under our 2010 Stock Option Plan outstanding and non-tradable warrants to purchase an aggregate of 2,025,458 ADSs (each representing 10 Ordinary Shares) outstanding. In addition, our board of directors reserved up to 30,000,000 Ordinary Shares for issuance 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 Capital Market since December 27, 2012. Trading in our securities on these markets takes place in different currencies (U.S. dollars on the NASDAQ Capital Market and NIS on the TASE), and at different times (resulting from different time zones, different trading days and different public holidays in the U.S and Israel). The trading prices of our securities on these two markets may differ due to these and other factors. Any decrease in the price of our securities on one of these markets could cause a decrease in the trading price of our securities on the other market.

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

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

While our ADSs began trading on the NASDAQ Capital Market 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 Capital Market, and we may need to devote substantial time and resources to new compliance initiatives and reporting requirements.

As a public company in the U.S. and Israel, we incur additional significant accounting, legal and other expenses as a result of the listing of our securities on both the NASDAQ Capital Market and the TASE. These include costs associated with the reporting requirements of the Securities and Exchange Commission ("SEC") and the requirements of the NASDAQ Listing Rules, as well as requirements under Section 404 and other provisions of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"). These rules and regulations have increased our legal and financial compliance costs, introduced new costs such as investor relations, travel costs, stock exchange listing fees and shareholder reporting, and made some activities more time consuming and costly. Any future changes in the laws and regulations affecting public companies in the U.S. and Israel, including Section 404 and other provisions of the Sarbanes-Oxley Act, the rules and regulations adopted by the SEC and the NASDAQ Listing Rules, 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 Securities Exchange Act of 1934, as amended, (the "Exchange Act"), 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 SEC 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 Listing Rules for domestic issuers. For instance, we follow home country practice in Israel with regard to, among other things, director nomination procedures and quorum at shareholders' meetings. In addition, we follow our home country law, instead of the NASDAQ Listing 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. domestic issuer listed on the NASDAQ Stock Market may provide less protection than is accorded to investors under the NASDAQ Listing Rules applicable to domestic issuers.

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

We may fail to maintain effective internal controls over financial reporting, which may adversely affect investor confidence in us 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, 2016, 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 reputation, business, financial condition, results of operations, and investor confidence in the accuracy and completeness of our financial reports, which would cause the price of our Ordinary Shares and ADSs to decline.

We currently do not anticipate paying cash dividends, and accordingly, investors must rely on the appreciation in our ADSs and our Ordinary Shares 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 and our Ordinary Shares will depend upon any future appreciation in their value. There is no guarantee that our ADSs or our Ordinary Shares will appreciate in value or even maintain the price at which our investors have purchased their securities.

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

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

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

Holders of our ADSs do not have the same rights as 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 shareholders' meeting is no less than 35 or 21 calendar days, depending on the proposals on the agenda for the shareholders' meeting. When a shareholders' 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 ADS 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 give voting instructions, 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 give voting instructions, 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
- we have informed the depositary that 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 our management. Holders of our Ordinary Shares are not subject to this discretionary proxy.

Risks Related to our Operations in Israel

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

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

Our commercial insurance does not cover losses that may occur as a result of events associated with the security situation in the Middle East. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, there is no assurance 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 material 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.

Some 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 40 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 have a material adverse effect on 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 or commercialization partners are payable in U.S. dollars, and we expect our revenues from future licensing and co-promotion 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, including 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 the RedHill Biopharma Ltd. 2010 Option Plan (the "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 "hostile takeover" of the Company. A "hostile 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 Ordinary Shares on the TASE, will become a "controlling shareholder" as defined in the Israel Securities Law, 1968. See "Item 6. Directors, Senior Management and Employees – E. Share Ownership – Option Plans" for a description of interested parties under 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 or any merger or consolidation involving the Company, in each case without a resolution by the board of directors of the Company supporting the transaction. In addition, if a "Significant Event" occurs and following which the employment of a grantee with the Company or a related company is terminated by the Company or a related company other than for "Cause", and unless the applicable agreement provides otherwise or the board of directors determines otherwise, all the outstanding options held by or for the benefit of any such grantee will be accelerated and immediately vested and exercisable. A "Significant Event" is defined in our 2010 Option Plan as a consolidation or merger of the Company with or into another corporation approved by the board of directors of the Company in which the Company is the continuing or surviving corporation or in which the continuing or surviving corporation assumes the option or substitutes it with an appropriate option in the surviving corporation.

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 may be no less than five persons and no more than seven, excluding the external directors whose appointment is required by law. The directors who are not 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 affect 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 directors and officers in Israel or the U.S., or to serve process on our directors and officers.

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

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

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

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

The Israeli Companies Law and our articles of association permit us to indemnify our directors and officers for acts performed by them in their capacity as directors and officers. The Israeli Companies Law provides that a company may

not exempt or indemnify a director or an officer 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 officer 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, 2016, 2015 and 2014 were approximately $85,000, $14,000 and $70,000, respectively. Our current capital expenditures involve equipment and leasehold improvements.

B. Business Overview

We are a specialty biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of GI and inflammatory diseases and cancer. From inception to the end of the period covered by this Annual Report, we have invested a total of $6.2 million on in-licensing and acquisitions of therapeutic candidates and related technologies.

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

We generate our pipeline of therapeutic candidates by identifying, rigorously validating and in-licensing or acquiring products that are consistent with our products strategy and that we believe exhibit a relatively high probability of therapeutic and commercial success. With the exception of RIZAPORT® which was approved for marketing in Germany, our therapeutic candidates have not yet been approved for marketing and, to date, our therapeutic candidates have not generated meaningful sales. We intend to commercialize our therapeutic candidates through licensing and other commercialization arrangements with pharmaceutical companies on a global and territorial basis. We also evaluate, on a case by case basis, co-development and similar arrangements and the independent commercialization of our therapeutic candidates in the U.S. We have recently entered into a Co-Promotion Agreement with a subsidiary of Concordia, pursuant to which we were granted certain rights to promote Donnatal® in the U.S., and we have begun building our own marketing and commercialization capabilities in the U.S. to support the promotion of Donnatal® as well as the potential future commercialization of our therapeutic candidates and any product we may sell or market.

Our Strategy

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

Key elements of our strategy are to:

- identify and acquire rights to products from pharmaceutical companies that have encountered cash flow or operational problems or that decide to divest one or more of their products for various reasons. Specifically, we seek to acquire rights to and develop products that are intended to treat pronounced clinical needs, have patent or other protections, and have target markets totaling tens of millions to billions of dollars. Additionally, we seek to acquire rights to and develop products based on different technologies designed to reduce our dependency on any specific product or technology. We identify such opportunities through our broad network of contacts and other sources in the pharmaceutical field;
- advance our initiative to become a revenue-generating, GI-focused, specialty biopharmaceutical company with a commercial presence in the U.S. to support potential future commercialization of our therapeutic candidates and products approved for marketing by identifying and acquiring rights to products that have been approved for marketing in the U.S from pharmaceutical companies that are interested in divesting one or more of their products. Specifically, we seek to acquire rights to products that are already commercialized in the U.S., preferably with a therapeutic focus on GI, inflammation or cancer, which would enable us to commercialize such products independently and build our own marketing and commercialization capabilities. We identify such opportunities through our broad network of contacts and other sources in the pharmaceutical field;
- enhance existing pharmaceutical products, including broadening their range of indications, or launching innovative and advantageous pharmaceutical products based on existing active ingredients. Because there is a large knowledge base regarding existing products, the preclinical, clinical and regulatory requirements needed to obtain marketing approval for enhanced formulations are relatively well- defined. In particular, clinical trial designs, inclusion criteria and endpoints previously accepted by regulators may sometimes be re-used. In addition to reducing costs and time to market, we believe that targeting therapeutics with proven safety and efficacy profiles provides us a better prospect of clinical success;
- where applicable, utilize the FDA's 505(b)(2) regulatory pathway to potentially obtain more timely and efficient approval of our formulations of previously approved products. Under the 505(b)(2) process, we are able to seek FDA approval of a new dosage form, strength, route of administration, formulation, dosage regimen, or indication of a pharmaceutical product that has previously been approved by the FDA. This process enables us to partially rely on the FDA findings of safety or efficacy for previously approved drugs, thus avoiding the duplication of costly and time-consuming preclinical and various human studies. See "Item 4. Information on the Company – B. Business Overview – Government Regulations and Funding – Section 505(b)(2) New Drug Applications"; and
- cooperate with third parties to develop or commercialize therapeutic candidates in order to share costs and leverage the expertise of others.

Our seven current clinical stage therapeutic candidates include "RHB-105", "RHB-104", "BEKINDA ®", "RHB-106", "YELIVA ®", "MESUPRON" and "RIZAPORT ®" and related research and development programs, the most advanced of which are described below. We have also entered into a co-promotion agreement with Concordia pursuant to which we were granted certain rights to promote Donnatal® in the U.S..

Our Therapeutic Candidates and Donnatal®

Summary

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

Name of Product	Relevant Indication	Potential Advantages Over Most Existing Treatments	Development Stage	Rights to the Product
RHB-105	*H. pylori* infection	Improved efficacy, potential to overcome bacterial resistance; all-in-one pill	First Phase III study in the U.S. completed. Confirmatory Phase III study planned	Acquired all rights to the composition and use of two antibiotics and a proton pump inhibitor, worldwide and exclusive. We filed our own IP applications directed to the proposed commercial formulation and use
RHB-104	Crohn's disease	Novel mechanism of action and improved clinical benefit (targeting suspected underlying cause of Crohn's disease)	First Phase III study in N. America, Israel, Australia, New Zealand and Europe ongoing	Acquired all rights to the triple antibiotic combination and its use, worldwide and exclusive. We filed our own IP applications directed to the proposed commercial formulation and use
RHB-104	Multiple sclerosis (MS)	Oral formulation and novel mechanism of action	Phase IIa proof of concept study in Israel completed	Acquired all rights to the triple antibiotic combination and its use, worldwide and exclusive. We filed our own IP applications directed to the proposed commercial formulation and use
RHB-104	Nontuberculous Mycobacteria (NTM) infections	Oral formulation targeting suspected underlying cause of NTM infections	Under review	Acquired all rights to the triple antibiotic combination and its use, worldwide and exclusive. We filed our own IP applications directed to the proposed commercial formulation and use
BEKINDA® 24 mg	Acute gastroenteritis and gastritis	No other approved 5-HT3 serotonin receptor inhibitor for this indication; once daily dosing	Phase III ongoing in the U.S.	Worldwide, exclusive license to technology used in the commercial formulation. We filed our own IP applications directed to the proposed commercial formulation and use
BEKINDA® 12 mg	IBS-D	Potential 5-HT3 serotonin receptor inhibitor with improved safety, while maintaining efficacy, for broader use in the indication	Phase II ongoing in the U.S.	Worldwide, exclusive license to technology used in the commercial formulation. We filed our own IP applications directed to the proposed commercial formulation and use
RHB-106	Bowel preparation	Oral pill, avoid severe bad taste of chemical solutions, no known nephrotoxicity issues	Licensed to Valeant (which acquired Salix Pharmaceuticals, Inc.)	Worldwide rights licensed to Valeant
YELIVA®	Advanced solid tumors	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities	Phase I study in the U.S. completed (ABC-101)	Worldwide, exclusive license
YELIVA®	Refractory or relapsed diffuse large B-Cell lymphoma (DLBCL), including patients with virus-induced (e.g., KSHV- or EBV-associated) lymphoma, or Kaposi sarcoma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities	Phase I/IIa study in the U.S. initiated (ABC-102)	Worldwide, exclusive license
YELIVA®	Refractory or relapsed multiple myeloma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities	Phase Ib/II study in the U.S. initiated (ABC-103)	Worldwide, exclusive license

YELIVA®	Advanced hepatocellular carcinoma	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities	Phase II study in the U.S. initiated (ABC-106)	Worldwide, exclusive license
YELIVA®	Oncology support, prevention of radiation - associated mucositis in the treatment of head and neck cancer	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities.	Phase Ib study planned (ABC-104)	Worldwide, exclusive license
YELIVA®	Moderate to severe ulcerative colitis	Oral administration, first-in-class SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities.	Phase II study planned (ABC-105)	Worldwide, exclusive license
MESUPRON	Gastrointestinal and other solid tumors	Oral administration; new non-cytotoxic approach to cancer therapy potentially inhibiting both tumor invasion and metastasis	Completed two Phase II studies; Pre-clinical studies ongoing, preparations for Phase I/II study for resected pancreatic cancer	Worldwide exclusive license; excludes China, Hong Kong, Taiwan and Macao
RIZAPORT®	Acute migraine	Oral thin film formulation; Avoids exacerbation of nausea, administered without water, ease of use, convenient portability and discrete carriage and use	NDA filed and accepted, Complete Response Letter (CRL) received and preparing for resubmission in the U.S.; European marketing application approved in Germany	Worldwide, exclusive license and co-development
Combination against Ebola virus	Ebola virus disease	Efficacy and safety	Nonclinical research collaboration with a U.S. government agency ongoing	All worldwide rights to the product. We filed our own IP applications directed to the combination formulations and their use

RHB-105

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

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

Gastric cancer is one of the most commonly diagnosed cancers worldwide and one of the most common causes of cancer-related deaths, accounting for approximately 700,000 deaths annually. According to a 2010 report by Polk DB *et al.* published in Nature Reviews Cancer, *H. pylori*-induced gastritis is the strongest singular risk factor for cancers of the stomach, and eradication of *H. pylori* significantly decreases the risk of developing cancer in infected individuals without pre-malignant lesions.

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 Act, which is intended to encourage development of new antibiotic drugs for the treatment of serious or life-threatening infections that have the potential to pose a serious threat to public health. The granted QIDP designation allows us to benefit from Fast-Track development

status with an expedited development pathway for RHB-105 and Priority Review status which potentially provides shorter review time by the FDA of a future potential marketing application. If approved, RHB-105 will also receive an additional five years of U.S. market exclusivity on top of the standard exclusivity period, for a total of eight years of market exclusivity.

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.

We acquired the rights to RHB-105 pursuant to an agreement with Giaconda Limited. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106."

Competition and Market

The most common treatments of *H. pylori* type bacteria combine clarithromycin or metronidazole antibiotics with amoxicillin and a proton pump inhibitor. Such current standard of care treatments fail in approximately 30% of the patients due to the development of antibiotic resistance, based on reports by Prof. David Y. Graham, M.D., *et al.* published in Nature Clinical Practice Gastroenterology & Hepatology in 2008 and in Gut in 2010 and by Malfertheiner P. *et al.* published in Gut in 2012.

As published in the 2006 study report by Dr. T.J. Borody, et. al. in Alimentary Pharmacology & Therapeutics, the potential advantage of RHB-105 over these drugs (such as PrevPac® of Takeda Pharmaceuticals and Pylera® of Allergan Plc) was shown in a Phase II study comprised of 130 subjects. In the study, a different formulation of RHB-105, using the same antibiotic ingredients and a similar proton pump inhibitor, was shown to eradicate *H. pylori* in over 90% of treated patients who failed previous eradication attempts using standard of care treatments. Furthermore, final results from the first Phase III study in the U.S. (the "ERADICATE Hp Study") conducted by us demonstrated 89.4% efficacy in eradicating *H. pylori* infection with RHB-105 in 118 dyspepsia patients with confirmed *H. pylori* infection.

In the U.S., we estimate that approximately three million patients per annum that present with first time dyspeptic symptoms caused by an *H. pylori* infection, based on a 2007 report by Colin W. Howden, M.D., et. al. published in The American Journal of Managed Care and a 2005 report by Nicholas J. Talley, M.D., *et al.* published in The American Journal of Gastroenterology. Based on this figure, combined with the price of branded treatments, we estimate the potential global and U.S. market for RHB-105 was approximately $4.83 billion and $1.45 billion in 2015, respectively.

Clinical Development

A Phase II clinical trial in Australia was completed with a different formulation of RHB-105, using the same antibiotic ingredients and a similar proton pump inhibitor. A first Phase III trial in the U.S., the ERADICATE Hp Study, which was completed in 2015, showed 89.4% eradication of *H. pylori* with RHB-105 therapy while open-label standard-of-care yielded an *H. pylori* eradication rate of 63% in placebo subjects.

Professor David Y. Graham, MD, from Baylor College of Medicine, Houston, Texas, served as the lead investigator of the ERADICATE Hp Study.

We met with the FDA in April 2016 to discuss the successful results of the ERADICATE Hp Study and the proposed design of the confirmatory Phase III study for the treatment of *H. pylori* infection. In light of the feedback received from the FDA, we expect to initiate a confirmatory Phase III randomized, double-blind, active comparator, two-arm clinical study, comparing RHB-105 against a dual therapy amoxicillin and omeprazole regimen at equivalent doses in the second quarter of 2017. In January 2017, we entered into an agreement with ICON Clinical Research Limited to perform clinical trial services for the confirmatory Phase III study.

Pursuant to a recommendation from the FDA, we intend to complete a supportive pharmacokinetic (PK) program by end of the first quarter of 2017, prior to initiating the confirmatory Phase III study. Subject to their successful outcome, we expect that the supportive PK program and the confirmatory Phase III study will complete the clinical package required for a submission of an NDA for RHB-105, if we proceed to file an NDA.

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

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Number of subjects of the trial	Nature and status of the trial	Schedule
-	Phase IIa	Examining the therapeutic candidate's effectiveness in treating *H. pylori* infection in patients for whom standard of care had failed to treat the infection	Center for Digestive Disease, Australia	130	The trial was completed and indicated that the treatment is effective for *H. pylori*-infected patients for whom standard of care had failed to treat the infection	Completed in 2005
-	Comparative Bioavailability	Comparing the bioavailability of RHB-105 to the bioavailability of an equivalent dose of commercially available active ingredients	Algorithme Pharma,Canada	16	Completed	Completed in 2013
ERADICATE Hp Study	Phase III	Examining the effectiveness, safety and PK of the final formulation	13 sites in the U.S.	Up to 118	Completed	Completed in 2015
-	Comparative Bioavailability	Comparing the bioavailability of RHB-105 in fed and fasted state and to the bioavailability of the active comparator for the confirmatory Phase III study	Algorithme Pharma,Canada	18	Ongoing	Ongoing
TBD	Phase III	Assess the safety and efficacy of RHB-105 as compared to active comparator	Up to 55 sites in the U.S.	440	Planned	Planned for initiation in Q2 2017

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

RHB-104

Crohn's Disease

RHB-104 is intended to treat Crohn's disease, which is a serious inflammatory disease of the GI 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.

To date, Crohn's disease has been considered an autoimmune disease, but the exact pathological mechanism is unclear. Dr. Robert J. Greenstein suggested in *The Lancet Infectious Diseases*, 2003 that Crohn's disease is caused by MAP, the same organism responsible for a major cause of disease in animal agriculture production, domestic and wild animals. This hypothesis is supported by an expanding number of scientific and clinical studies published in peer-reviewed journals since a National Institute of Allergy and Infectious Diseases conference that focused on MAP in Crohn's disease took place in 1998. Specific genetic loci like NOD2 have been implicated in the pathogenesis of Crohn's disease with mutations in NOD2 suspected of leading to defective recognition of MAP and increased compensatory immune activation in patients with Crohn's disease. Recent advances in diagnostic technology have led to increasingly higher identification of MAP, with studies, such as Bull TJ *et al.* J Clin Microbiol, 2003 and Shafran I *et al.* Dig Dis Sci, 2002, demonstrating high prevalence of MAP in Crohn's disease patients. However, there is currently no FDA-approved commercial diagnostic test for MAP.

In 2011, we obtained FDA "Orphan Drug" status for RHB-104 for the treatment of Crohn's disease in the pediatric population. See "Item 4. Information on the Company – B. Business Overview – 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 pursuant to an asset purchase agreement with Giaconda Limited, a publicly traded Australian company. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106."

A diagnostic technology enabling the identification of the presence of MAP bacterial DNA in patients was developed and patented by Professor Saleh Naser of the University of Central Florida in Orlando. On September 15, 2011, we entered into an agreement with the University of Central Florida Research Foundation, Inc. ("UCF"), pursuant to which we acquired the exclusive rights in this patented diagnostic test. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement related to RHB-104."

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

We reported in October 2016 the results from the MAP diagnostic development program, including an initial validation of our platform PCR (polymerase chain reaction) detection methodology licensed from UCF and developed by Professor Saleh A. Naser, a leading investigator in the field of *Mycobacterium avium subspecies paratuberculosis* (MAP) and its association with Crohn's disease. Further testing of the methodology at three different U.S. laboratories has successfully identified MAP DNA in blood samples drawn from patients with Crohn's disease, including a test in collaboration with the Baylor College of Medicine intended to further advance the development of a companion diagnostic for MAP. Further optimization of the processes for rapid detection of MAP is currently in progress. We believe that ensuring that any future commercial test is accurate and reproducible is critical to the successful development of a companion diagnostic.

Competition and Market

According to GlobalData, a provider of market intelligence for the pharmaceutical sector, there were approximately 1.39 million prevalent cases of Crohn's disease in the 10 major markets in 2016. This number of prevalent cases is expected to increase to 1.48 million by 2022.

According to a report by EvaluatePharma, a leading market intelligence and information resource, the market of drug treatments for Crohn's disease was estimated to exceed $7.6 billion worldwide in 2016. The report also estimates that the worldwide market for drug treatment of Crohn's disease will exceed $8 billion in 2017.

Therapeutic interventions in Crohn's disease patients are based on the disease location, severity and associated complications. Therapeutic approaches for the treatment of Crohn's disease are individualized according to the patient's symptomatic response and tolerance to the prescribed treatment. Since the existing treatments are not curative, the current therapeutic approaches are sequential and involve treatment of an acute disease or inducing clinical remission through mucosal healing, followed by maintenance of the response or remission to improve the patient's quality of life.

Currently available drugs on the market for the treatment of Crohn's disease offer only symptomatic relief, the effects of which are largely temporary or partial and are accompanied by numerous adverse effects. The most commonly prescribed drugs for treatment of Crohn's disease include 5 Aminosalicylates (5-ASA, such as mesalamine), corticosteroids (such as prednisone), immunosuppressant drugs (such as azathioprine and methotrexate) and biologic agents, including TNF-α inhibitors (such as Remicade®, Humira® and Cimzia®), an integrin inhibitor (Tysabri®, Entyvio®) and an IL 12 and IL23 inhibitor (Stelara®).

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

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

Clinical Development

A Phase III clinical trial for RHB-104 was conducted in Australia, sponsored by Pharmacia, a Swedish company (which merged with Pfizer), with the primary objective of evaluating the ratio of patients with recurrent symptoms of Crohn's disease following the 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. The results of the trial were published by Professor Warwick Selby *et al.* in 2007 in the medical journal *Gastroenterology*. 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.

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 additional manufacturing agreements directly with the Canadian manufacturer.

In June 2011, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with PharmaNet Canada Inc. for the provision of clinical trial services for the RHB-104 adult studies in North America and Europe. PharmaNet was subsequently acquired by inVentiv Health and our agreements were transferred to inVentiv. See "– Master Service Agreement with 7810962 Canada Inc. and see also "Clinical Services Agreement – Clinical Services Agreement related to RHB-104."

Subsequent to our discussions with the FDA for approval to conduct the North American trial based upon an Investigative New Drug (IND) approved by the FDA on July 18, 2007, we made a number of changes to the original protocol. On August 29, 2012, we revised the IND filed by Giaconda with the submission of a new Phase III protocol to the FDA, and after 30 days, the IND became effective. Based upon the response from the FDA on issues relating to the clinical study, additional changes have been made, and will be made, to the clinical study in North America, Israel, and other countries. Further amendments to the protocol were submitted to the FDA in 2014 and 2016 responding to recommendations from the investigators, and in order to expedite recruitment in the study.

In October 2013, we commenced a randomized, double-blind, placebo-controlled first Phase III clinical trial in North America, Europe, Israel, Australia and New Zealand, and other countries with RHB-104 ("MAP US"), based on the analysis and data from a Phase III trial conducted in Australia with the RHB-104 active ingredients in a different formulation. The MAP US study is ongoing and is expected to enroll 410 patients with moderately to severely active

Crohn's disease at up to 150 clinical sites in the U.S., Canada, Europe, Israel, Australia and New Zealand. Patients are randomized 1:1 to receive either RHB-104 or a placebo for 52 weeks and are evaluated for the primary endpoint of remission (Crohn's disease active index ("CDAI") <150) at week 26 of treatment.

In February 2017, we entered into an agreement with our Canadian service provider which entered into a back-to-back agreement with inVentiv Health for the provision of clinical trial services for an RHB-104 open-label extension study that would allow patients who complete 26 weeks of study drug administration and remain out of remission (CDAI>150) the opportunity to receive treatment with RHB-104 for a 52-week period.

Following a pre-planned review of safety data, an independent interim Data and Safety Monitoring Board (DSMB) unanimously recommended in December 2016 that the MAP US study continue as planned, without any modifications. Two additional DSMB meetings are planned to take place after 50% and after 75% of the 410 patients planned to be enrolled in the study complete the 26 weeks of study participation. Over half of the patients have already been enrolled in the MAP US study, with the 205th patient enrolled in August 2016. As a result, we expect the second independent DSMB meeting to be held in the second quarter of 2017, after the first 205 patients complete 26 weeks of study participation. The second DSMB meeting will include safety and interim efficacy analysis and will evaluate the option of an early stop for success, according to a pre-specified statistical significance threshold for analysis requiring overwhelming efficacy of RHB-104 versus placebo in the primary endpoint (two sided p-value <0.003). Assuming that the study is not stopped early for success or inefficacy following the second DSMB meeting, we expect to complete the recruitment of all 410 subjects planned to enroll for the study by the end of 2017. Additional studies will be required to support a U.S. NDA for RHB-104.

We also plan to initiate two additional ex-U.S. small-scale open-label clinical studies with RHB-104, each with up to 20 Crohn's disease patients, to provide additional supportive clinical data for potential future marketing applications, as well as to evaluate RHB-104's efficacy in newly diagnosed and treatment-naïve Crohn's disease patients and as an add-on therapy to current standard of care.

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

Clinical trial author/designnation	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
Borody 2002	Phase IIa	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	12	Performed	Completed in 2002
Borody 2005	Phase II	Examining the effect of the treatment on Crohn's disease patients	Center for Digestive Disease, Australia	52	Performed	Completed in 2005
Selby	Phase III	Examining the effect of the treatment with the product on Crohn's disease patients	20 clinical centers in Australia	213	The trial was performed and indicated promising improvement rates, although it did not meet the main trial objective, as defined	Published in 2007
Biovail PK study 2007	PK Study	Optimize the formulation of RHB-104 on a PK basis	Toronto, Ontario	24	Trial compared two formulations to determine the optimum formulation for RHB-104	Completed in 2007
MAP US	Phase III	Assess the safety and efficacy of RHB-104 in Crohn's disease patients	U.S., Canada. Israel, Australia, New Zealand and Europe	410	Phase III trial in North America, Israel, and other countries has commenced	First patient entered study in Q3 2013
Food Effect Study	PK Study	Determine the effect of food on the bioavailability of RHB-104 in healthy volunteers	Algorithme Pharma, Canada	84	Completed	Completed in 2014
Drug-Drug Interaction Study	PK Study	To assess the net PK effect of multiple doses of RHB-104 on CYP3A4 enzymes in healthy volunteers	Algorithme Pharma, Canada	36	Ended	Ended in 2014

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

Multiple Sclerosis ("MS")

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.

Clinical Development

We have performed several preclinical studies, including studies in an experimental autoimmune encephalomyelitis (EAE) mouse model of MS, to investigate the potential impact of RHB-104 in treating MS. The first preclinical study measured cytokine production (biomarkers of inflammation) and demonstrated that the RHB-104 treatment led to a significant reduction of pro-inflammatory cytokine concentrations of IL-6 and TNF, which are associated with inflammation and MS, compared to the control group. The second preclinical study measured the efficacy of RHB-104 as prophylactic therapy, and the treatment with RHB-104 demonstrated a significant reduction in the inflammatory area and level of demyelination, compared with the control group. The third preclinical study measured relapses, demonstrating RHB-104's efficacy in significantly reducing the incidence of relapse compared with the control group.

Following these preclinical studies, in June 2013, we initiated a Phase IIa proof-of-concept study with RHB-104 for relapsing remitting multiple sclerosis ("RRMS") (the "CEASE MS" study) at two clinical sites in Israel. The study was completed, and the top-line final results (48 weeks) were announced in December 2016. The top-line final results (48 weeks) were consistent with the interim results (24 weeks) suggesting meaningful positive safety and clinical signals upon 24 weeks of treatment with RHB-104 as an add-on therapy, including an encouraging relapse-free rate, Expanded Disability Status Scale scores and MRI results, which support further clinical development.

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
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
EAE Prophylaxis Study	Pre-Clinical	Scoring EAE severity in mice treated prophylactically with RHB-104 vs. negative controls	-			Completed 2012
EAE Relapse Study	Pre-Clinical	Scoring EAE severity in mice treated with RHB-104 vs. negative and positive controls	-			Completed 2012
Lipopolysaccharide (LPS)-induced cytokine production study	Pre-Clinical	Measure LPS induced cytokine production in C57BL/6 mice treated with RHB-104 vs. negative and positive controls	-			Completed 2013
CEASE-MS	Phase IIa	Proof of concept study to assess the safety and efficacy of RHB-104 in RRMS	Israel	18	Completed	Completed 2016. Final top-line results announced in December 2016

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

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

Nontuberculous Mycobacteria Infections

In January 2017, RedHill announced that RHB-104 had been granted Qualified Infectious Disease Product ("QIDP") designation by the FDA for the treatment of Nontuberculous Mycobacteria ("NTM") infections. RedHill plans to consult with the FDA regarding the RHB-104 development program for NTM infections.

BEKINDA® (RHB-102)

BEKINDA® is a once-daily bi-modal extended release oral formulation of ondansetron, a leading member of the family of 5-HT3 serotonin receptor inhibitors. We are developing BEKINDA® with two dosages: 24 mg and 12 mg. BEKINDA® is under development for the intended use in the following indications, which are novel indications for ondansetron targeting large potential markets:

1) Acute gastroenteritis and gastritis - 24 mg strength

2) Irritable Bowel Syndrome with Diarrhea (IBS-D) - 12 mg strength

RedHill is also exploring the development of BEKINDA® 24 mg for the oncology support indications of chemotherapy and radiotherapy-induced nausea and vomiting in Europe. This is an existing indication for ondansetron targeting a smaller potential market. This program is currently on hold given the focus on the gastroenteritis and IBS-D programs.

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, which announced that they had ceased business operations in 2013. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for BEKINDA®".

Acute Gastroenteritis and Gastritis

Acute gastroenteritis and gastritis both involve inflammation of the mucus membranes of the GI tract. Symptoms of gastroenteritis and gastritis include nausea, vomiting, diarrhea and abdominal pain. Acute gastroenteritis and gastritis are 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 and gastritis by offering them an effective and long-lasting treatment which can be taken in the comfort of their home.

Competition and Market

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

If BEKINDA® is approved for the treatment of acute gastroenteritis and gastritis, it could potentially hold substantial advantages over existing treatments. To the best of our knowledge, if approved, BEKINDA® will be the first 5-HT3 serotonin receptor inhibitor indicated for the treatment of acute gastroenteritis and gastritis in the U.S. If approved, BEKINDA® could be prescribed by primary care physicians to patients early on, potentially preventing emergency room visits, dehydration and the need to provide IV fluids.

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

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

To the best of our knowledge, a product that potentially directly competes with BEKINDA® is EUR-1025 for controlled release of ondansetron, based on a different technology of controlled release originally developed by Eurand N.V. (now owned by Adare Pharmaceuticals, Inc.). According to Eurand N.V.'s press release from March 4, 2010, Eurand N.V. completed two pivotal pharmacokinetic studies of EUR-1025 intended to establish the bioequivalence of EUR-1025 versus Zofran® (ondansetron hydrochloride). To the best of our knowledge, EUR-1025 was being developed for the indication of postoperative-induced nausea and vomiting, for which Zofran® and generic ondansetron were already approved, and according to Eurand N.V.'s press release, a Phase III study was planned to be conducted in this indication. To the best of our knowledge, the Phase III study was not initiated and there has not been further clinical development of EUR-1025 since the completion of the above-mentioned pharmacokinetic studies.

Clinical Development

We are conducting a randomized, double-blind, placebo-controlled, parallel group Phase III study (the "GUARD study") at 29 clinical sites in the U.S. We completed enrollment for the study in February 2017. Three hundred twenty (320) adults and children over the age of 12 were treated in the GUARD study. Patients were randomized to receive either BEKINDA® or a placebo. The primary endpoint for the study is the absence of vomiting and the need for rescue medications or intravenous hydration after 30 minutes and through 24 hours after the first dose of the study drug. Secondary endpoints include, among others, frequency of vomiting, severity and time to resolution of nausea and time to resumption of normal activities. We implemented a protocol amendment to the ongoing GUARD study to increase the safety data collected so that the study results may support a potential NDA filing, as recommended by the FDA. We expect to receive top-line results from the GUARD study in the second quarter of 2017. Following prior discussions with the FDA, the GUARD study is intended to support potential future submissions of marketing applications in the U.S. for this indication.

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 acute gastroenteritis and gastritis	29 sites in the U.S.	320	Evaluating the safety and efficacy of BEKINDA® in acute gastroenteritis and gastritis	Top-line data expected in Q2 2017

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

Irritable Bowel Syndrome with Diarrhea (IBS-D)

Irritable bowel syndrome (IBS) is a multifactorial disorder marked by recurrent abdominal pain or discomfort and altered bowel function. Certain factors that alter GI function can contribute to IBS symptoms, including stress, prior gastroenteritis, and changes in the gut microbiome, bile acids and short-chain fatty acids, which may stimulate 5-HT3 serotonin release and increase colonic permeability and motility. (Source: http://www.mayoclinic.org/medical-professionals/clinical-updates/digestive-diseases/better-agents-needed-irritable-bowel-syndrome-diarrhea).

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

BEKINDA® is a bimodal release formulation of ondansetron. It provides an initial release similar to immediate release ondansetron and then extended release over 24 hours. In light of the activity of ondansetron demonstrated in the preliminary studies described above, and because of its extended release properties and once daily dosing, we believe it is a promising candidate for treatment of IBS-D.

Competition and Market

IBS is one of the most common GI disorders, and IBS-D is the most common subtype of IBS in the U.S., according to a report by GlobalData.

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

According to a report from EvaluatePharma, the U.S. potential market for IBS-D treatments is estimated to reach approximately $830 million in 2017 and exceed $1 billion in 2018.

To the best of our knowledge, there is one other 5-HT3 serotonin receptor inhibitor indicated for this indication in the U.S. – alosetron (currently marketed under the brand name Lotronex® by Sebela Pharmaceuticals and generic versions marketed by Actavis plc, West-Ward and Amneal Pharmaceuticals). However, alosetron is approved only for the treatment of IBS in women with severe chronic IBS-D and is under a restricted prescribing program due to potential severe side effects. The active ingredient in BEKINDA®, ondansetron, is approved by the U.S. FDA as an oncology support antiemetic and has a good safety profile. Therefore, we believe that BEKINDA®, if approved for the treatment of IBS-D in the U.S., may provide improved safety while maintaining efficacy, for broader use in the treatment of IBS-D and has the potential to be the preferred 5-HT3 serotonin receptor inhibitor treatment for patients suffering from IBS-D. According to GlobalData, the U.S. sales of Lotronex® were approximately $60 million in 2016. Ramosetron, another 5-HT3 serotonin receptor inhibitor, is marketed by Astellas Pharma Inc. under the brand name Irribow® for the treatment of IBS-D in Japan and South Korea, for chemotherapy -induced nausea and vomiting in Japan, South Korea and China, and for and postoperative nausea and vomiting in South Korea. To the best of our knowledge, there is currently no clinical development of ramosetron for marketing approval in the U.S. for any indication.

To the best of our knowledge, one of the main competitors of BEKINDA® for the treatment of IBS-D is Xifaxan® (rifaximin), marketed in the U.S. by Valeant. Xifaxan® is an antibiotic treatment that was approved for the treatment of IBS-D in 2015. Xifaxan® is also approved in the U.S. for the treatment of hepatic encephalopathy and traveler's diarrhea. According to a report by GlobalData, it is believed that Xifaxan® exerts its therapeutic effects in patients with IBS by treating intestinal bacteria overgrowth. In the treatment of IBS-D patients, Xifaxan® is administered orally at a dose of 550 mg three times daily for two weeks. According to a GlobalData analysis, due to the chronic nature of IBS, physicians may have safety concerns associated with the long-term use of antibiotics, such as the induction of antibiotic resistance and imbalance in the intestinal flora. According to a report by EvaluatePharma, the worldwide annual sales of Xifaxan® for the treatment of IBS are estimated to exceed $920 million by 2020.

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

Donnatal® (Phenobarbital, Hyoscyamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide) is also used as a treatment for IBS and included in the FDA DESI review program, although it is not approved by the FDA. In December 2016, we were granted certain rights to promote Donnatal® (tablets and elixir) in the U.S. pursuant to an exclusive Co-Promotion Agreement with Concordia.

Clinical Development

We are conducting a randomized, double-blind, placebo-controlled, Phase II study to evaluate the safety and efficacy of BEKINDA® 12 mg in patients with IBS-D. The study is expected to enroll 120 adults over the age of 18 who suffer from

IBS-D in up to 16 clinical sites in the U.S. Patients are randomized to receive either BEKINDA® 12 mg once daily or a placebo. Top-line results are expected in mid-2017.

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

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

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 II	Randomized double blind placebo-controlled Phase II study in IBS-D	Up to 16 sites in the U.S.	Up to 120	Evaluating the safety and efficacy of BEKINDA® 12 mg in IBS-D	Top-line data expected in mid-2017

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

Oncology Support

Clinical Development

We completed two comparative bioavailability studies with BEKINDA® 24 mg given once daily as compared to approved regimens of Zofran® 8 mg tablets given in multiple doses per day, a food-effect study and a comparative bioavailability study with BEKINDA® 24 mg given once daily as compared to Zofran® 16 mg suppository, which is approved in major territories in the EU.

The following chart summarizes the PK trial history and status of BEKINDA®:

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Number of subjects of the trial	Nature and status of the trial	Schedule
PK Program	Comparative Bioavailability	Five PK studies with BEKINDA®	Algorithme Pharma, Canada	80	To support marketing applications in EU and U.S. in oncology support	Completed in 2016
-	Comparative Bioavailability	Comparative Bioavailability of BEKINDA® 12 mg	Algorithme Pharma, Canada	44	To support marketing applications in EU in oncology support	Completed in 2017

We submitted a Marketing Authorization Application (MAA) for BEKINDA® 24 mg in Europe for chemotherapy and radiotherapy-induced nausea and vomiting in December 2014, which we subsequently decided to withdraw. We conducted another comparative bioavailability study with BEKINDA® 12 mg compared to Zofran® 16 mg suppository and Zofran 8 mg bid regimens and concluded, subject to final clinical study report yet to be received, that bioequivalence of the two

approved regimens is unlikely. Given the focus on the gastroenteritis and IBS-D programs, the oncology support program for the EU is currently on hold.

In the U.S., FDA feedback in 2015 indicated that clinical efficacy data is required to support a U.S. NDA for BEKINDA® for oncology support indications under the 505(b)(2) regulatory path. Further development for oncology support indications will be decided as data from the ongoing and planned efficacy studies with BEKINDA® for acute gastroenteritis and gastritis and IBS-D becomes available.

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

RHB-106

RHB-106 is a tablet intended for the preparation and cleansing of the GI 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 "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 Pharmaceuticals, Ltd. ("Salix"), which was later acquired by Valeant, pursuant to which Salix licensed the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation and rights to other purgative developments. Pursuant to this agreement, we received an upfront payment of $7 million and are entitled to an additional potential $5 million in subsequent milestone payments. In addition, as part of the terms of the agreement, Salix agreed to pay us tiered royalties on net sales of RHB-106, ranging from the low single-digits up to low double-digits. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Exclusive License Agreement with Valeant Pharmaceuticals International, Inc."

Competition and Market

According to a report by EvaluatePharma, the worldwide market of laxative products intended for cleansing the GI system was estimated at approximately $900 million in 2016 and is expected to exceed $1 billion in 2021.

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

An additional product, called PrepoPik® in the U.S., is marketed by Ferring Pharmaceuticals and received FDA approval on July 17, 2012. The product, marketed under the name PicoPrep® in other countries, is based on an active chemical ingredient called sodium picosulfate, the same active ingredient used in RHB-106. This product is intended to be used for clearing the GI system and it is given in the form of a water-soluble powder and requires drinking quantities of fluids. Another product, called Suprep® in the U.S., is marketed by BrainTree Laboratories Inc. and received FDA approval in 2010 as an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults. Suprep®'s active ingredients include sodium sulfate, potassium sulfate and magnesium sulfate in oral solution, and it is administered as a split-dose regimen (taken in the evening before and on the day of the colonoscopy). In August 2016 Perrigo Company Plc announced tentative FDA approval of its generic version of Suprep®; however, it has not begun marketing the generic version of Suprep®, and, to the best of our knowledge, no other generic version of Suprep® is currently marketed in the U.S.

Products administered in the form of tablets or capsules that were released on the market in the U.S., such as OsmoPrep® and Visicol® (marketed by Valeant), are based on a chemical substance called sodium phosphate. In December 2008, the

FDA published a severe warning against the use of these products due to rare but severe side effects linked to kidney damage. As a consequence of this development, the FDA required in 2008 that oral sodium phosphate products carry a severe warning (black box label). As announced by Salix (now Valeant), following the black box warning received from the FDA, sales in 2009 of these products declined by 39% compared to 2008.

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

To the best of our knowledge, Norgine B.V. is also developing a new PEG-based bowel preparation oral solution named Plenvu™ (NER1006), administered as a 2-day split dose regimen. According to Norgine B.V., Plenvu™ is being developed to provide whole bowel cleansing, with an additional focus on the ascending colon. Norgine B.V. announced in October 2016 that a third Phase III study of Plenvu™ met its primary endpoints. On August 8, 2016, Norgine B.V. announced that the commercial rights to Plenvu™ in the U.S. and Canada were licensed to Valeant.

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

Clinical Development

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

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

YELIVA® (ABC294640)

YELIVA® is a proprietary, first-in-class, orally-administered SK2 selective inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple inflammatory, GI and oncology indications.

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

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

Competition and Market

YELIVA®, an orally-administered, first-in-class SK2 inhibitor is being developed for several indications, including for the treatment of refractory/relapsed diffused large B-cell lymphoma ("DLBCL") and Kaposi sarcoma, for refractory or relapsed multiple myeloma, for advanced hepatocellular carcinoma ("HCC") and for radioprotection in head and neck cancer patients undergoing therapeutic radiotherapy. Additional oncology and GI and inflammatory disease indications are currently being explored.

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

According to the American Cancer Society, DLBCL is the most common subtype of non-Hodgkin's lymphoma in the U.S., accounting for an estimated 30% of the approximately 72,000 projected non-Hodgkin's lymphoma cases to be diagnosed in the U.S. in 2017. The total worldwide sales of DLBCL therapies are estimated at approximately $1.5 billion in 2017 according to GlobalData. There are several drugs in late-stage clinical development for DLBCL.

Kaposi sarcoma ("KS") is a cancer that develops from the cells that line lymph or blood vessels, mostly commonly appearing as tumors on the skin and on mucosal surfaces. Human herpesvirus-8 ("HHV-8"), also called Kaposi sarcoma herpesvirus ("KSHV"), is found in the lesions of all patients with Kaposi sarcoma. There are several types of KS, defined by the different populations it develops in. According to the American Cancer Society, the most common type of KS in the U.S. is epidemic or HIV-related KS, which develops in people infected with HIV. According to the American Cancer Society, KS occurs at a rate of about 6 cases per million people each year; it is more common in men than in women and rarely seen in children. Treatment of KS is decided based on the patient's immune system as well as the number, location, and size of the KS lesions, and may include local therapy, radiation, chemotherapy and treatment with biologic agents (immunotherapy).

The American Cancer Society estimated that approximately 30,200 new cases of multiple myeloma will be diagnosed in the U.S. in 2017 and approximately 12,500 deaths are expected to occur. The risk of multiple myeloma increases as people age. Standard treatment options for multiple myeloma include biological therapy, chemotherapy, corticosteroids, stem cell transplantation and radiation therapy. The total worldwide sales of multiple myeloma therapies were estimated to exceed $12 billion in 2016 according to GlobalData. There are several drugs in late-stage clinical development for multiple myeloma.

Hepatocellular carcinoma is the most common primary malignant cancer of the liver, accounting for approximately 85% of liver cancer cases, according to GlobalData. It is the second and sixth most frequent cause of cancer-related deaths worldwide in men and women, respectively. Annual worldwide incidence of liver cancer was estimated to have reached 782,000 cases in 2012, with a mortality rate of 95%; the corresponding U.S. numbers are 30,000 and 80%, respectively, according to a 2012 report by the World Health Organization International Agency for Research on Cancer. Most patients with HCC suffer from liver cirrhosis, which develops following long periods of chronic liver disease. The majority of HCC cases are associated with hepatitis B and hepatitis C virus infections. Few treatment options exist for patients diagnosed at an advanced stage, representing the majority of HCC patients. Sorafenib (Nexavar®) is a targeted drug approved for the treatment of HCC in patients who are not candidates for surgery and do not have severe cirrhosis. According to Globaldata, the worldwide market for the treatment of HCC is estimated to reach approximately $780 million in 2020. There are several drugs in late-stage clinical development for hepatocellular carcinoma.

Radiation therapy can cause both acute and chronic side effects. The side effects that develop depend on, among other things, the area of the body being treated, the dose given per day, the total dose given, the patient's general medical condition, and other treatments given at the same time. Acute side effects may include skin irritation or damage at regions exposed to the radiation beams. The oral cavity is highly susceptible to direct and indirect toxic effects of cancer chemotherapy and ionizing radiation. According to a 2011 publication by Peterson DE *et al.*, the incidence of World Health Organization grades 3 or 4 oral mucositis in patients receiving high-dose head and neck radiation (e.g. 60–70 Gy) to the oral cavity approaches 85%, but all treated patients have some degree of oral mucositis. There are currently limited therapeutic options to prevent oral mucositis in cancer patients undergoing radiotherapy. To the best of our knowledge, several drugs are currently in development for prevention of oral mucositis in cancer patients undergoing radiation therapy. These development programs include Phase II clinical studies for IZN-6N4, an oral rinse developed by Izun

Pharamaceuticals Corp., for GC-4419, a small molecule enzyme replacement developed by Galera Therapeutics, Inc. and for Brilacidin, a defensin-mimetic antibiotic developed by Cellceutix Corporation.

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

Clinical Development

ABC-101: Advanced solid tumors

A Phase I study, first-in-man evaluation of YELIVA® in advanced solid tumors was completed in the summer of 2015. Final results demonstrated that the study, conducted at the Medical University of South Carolina (MUSC), successfully met its primary and secondary endpoints, demonstrating that the compound is well tolerated and can be safely administered to cancer patients at doses predicted to have therapeutic activity.

Twenty-one patients with advanced solid tumors were treated with YELIVA® in the study, the majority of who were GI cancer patients, including pancreatic, colorectal and cholangiocarcinoma cancers.

The study included the first-ever longitudinal analysis of plasma S1P levels as a potential pharmacodynamic biomarker for activity of a sphingolipid-targeted drug. Administration of YELIVA® resulted in a rapid and pronounced decrease in levels of S1P with several patients having prolonged stabilization of disease.

The study was supported by grants from the U.S. National Cancer Institute (NCI) awarded to MUSC Hollings Cancer Center, an NCI-Designated Cancer Center, and from the FDA Office of Orphan Products Development (OOPD) awarded to Apogee.

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

In June 2015, we initiated a Phase I/IIa study in the U.S. evaluating YELIVA® in patients with refractory/relapsed DLBCL at the Louisiana State University Health Sciences Center (LSUHSC) in New Orleans. In view of improving recruitment prospects, the study was recently modified to include Kaposi sarcoma subjects.

The study is intended to evaluate the safety and tolerability of YELIVA®, as well as to provide a preliminary evaluation of efficacy of the study drug in patients with refractory/relapsed DLBCL, primarily patients with HIV-related DLBCL and in patients with Kaposi sarcoma.

Up to 33 patients are expected to be enrolled in the study. The study is funded primarily by a grant awarded to Apogee by the National Cancer Institute Small Business Technology Transfer program. Dr. Chris Parsons, MD, an associate professor in the Departments of Medicine and Microbiology, Immunology & Parasitology at LSUHSC, is the lead investigator for the study.

ABC-103: Refractory or relapsed multiple myeloma

A Phase Ib/II study with YELIVA® for the treatment of refractory or relapsed multiple myeloma was initiated in the third quarter of in 2016. The study is being conducted at Duke University Medical Center and is planned to enroll up to 77 patients. The study is funded primarily by a grant awarded by the NCI Small Business Innovation Research program, awarded to Apogee in conjunction with Duke University.

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

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

ABC-106: Advanced hepatocellular carcinoma

A Phase II study to evaluate the efficacy and safety of YELIVA® as a second-line monotherapy in patients with advanced hepatocellular carcinoma *("*HCC") was initiated in the third quarter of 2016. The study is currently being conducted at MUSC and will include additional collaborating clinical sites. The study is planned to enroll up to 39 patients who have experienced tumor progression following treatment with first-line single-agent sorafenib (Nexavar®).

A U.S. NCI grant awarded to MUSC for a research program covering a variety of solid tumor cancers will partially support this study. The trial is additionally funded by us.

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

A Phase Ib study is planned to evaluate YELIVA® as a radioprotectant in head and neck cancer patients undergoing therapeutic radiotherapy. We expect to initiate the study with YELIVA® mid-2017.

The primary objective of the study is to determine a recommended Phase II dose of YELIVA® in combination with cisplatin chemoradiotherapy. The secondary objectives include determining PK properties of YELIVA® (e.g., the effect of food and interaction with cisplatin) and pharmacodynamic assessments by measuring plasma levels of various markers. Furthermore, severity of mucositis and quality of life will be assessed in placebo and YELIVA® treated patients to plan for a randomized placebo-controlled study.

Following the successful Phase I study with YELIVA® in patients with advanced solid tumors, and in light of the compound's novel mechanism of action, we are evaluating potential clinical studies in inflammatory indications.

ABC-105: Ulcerative Colitis ("UC")

We plan to initiate a Phase II study in the second half of 2017 post-expanded toxicology studies. The primary objective of this study is to evaluate efficacy of YELIVA® in patients with moderate to severe UC by the proportion of patients who are in remission at the end of treatment. Secondary objectives include assessing pharmacodynamics and PKs of YELIVA® in this study population, as well as the safety in UC patients.

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

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Planned number of subjects of the trial	Nature and status of the trial	Schedule
ABC-101	Phase I	Safety, PK and pharmacodynamic study in patients with advanced solid tumors	Medical University of South Carolina, Charleston, U.S.	22	Completed. Top-line results indicate the study drug is well tolerated and can be safely administered to cancer patients	Completed in 2015; final clinical study report in 2016
ABC-102	Phase I/IIa	Safety and preliminary efficacy study in refractory or relapsed DLBCL, including patients with virus-induced (e.g., KSHV- or EBV-associated) lymphoma, or Kaposi sarcoma	Louisiana State University, New Orleans, U.S.	Up to 33	Study was initiated and recently modified to increase recruitment prospects. Patient enrollment is anticipated	Initiated Q2 2015
ABC-103	Phase Ib/II	Safety and efficacy study in patients with refractory or relapsed multiple myeloma that have previously been treated with proteasome inhibitors and immunomodulatory drugs	Duke University, North Carolina, U.S. and collaborating sites (multicenter, U.S.)	Up to 77	Study was initiated	Initiated Q3 2016
ABC-104	Phase Ib	Safety and efficacy study in the prevention of mucositis in combination with radiotherapy for treatment of squamous head and neck carcinoma	Multicenter study across the U.S.	Up to 32	Planned	Mid-2017
ABC-105	Phase II	A study for the treatment of moderate to severe ulcerative colitis	Multicenter study	Up to 94	Planned	Expected H2 2017
ABC-106	Phase II	A Safety and Efficacy Study in Patients with Advanced Hepatocellular Carcinoma Who Have Progressed on Sorafenib	Medical University of South Carolina, Charleston, U.S.A. and collaborating sites (Multicenter, U.S.)	From 12 to 39	Study was initiated	Initiated Q3 2016

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

MESUPRON

MESUPRON (INN: upamostat) is a proprietary small molecule, first-in-class, protease inhibitor administered by oral capsule.

MESUPRON has several potential mechanisms of action to inhibit tumor invasion and metastasis and it presents a new non-cytotoxic approach to cancer therapy.

As mentioned under "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for MESUPRON", on June 30, 2014 we signed an exclusive license agreement for this oncology therapeutic candidate. Under this agreement, we are responsible for all development, regulatory and commercialization of MESUPRON in the entire world, excluding China, Taiwan, Macao and Hong Kong.

Competition and Market

MESUPRON is an orally-administered protease inhibitor with several potential mechanisms of action to inhibit tumor invasion and metastasis and has been developed for the treatment of solid tumor cancers, including GI cancers, with the focus on locally advanced non-metastatic pancreatic cancer.

Pancreatic cancer is the fourth leading cause of cancer mortality in western countries. It is characterized as a disease with very high unmet need in oncology. According to data from the National Cancer Institute, with approximately 53,000 new cases diagnosed in 2016 and approximately 41,000 deaths, pancreatic cancer is the 12th most common cancer in the U.S. and the third most common cause of cancer-related death. The overall five-year survival rate for the disease is only 7.7% in the U.S., representing one of the poorest prognoses across the GI cancers. The total worldwide sales of pancreatic cancer therapies are estimated to reach approximately $1.6 billion in 2017, according to GlobalData.

According to the same GlobalData report, the majority of pancreatic cancer cases are diagnosed late, at which point the disease is already locally advanced or metastatic. 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.

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

There are a number of drugs in late-stage clinical development for pancreatic cancer. There are several drugs in late-stage clinical development for pancreatic cancer.

Clinical Development

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

None of the prior studies used any molecular markers to target certain patient populations. Using technologies developed since the original clinical trials were performed, we are currently performing several preclinical studies, including biomarker analysis and mechanism of action studies. Some of these studies were completed in 2016, while others are still ongoing. We expect that the findings from these studies can help us determine the patient populations to be studied in subsequent clinical trials. We are preparing a protocol for a Phase I/II study of the safety, efficacy and dose evaluation of MESUPRON in combination with chemotherapy in patients receiving adjuvant chemotherapy for resected pancreatic cancer. We anticipate the Phase I/II study to be initiated in up to 6 sites in Germany in the second half of 2017.

In the third quarter of 2016, we initiated a manufacturing campaign for the preparation of MESUPRON.

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

RIZAPORT®

RIZAPORT® is an oral thin film formulation of rizatriptan intended for the treatment of acute migraine headaches. Migraines are commonly treated with 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 API 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 "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for RIZAPORT®".

Competition and Market

To the best of our knowledge, the main competitors of RIZAPORT® are oral drugs from the triptan family (5-HT 1B/1D serotonin agonists), such as rizatriptan from Merck and Co., Inc., which is marketed in the U.S. under the name of Maxalt® and in generic form since 2012, and sumatriptan, produced by GlaxoSmithKline and marketed in the U.S. as Imitrex® and in generic form since 2009. According to a report from GlobalData, the prevalence of migraines in the U.S. is estimated to reach over 30 million cases in 2017. The triptan market, the target market for RIZAPORT®, was estimated at approximately $593 million worldwide in 2016 according to EvaluatePharma.

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

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

Clinical Development

In April 2012, we completed, together with our development partner IntelGenx Corp., a bioequivalence clinical study to examine the PK equivalence between the soluble film of RIZAPORT® and rizatriptan of Merck & Co. Inc. (Maxalt MLT®), with 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 NDA with the FDA for U.S. marketing approval under the 505(b)(2) regulatory path for RIZAPORT®.

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

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

Based on the data from that trial, we submitted a MAA to BfArM, as the reference member state under the European Mutual Recognition Procedure. In October 2015, BfArM informed us that the MAA had been approved. Approval from Luxembourg is anticipated in 2017.

In July 2016, we, together with IntelGenx Corp., entered into an exclusive license agreement with Grupo JUSTE S.A.Q.F., pursuant to which we granted Grupo JUSTE an exclusive license to commercialize RIZAPORT® in Spain and a right of first refusal for the commercialization rights in certain additional territories. Under the terms of the agreement, we granted Grupo JUSTE the exclusive rights to register and commercialize RIZAPORT® in Spain and a right of first refusal for a predetermined term for the territories of Belize, the Caribbean, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, the Middle East and Morocco. An upfront payment was paid by Grupo JUSTE, and we and IntelGenx Corp. are entitled to receive additional milestone payments upon the achievement of certain predefined regulatory and commercial targets, as well as tiered royalties. The initial term of the agreement is ten years from the date of the first commercial sale and will automatically renew for an additional two-year term. Commercial launch of RIZAPORT® in Spain is expected to take place in the second half of 2017. In January 2017, Exeltis Healthcare, S.L. acquired from Grupo JUSTE S.A.Q.F. all activities of Grupo JUSTE S.A.Q.F. related to the pharmaceutical business.

In the third quarter of 2016, Grupo JUSTE filed an MAA for RIZAPORT® to the Spanish regulatory authorities.

On December 13, 2016, we, together with IntelGenx Corp., entered into an exclusive license agreement with Pharmatronic Co. granting Pharmatronic Co. an exclusive license to commercialize RIZAPORT® in the Republic of Korea (South Korea). Under the terms of the agreement, we and IntelGenx Corp. are entitled to receive an upfront payment and are entitled to receive additional milestone payments upon the achievement of certain predetermined regulatory and commercial targets, as well as tiered royalties. The initial term of the agreement is ten years from the date of the first commercial sale and will automatically renew for an additional two-year term. Commercial launch of RIZAPORT® in South Korea is expected to take place in the first quarter of 2019.

Following the receipt of a complete response letter from the FDA, as announced on February 4, 2014, we, together with IntelGenx Corp., expect to re-submit the NDA for RIZAPORT® to the FDA in the third quarter of 2017 and subsequently receive a new Prescription Drug User Fee Act (PDUFA) date.

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

Clinical trial name	Development phase of the clinical trial	Purpose of the clinical trial	Clinical trial site	Number of subjects of the trial	Nature and status of the trial	Schedule
PLT-008-09	Phase I	PK comparison with a parallel product	RA Chem Pharma, India	10	The trial was performed and indicated similarity between the PK profile of the therapeutic candidate and the profile of the reference product	Completed in 2009
RZA-P9-688	Comparative Bioequivalence	PK comparison with Maxalt MLT®	Algorithme Pharma, Canada	26	Completed the study demonstrating bioequivalence as defined by the FDA	Completed in 2012
RZA-P3-697	Comparative Bioequivalence	PK comparison with Maxalt® Lingua	Algorithme Pharma, Canada	26	Completed the study demonstrating bioequivalence as defined by the European Medicines Agency ("EMA")	Completed in 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 – Risks Related to Our Financial Condition and Capital Requirements."

Donnatal®

Regulatory status

In December 2016, we entered into the Co-Promotion Agreement with Concordia to promote Donnatal® (Phenobarbital, Hycosamine Sulfate, Atropine Sulfate, Scopolamine Hydrobromide). The prescription drug product is sold in two formulations: an immediate-release tablet and an immediate-release fast-acting liquid (tablets and elixir).

Based on Concordia's 2015 Annual Information Form, Concordia currently, markets its Donnatal ® products as the owner of the conditionally approved abbreviated NDA for Donnatal® and as a party to the unresolved Notice of Opportunity Hearing for anticholinergic and barbiturate combination drug products. Donnatal® is included in the FDA DESI review program. The DESI program was created, in part, to require the FDA to conduct a retrospective evaluation of the effectiveness of drug products that were approved as safe between 1938 and 1962 through the new drug approval process. According to the DESI program, drugs approved before October 10, 1962, were reviewed to evaluate whether there was substantial evidence of their effectiveness. When a review was completed, the FDA would issue a DESI notice describing the marketing conditions for the class of drug products covered by the notice.

Donnatal® has been approved for safety but not for efficacy for its labeled uses. As a DESI drug, Donnatal® is classified as "possibly effective" as an adjunctive therapy in the treatment of IBS (irritable colon, spastic colon, and mucous colitis)

and acute enterocolitis. Donnatal® may also be useful as adjunctive therapy in the treatment of duodenal ulcer. It has not been shown conclusively whether articholinergic/antispasmodic drugs aid in the healing of duodenal ulcers, decrease the rate of recurrences or prevent complications. Donnatal® slows the natural movements of the gut by relaxing the mucous in the stomach and intestines and acts on the brain to produce a calming effect.

The FDA has said that all products marketed as drugs under the DESI Program are new drugs, requiring FDA approval of an NDA or an abbreviated NDA for marketing. The agency has issued guidance that outlines its priorities for enforcement action relating to a particular drug's effect on public safety and other factors. The FDA has used enforcement discretion concerning many DESI drugs, particularly where there is a pending hearing on a final determination regarding efficacy that has not yet been made. There is a long and complicated regulatory history involving Donnatal®, but currently there is an open hearing request for anticholinergic and barbiturate combination drug products, of which Donnatal® is one. While Concordia is ultimately responsible for regulatory compliance as the application holder, if the FDA convenes a hearing and concludes the product has not been shown to be effective, it may take enforcement action, including requiring Donnatal® to be removed from the market.

Market and Competition

According to reports by Saito YA. *et al.* published in 2002 in The American Journal of Gastroenterology and by Lovell RM *et al.*, published in 2012 in Clinical Gastroenterology and Hepatology, it is estimated that at least 30 million Americans may suffer from IBS. The U.S. potential market for IBS treatments is estimated by EvaluatePharma to exceed $2.4 billion by 2018. According to Concordia International Corp. Investor Presentation from October 2016, Donnatal® accounted for 7.7% of Concordia's consolidated revenues in the first half of 2016.

According to Medi-Span Price Rx® Pro service, a third party is distributing an unapproved generic version of Donnatal® in the U.S. Concordia International Corp. reported in its third quarter 2016 Management's Discussion and Analysis report (dated November 7, 2016) that it had commenced a lawsuit against the third party and its principal owner claiming damages from such conduct.

According to GlobalData, antispasmodic drugs, such as Donnatal®, are commonly prescribed as first-line therapies for IBS patients. There are several competing antispasmodic drugs indicated for the treatment of IBS on the U.S. market, including formulations of hyoscyamine sulfate, one of the active ingredients in Donnatal®. Hyoscyamine sulfate is marketed in generic form and also under the brand names Levsin® and Nulev® (by Meda Pharmaceuticals Inc.). Another competing drug which includes both antispasmodic and a sedative activity, as Donnatal® does, is a fixed-dose combination of chlordiazepoxide and clidinium bromid marketed in generic form and under the brand name Librax® (by Valeant). An additional competing anticholinergics/antispasmodics drug is dicyclomine hydrochloride, marketed in generic form and under the brand name Bentyl® (by Allergan Inc.).

Additional competing drugs in the U.S. include Linzess® (Ironwood Pharmaceutical Inc. and Allergan Inc.) and Amitiza® (Takeda Pharmaceuticals U.S.A) which are used as second-line treatments in patients with IBS with constipation ("IBS-C"), and Xifaxan® (Valeant), Viberzi® (Ironwood Pharmaceutical Inc. and Allergan Inc.) and Lotronex® (Sebela Pharmaceuticals) which are used as second or third-line therapies for patients with IBS-D. Antidepressants, mainly tricyclic antidepressants and selective serotonin reuptake inhibitors, are also used as second or third-line treatments in patients with IBS. There are several drugs in late-stage clinical development for IBS.

Termination of Rights in RP101 and RHB-101

RP101

On August 13, 2014, we entered into a binding exclusive option agreement with RESprotect GmbH, a German company, granting us an option to acquire the oncology therapeutic candidate RP101 and the next generation compounds. On February 23, 2017, we provided RESprotect a notice of termination of the option agreement, clarifying that we would not exercise or extend the option to acquire RP101 and thus terminated the exclusive option agreement for RP101.

RHB-101

On November 18, 2009, we entered into an exclusive license 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 a therapeutic candidate

containing the active ingredient "carvedilol", named by us "RHB-101". On January 23, 2017, we provided Egalet a/s a notice of termination of the exclusive license agreement for RHB-101.

Acquisition and License Agreements

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

On August 11, 2010, we entered into an asset purchase agreement with Giaconda Limited, a publicly traded Australian company, pursuant to which Giaconda Limited transferred all of its patents, tangible assets, production files, regulatory approvals and other data related to the "Myoconda", "Heliconda" and "Picoconda" products to us. We renamed these products RHB-104, RHB-105 and RHB-106, respectively. Giaconda Limited further transferred to us products in process, product samples and raw materials, as well as certain rights of first refusal with respect to intellectual property in relation to digestive condition treatments. The agreement excluded the transfer of the rights to two 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 may be required for the research, development, manufacture, registration, import/export, use, commercialization, distribution, sale or offer for sale of any of RHB-104, RHB-105 and RHB-106, Giaconda Limited granted us an exclusive worldwide assignable right to such intellectual property for such purposes. The closing of this transaction occurred on August 26, 2010.

We paid Giaconda Limited $500,000 in consideration for the assets purchased by us. 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, the developer of the products, nor any of 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 will 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, or other reasons beyond our control will not constitute a breach of this obligation. Should we breach this obligation with respect to the development of any of the products, and fail to cure the breach within 90 days from the date that Giaconda Limited sends us a default notice, Giaconda Limited may buy back all of the intellectual property rights with respect to such product for the original purchase price, plus the related development costs incurred by us through the date of the buy-back.

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

License Agreement for BEKINDA®

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

License Agreement for YELIVA®

On March 31, 2015 we entered into an exclusive license agreement with Apogee, a privately-held biotech company located in Hummelstown, Pennsylvania, U.S., under which Apogee granted us the exclusive, world-wide development and commercialization rights to ABC294640 (which we then renamed to YELIVA®) and additional intellectual property rights. YELIVA® is a proprietary, first-in-class, orally-administered SK2 inhibitor, with anti-inflammatory and anti-cancer activities, targeting multiple inflammatory, GI and oncology indications. Under the terms of the agreement, we agreed to pay Apogee an upfront payment of $1.5 million, as well as an additional amount of $2 million which will be paid on the earlier of (i) a specific date or (ii) reaching a specific development milestone. In addition, we undertook to pay up to an additional $2 million in potential development milestone payments and potential tiered royalties starting in the low double-digits. Such potential royalties are due until the later of: (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2016, we paid Apogee the initial amount of $1.5 million and recognized an amount of $2 million as a current liability. The license agreement will stay in effect as of its effective date unless terminated earlier as described in the agreement. We are entitled to terminate the agreement at any time upon 30 days' prior written notice to Apogee. The agreement also provides for the right of termination for each party in the event of a material breach committed by the other party.

License Agreement for MESUPRON

On June 30, 2014, we entered into an exclusive license agreement with Wilex AG ("Wilex"), a German biopharmaceutical company focused on oncology, under which Wilex granted us the exclusive worldwide (excluding China, Hong Kong, Taiwan and Macao) development and commercialization rights for all indications to MESUPRON, a small molecule, proprietary, 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 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, which we call RIZAPORT®.

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

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

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

The joint development of the product is to be conducted through a steering committee, comprised of an equal number of members appointed by us and IntelGenx Corp. The committee is charged with supervising progress of our research and development efforts, reporting on possible delays and deciding on required revisions in the plan. IntelGenx Corp. has the deciding vote in any vote relating to issues of development, regulation and manufacture, while we have the deciding vote

in any vote relating to issues of licensing, commercialization and collaborations. In consideration for the license, we made up-front and milestone payments in the aggregate amount of $800,000 and we are required to make additional milestone payments of up to $500,000 upon receipt of FDA marketing approval for the product.

Under the agreement, after recovery of certain costs and expenses, the Company will pay 60% royalties on sublicense revenues, less certain deductible amounts, as detailed in the agreement, for the first $2 million of such revenues. For revenues beyond the $2 million, the Company will pay royalties at 20% - 40% of the Company's revenues, after recovery of certain costs and expenses as detailed in the agreement. The 20% rate also applies until the Company recovers additional fees covered by the Company, as detailed in the agreement.

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. Additionally, we may terminate the agreement for convenience upon providing thirty (30) days written notice to IntelGenx Corp.

On February 18, 2016, the parties agreed that IntelGenx Corp. will manufacture RIZAPORT® for regulatory and commercial purposes and the parties have set allocation of certain costs associated with the manufacturing of RIZAPORT® for the obtainment of regulatory approval for marketing.

License Agreement for MAP diagnostic test related to RHB-104

On September 18, 2011, we entered into a license agreement with the UCF 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 UCF, from whom consent may not be unreasonably withheld.

To date, in consideration for the license, we have made payments in the aggregate amount of $125,000, and are required to make additional annual minimum royalty payments of $35,000 in each subsequent year until the last patent covered by the agreement expires. These annual minimum payment amounts will be deducted from future royalty payments.

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

The agreement will remain in force on a country by country basis until the last patent covered by the agreement expires. UCF 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 UCF.

Additional License Agreements related to MAP diagnostic test for RHB-104

We are developing a diagnostic test for MAP in conjunction with Q Squared, University of Minnesota and Baylor College of Medicine. This 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.

Exclusive License Agreement with Valeant Pharmaceuticals International, Inc.

On February 27, 2014, we entered into a worldwide exclusive license agreement with Salix (now Valeant), pursuant to which Salix licensed the worldwide exclusive rights to our RHB-106 encapsulated formulation for bowel preparation and

rights to other purgative developments. Pursuant to the agreement, we granted Salix the right to develop and commercialize RHB-106 or the related rights.

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

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

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

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

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

Master Service Agreement with 7810962 Canada Inc.

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

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

Furthermore, pursuant to the agreement, the Canadian service provider may provide us with a discount to the research and development services with respect to incentives programs from various authorities that may be granted to the Canadian service provider in the future. As of December 31, 2016, the estimated discount we will receive from our Canadian service provider is approximately $0.2 million.

Clinical Services Agreements

Clinical Services Agreement related to RHB-104

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

Pursuant to this agreement and subsequent amendments, inVentiv Health is entitled to receive $14.0 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 $6.1 million. The payments will be spread over the period of the clinical trial based upon quarterly administration fees and milestone payments based on patient recruitment, completion of subject dosing and report preparation, investigators grants paid to research centers that participate in the trial, as well as reimbursements of certain expenses. These fees, however, are partial costs for the RHB-104 program and may increase 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 and additional service providers, including other clinical research organizations.

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.

Co-Promotion Agreement

On December 30, 2016, we entered into a Co-Promotion Agreement with a subsidiary of Concordia, an international specialty pharmaceutical company focused on generic and legacy pharmaceutical products and orphan drugs, as part of our strategic initiative to become a revenue-generating, GI-focused, specialty pharmaceutical company with a commercial presence in the U.S. to support potential future commercialization of our therapeutic candidates. In connection with the Co-Promotion Agreement and such strategic initiative, we formed Redhill Biopharma Inc., a wholly-owned subsidiary, in the state of Delaware on January 19, 2017. We intend to pursue our commercial activities in the U.S. through this subsidiary.

Under the Co-Promotion Agreement, we will be responsible for certain promotional activities related to Donnatal® in the U.S., and Concordia will continue to be responsible for, among other things, the manufacturing and supply and pricing of Donnatal® in all territories. We and Concordia will share the revenues generated from the promotion of Donnatal® by us based upon an agreed upon split. There are no upfront or milestone payments required to be paid by us under the Co-Promotion Agreement. The initial term of the Co-Promotion Agreement is three years. We may terminate the Co-Promotion Agreement after six months from the effective date of the Co-Promotion Agreement upon three months' notice for reasons set forth in the Co-Promotion Agreement. Concordia may terminate the Co-Promotion Agreement after an agreed upon period and for reasons set forth in the Co-Promotion Agreement. We expect to initiate gradual promotion of Donnatal® in the coming months.

Intellectual Property

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

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

RHB-105

RHB-105 is protected by two patent families. The first patent family, titled "Improved Method of Eradication of *H. pylori*", was acquired as part of our asset purchase agreement with Giaconda Limited, and provides patent protection until 2019. This family includes one U.S. patent and over 15 foreign patents.

The second patent family, titled "Pharmaceutical Compositions for the Treatment of Helicobacter Pylori", was filed by us and will provide patent protection until 2034. This family includes two U.S. patents, one pending U.S. patent application, and over 15 pending foreign patent applications.

RHB-104 – Inflammatory Bowel Disease

RHB-104 for Inflammatory Bowel Disease is protected by two patent families. The first patent family, titled "Methods and Compositions for Treating Inflammatory Bowel Disease", was acquired as part of our asset purchase agreement with from Giaconda Limited, and provides patent protection until 2018. This family includes one U.S. patent and over 20 foreign patents.

The second patent family, titled "Method and Composition for Treating Inflammatory Bowel Disease", was filed by us and will provide patent protection until 2029. This family includes four U.S. patents, one pending U.S. patent application, six foreign patents and two pending foreign patent applications.

We have also in-licensed from UCF U.S. Patent No. 7,488,580 entitled "Protocol for Detection of *Mycobacterium Avium Subspecies Paratuberculosis* in Blood", which will expire in 2026. This patent relates to a method of diagnosing inflammatory bowel disease caused by MAP using a sample of peripheral tissue. In addition, inflammatory bowel disease caused by MAP can be monitored and evaluated.

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

RHB-104 – Multiple Sclerosis ("MS")

Another patent family that we filed relates to "A Composition and Method for Treating an Autoimmune Disease" and covers compositions comprising effective amounts of rifabutin, clarithromycin and clofazimine to enable treatment of MS. This patent family will provide patent protection for methods of treating MS, with RHB-104, up until 2032. This family includes one pending U.S. patent application and over 15 pending foreign patent applications.

BEKINDA® - Gastritis, Gastroenteritis, IBS-D and Oncology Support

We have in-licensed a patent from Temple University entitled "Monolithic tablet for controlled drug release", with a U.S. patent expiry date in 2018. This patent relates to formulations based on a swellable hydrodynamically balanced monolithic matrix.

BEKINDA® and its use in treating gastroenteritis and other conditions is protected by two patent families that were filed by us, titled "Antiemetic Extended Release Solid Dosage Forms" and "Ondansetron Extended Release Solid Dosage Forms for Treating Either Nausea, Vomiting or Diarrhea Symptoms", and if issued would provide patent protection through 2034 and 2035, respectively. This family includes three pending U.S. patent applications and over 35 foreign patent applications.

RHB-106 - Colonic Evacuation

We acquired from Giaconda Limited, as part of our asset purchase agreement, two patent families titled "Picosulfate-containing preparation for colonic evaluation" and "Administering osmotic colonic evacuant containing a picosulfate", both of which expired in 2016. These patents did not protect our RHB-106 colonic formulation.

The RHB-106 colonic formulation is protected by a patent family filed by us and entitled "Formulations and Methods of Manufacturing Formulations for use in Colonic Evacuation". If issued, this patent will provide protection until 2033.

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

YELIVA® - Inflammatory, Oncology, and GI Indications

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

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

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

MESUPRON – Oncology

This patent portfolio was in-licensed by us from Wilex. MESUPRON is a first-in-class uPA inhibitor administered by oral capsule.

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

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

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

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

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

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

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

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

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

RIZAPORT® - Acute Migraines

We have in-licensed from IntelGenx Corp., three issued U.S. patents, three pending U.S. non-provisional patent applications, and 15 pending international patent applications covering various aspects of the VersaFilm™ technology. U.S. Patent No. 9,301,948, which provides patent protection through 2034, covers our RIZAPORT® product. Fifteen (15) foreign counterpart patent applications are currently pending.

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 EMA. The manufacture, clinical trials, distribution, marketing and sale of pharmaceutical products are subject to government regulation in the U.S. and various foreign countries. To manufacture both new therapeutic drug candidates for clinical trials and approved therapeutic drugs for sale and distribution in the U.S., we must follow rules and regulations in accordance with current cGMP codified in 21 CFR 210 and 211. Additionally, we are responsible for ensuring that the API in of each therapeutic drug or therapeutic drug candidate is manufactured in accordance to the International Conference on Harmonization ("ICH") Q7 guidance that has been adopted by the FDA. Further, we are required to conduct clinical trials that present data indicating that our therapeutic drug candidates are safe and efficacious in accordance with current good clinical practice and codified in 21 CFR 312. If we do not comply with applicable requirements, we may be fined, the government may refuse to approve our marketing applications or not allow us to manufacture or market our products, and we may be criminally prosecuted. We and our contract manufacturers and clinical research organizations may also be subject to regulations under other federal, state and local laws, including, but not limited to, the U.S. Occupational Safety and Health Act, the Resource Conservation and Recovery Act, the Clean Air Act and import, export and customs regulations as well as the laws and regulations of other countries. The U.S. government has increased its enforcement activity regarding illegal marketing practices domestically and internationally. As a result, pharmaceutical companies must ensure their compliance with the Foreign Corrupt Practices Act and federal healthcare fraud and abuse laws, including the False Claims Act.

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

U.S. Food and Drug Administration ("FDA") Approval Process for New Molecular Entities

Our therapeutic drug candidates are classified as New Molecular Entities. The steps required to be taken before therapeutic drug candidate may be marketed in the U.S. generally include:

- completion of pre-clinical laboratory and animal testing;
- the submission to the FDA of an investigational new drug, or IND, application which must be evaluated and found acceptable by the FDA before human clinical trials may commence;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product candidate for its intended use; and
- the 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 therapeutic drug candidate generally is conducted in three sequential phases prior to approval, but the phases may overlap or be combined. However, safety information should be submitted before initiation of a subsequent clinical phase. A fourth, or post approval, phase may include additional clinical studies. The phases are generally as follows:

Phase I. In Phase I clinical studies, the therapeutic drug candidate is tested in a small number of healthy volunteers, though in cases where the therapeutic drug candidate may make the volunteer ill, clinical patients with the targeted condition may be used. These "dose-escalation" studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the therapeutic drug candidate in humans, side effects associated with increasing doses, and, in

some cases, to gain early evidence on efficacy. The number of participants included in Phase I studies is generally in the range of 20 to 80.

Phase II. In Phase II studies, in addition to safety, the sponsor evaluates the efficacy of the therapeutic drug 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 and involve control groups taking a reference compound or a placebo (an inactive compound identical in appearance to the study compound). 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 may be required of, or agreed to by, a sponsor after the FDA has approved a therapeutic drug candidate 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 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. The FDA recommends that data safety monitoring board should be used to perform regular interim analysis for long-term clinical studies where safety concerns may be unusually high. 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 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 therapeutic drugs and therapeutic drug candidates and their respective API are subject to requirements that drugs be manufactured, packaged and labeled in conformity with cGMP. In addition to our third-party API manufacturers, we are responsible for ensuring that our third-party excipient manufacturers conform to cGMP requirements. 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 a 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 ten months

of a completed 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 six months of a completed NDA submission. However, PDUFA goal dates are not legal mandates and the FDA response may occur several months beyond the original PDUFA goal date. Further, the review process and the target response date under PDUFA may be extended if the FDA 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 or any advisory committee it appoints may interpret data differently than the applicant.

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

If the FDA approves one of our therapeutic drug candidates, we will be required to comply with a number of post-approval regulatory requirements. We would be required to report to the FDA, among other things, certain adverse reactions and production problems, and 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 therapeutic drug, such as certain manufacturing changes, we may need the FDA to review and approve 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. At their discretion, physicians may prescribe approved pharmaceutical products for indications that pharmaceutical products have not been approved for use by the FDA. However, we may not label or promote pharmaceutical products for an indication that has not been approved. Securing FDA approval for new indications of an approved therapeutic drug requires a Section 505(b)(2) filing, 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 therapeutic drugs, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA, somewhat similar to the process for approval of the original indication or reference drug 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. Section 505(b)(2) of the Food, Drug, and Cosmetic Act, 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) was enacted to allow a company to avoid duplicative testing by permitting the applicant to leverage previously performed pertinent clinical and non-clinical studies into the current NDA submission. Some examples of therapeutic drugs candidates that may be allowed to follow a 505(b)(2) path to approval are candidates that have a new dosage form, strength, route of administration, formulation or indication.

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

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

Orphan Drug Designation

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

GAIN Act

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

C. Organizational Structure

Our wholly-owned and only subsidiary, Redhill Biopharma Inc., was incorporated in Delaware on January 19, 2017.

D. Property, Plant and Equipment

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

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

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

Company Overview

We are a specialty biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of GI and inflammatory diseases and cancer.

Depending on the specific development program, our therapeutic candidates are designed to provide improvements over existing drugs by improving their safety profile, reducing side effects, lowering the number of daily administrations, using a more convenient administration form, providing a cost advantage 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 development pipeline consists of seven late clinical development therapeutic candidates. In addition, we were recently granted certain rights to promote Donnatal®, for certain territories in the U.S., a specialty GI product currently included in the FDA DESI review program, as part of our strategy to build our own marketing and commercialization capabilities in the U.S., among others, to support potential future commercialization of our therapeutic candidates.

We have funded our operations primarily through public and private offerings of our securities. Because our therapeutic candidates and products are currently in development, and because we plan to commence promotion of Donnatal® in the coming months with no anticipation for significant revenues or profits in the near future, we cannot estimate when and if we will generate significant revenues or profits in the future from our therapeutic candidates, products or Donnatal®.

The following is a description of our seven therapeutic candidates and Donnatal®:

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

RHB-104 is a patented combination of three antibiotics (i.e. clarithromycin, clofazamine and rifabutin) in a single capsule that is intended for the treatment Crohn's disease and potentially other autoimmune diseases such as MS. 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 proprietary once-daily controlled release oral formulation of ondansetron, in combination with salts, intended for the prevention of chemotherapy and radiotherapy induced nausea and vomiting, by means of an oral formulation of ondansetron. BEKINDA® is anticipated to prevent chemotherapy and radiotherapy induced nausea and vomiting over a time frame of approximately 24 hours. On May 2, 2010, we received a worldwide, exclusive and perpetual license to use patents and know-how relating to BEKINDA® from SCOLR Pharma, Inc. in exchange for an up-front payment of $100,000, future potential milestone payments of up to $500,000 and future royalties, for a fixed period of time as determined under the agreement, of 8% of our net sales or sublicense fees. SCOLR 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 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 proprietary formulation in tablet form intended for the preparation and cleansing of the GI tract prior to the performance of abdominal procedures. We acquired ownership rights in patents, tangible assets, production files and regulatory approvals and other data and rights in certain third-party agreements related to RHB-106 pursuant to the Asset Purchase Agreement with Giaconda Limited described above. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Acquisition of RHB-104, RHB-105 and RHB-106." On February 27, 2014, we entered into a licensing agreement with Salix (later acquired by Valeant) by which Salix licensed the exclusive worldwide rights to our RHB-106 encapsulated formulation for bowel preparation, and rights to other purgative developments.

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

MESUPRON is a patent-protected protease inhibitor, administered by oral capsule, targeting GI and other solid tumor cancers. On June 30, 2014 we acquired from Wilex 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."

RIZAPORT® (RHB-103) is a patented oral thin film formulation of rizatriptan intended for the treatment of acute migraine headaches. On August 26, 2010, we entered into a joint development and commercialization agreement with IntelGenx Corp. pursuant to which IntelGenx Corp. granted us a worldwide, exclusive and perpetual license to use RIZAPORT® and to grant sublicenses. In consideration for the license, we made up-front and milestone payments in the aggregate amount of $800,000 and are required to make additional milestone payments of up to $500.000. In addition, we are required to make royalty payments to IntelGenx Corp., after recovery of certain costs and expenses, of 60% royalties on sublicense revenues, less certain deductible amounts as detailed in the agreement, for the first $2 million of such revenues. For revenues beyond the $2 million, we will pay royalties at 20% - 40% of our revenues from the therapeutic candidate, after recovery of certain costs and expenses as detailed in the agreement. The 20% rate also applies until we recover additional fees covered by us as detailed in the agreement. The term of the agreement is for an indefinite period and is subject to certain termination rights.

See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – License Agreement for RIZAPORT®."

Donnatal® is a prescription oral drug used in the treatment of IBS. On December 30, 2016, we entered into the Co-Promotion Agreement with a subsidiary of Concordia, pursuant to which we were granted certain rights to promote Donnatal® in the U.S.. We expect to initiate gradual promotion of Donnatal® in the coming months.

JOBS Act

We are an emerging growth company. As an "emerging growth company", we have 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, 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 2016 we recorded revenues with respect to RIZAPORT®, for which we have received marketing approval in Germany and have entered into exclusive license agreements to commercialize in Spain and South Korea. In 2015 we recorded non-significant revenues in connection with royalty payments received from a third-party licensee of limited rights to a patent that we acquired from Giaconda Limited. In 2014, for the first time, we had meaningful revenues as a result of our licensing agreement with Salix with respect to RHB-106 and related rights.

Cost of Revenues

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

Research and Development Expenses

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

General, Administrative Expenses and Business Development

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

Financial Income and Expense

Financial income and expense consists of non-cash financing expenses in connection with changes in the fair value of derivative financial instruments, 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 against other currencies, in which a portion of our assets and liabilities are denominated like NIS, for example.

Critical Accounting Policies and Estimates

The preparation of financial statements, in conformity with 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 asset's carrying amount exceeds its recoverable amount. The recoverable amounts of cash generating units are based on our estimates as to the development of the therapeutic candidates, changes in market scope, market competition and timetables for regulatory approvals. Since the above require certain judgments and the use of estimates, actual results may differ from our estimations and as a result would increase or decrease our related actual results.

Recent Accounting Pronouncements

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

A. Operating Results

History of Losses

Since inception in 2009, we have generated significant losses mainly in connection with the research and development of our therapeutic candidates. Such research and development activities are expected to expand over time and will require further resources. 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, 2016, we had an accumulated deficit of approximately $89.6 million.

We expect to continue to fund our operations over the next several years through public or private equity offerings, debt financings, commercialization of our therapeutic candidates, products we may sell or market, or through revenues from marketing of Donnatal®.

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.

Three Months Ended

	March 31	June 30	Sep. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31	March 31	June 30	Sep. 30	Dec. 31
Statements of operations	2014				2015				2016			
Revenues	7,005	4	4	1	1	1	1	—	—	1	—	100
Cost of revenue	1,050	—	—	—	—	—	—	—	—	—	—	—
Research and development expenses, net	1,736	3,157	4,103	3,704	3,829	5,090	3,901	4,951	4,676	6,031	7,038	7,496
General, administrative and business development expenses	1,027	961	912	1,111	927	801	692	1,714	1,227	1,164	1,416	1,596
Other (income) expenses	(100)	—	—	—	—	—	—	100	—	—		
Operating loss (income)	(3,292)	4,114	5,011	4,814	4,755	5,890	4,592	6,765	5,903	7,194	8,454	8,992
Financial income	89	133	415	—	286	167	1,420	235	380	666	109	1,013
Financial expenses	4	543	(360)	514	173	873	120	30	1	24	599	370
Net loss (income)	(3,377)	4,524	4,236	5,328	4,642	6,596	3,292	6,560	5,524	6,552	8,944	8,349

Our quarterly revenues and operating results 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, 2016 to the Year Ended December 31, 2015

Revenues

Revenues for the year ended December 31, 2016 were $0.1 million, compared to immaterial revenues for the year ended December 31, 2015. The revenues in the year ended December 31, 2016 were licensing revenues regarding RIZAPORT®.

Research and Development Expenses

Research and development expenses for the year ended December 31, 2016 were approximately $25.2 million, an increase of $7.4 million, or approximately 42%, compared to $17.8 million for the year ended December 31, 2015. The increase resulted primarily from the ongoing Phase III MAP US study with RHB-104 (Crohn's disease), the ongoing Phase III and Phase II studies with BEKINDA® (acute gastroenteritis and IBS-D, respectively) and from several Phase I/II studies with YELIVA® for multiple indications.

General, Administrative and Business Development Expenses

General, administrative and business development expenses for the year ended December 31, 2016 were approximately $5.4 million, an increase of $1.3 million, or approximately 32%, compared to $4.1 million for the year ended December 31, 2015. The increase was mainly due to an increase in professional services, enhanced business development, investor relations activities and operating expenses.

Operating Loss

Operating loss for the year ended December 31, 2016 was approximately $30.5 million, compared to $22.0 million for the year ended December 31, 2015. The increase was mainly due to an increase in research and development expenses, as detailed above.

Financing Income and Expenses

We recognized financial income, net of $1.2 million for the year ended December 31, 2016, compared to financial income, net of $0.9 million for the year ended December 31, 2015. The increase was mainly related to a fair value gain on derivative financial instruments.

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

Revenues and Cost of revenues

Revenues for the year ended December 31, 2015 were immaterial in connection with payments received from a third-party licensee of limited rights to a patent that we acquired from Giaconda Limited compared to $7 million for the year ended December 31, 2014 from the Salix transaction.

Research and Development Expenses

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

General and Administrative Expenses

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

Operating Loss

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

Financing Income and Expenses

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

B. Liquidity and Capital Resources

Liquidity and Capital Resources

Our therapeutic candidates are in research and development stage, and therefore, we 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. In December 2016, we entered into the Co-Promotion Agreement with Concordia, pursuant to which we were granted certain rights to promote Donnatal® in the U.S. As of December 31, 2016, we had approximately $66.2 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 TASE of 14,302,300 Ordinary Shares and 7,151,150 tradable Series 1 Warrants. Each tradable Series 1 Warrant was exercisable into one Ordinary Share. By February 2, 2014, the tradable Series 1 Warrants 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 per share, depending on the date of exercise. By January 10, 2015, the warrant expiration date, 682,200 warrants had been exercised for an aggregate amount of approximately $1.0 million. The remaining 2,558,440 unexercised warrants expired.

On January 8, 2014, we issued in a private placement a total of 894,740 units, each unit 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 an aggregate of 357,896 ADSs, 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 10, 2017, warrants to purchase an aggregate of 252,632 ADSs were exercised for aggregate proceeds of approximately $2.63 million, and the unexercised warrants expired.

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 an aggregate of 4,183,496 Ordinary Shares at an exercise price of NIS 4.9 per share, linked to changes in the NIS-U.S. 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, among others were Migdal Insurance Company, Yelin Lapidot, Excellence Nessuah and Sphera Global Healthcare Master Fund. On January 21, 2017, all of these warrants expired unexercised.

On February 27, 2014, we entered into a Worldwide Exclusive License Agreement with Salix (now Valeant), pursuant to 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 "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements – Exclusive License Agreement with Valeant Pharmaceuticals International, Inc."

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

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

On December 27, 2016, we sold 2,250,000 ADSs and warrants to purchase 1,125,000 ADSs in an underwritten public offering for gross proceeds of approximately $23 million. Concurrent with the underwritten public offering, we sold 1,463,415 ADSs and warrants to purchase 731,708 ADSs in a concurrent registered direct offering in the U.S. for gross proceeds of approximately $15 million. The offering price in both offerings was $10.25 for a fixed combination of one ADS and a warrant to purchase 0.5 of an ADS. The warrants in both offerings have a per ADS exercise price of $13.33 and have a term of three years. In addition, on December 27, 2016, the underwriters partially exercised their option and purchased warrants to purchase 168,750 ADSs for a purchase price of $0.0047 per warrant. On January 3, 2017, the underwriters partially exercised their option and purchased 133,104 ADSs. Following the second partial exercise of the underwriters' option, our underwritten public offering and the concurrent registered direct offering totaled 3,846,519 ADSs and warrants to purchase 2,025,458 ADSs, representing aggregate gross proceeds from both offerings combined of approximately $39.4 million before deducting underwriting discounts and commissions, placement agent fees and other offering expenses.

We estimate that so long as no significant revenues are generated from our therapeutic candidates or from out-licensing transactions or from marketing of Donnatal®, 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 and products we may sell or market, including securing commercialization agreements with third parties and favorable pricing and market share;
- the progress, success and cost of our clinical trials and research and development programs;
- the costs, timing and outcome of regulatory review and obtaining regulatory approval of our therapeutic candidates and addressing regulatory and other issues that may arise post-approval;
- the costs of enforcing our issued patents and defending intellectual property-related claims;
- the costs of developing sales, marketing and distribution channels;
- consumption of available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated; and
- we may consume available resources more rapidly than currently anticipated, resulting in the need for additional funding sooner than anticipated.

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

Cash Flow

Operating activities

For the year ended December 31, 2016, net cash flow used in operating activities was approximately $28.2 million, compared to approximately $17.8 million for the year ended December 31, 2015 and $12.2 million for the year ended December 31, 2014. The increase in net cash flow used in operating activities was a direct result of the increase in our operations, reflected by increased research and development activities and increased general, administrative and business development expenses.

Investment activities

Net cash flow provided by investing activities for the year ended December 31, 2016 was approximately $24.5 million, compared to approximately net cash flow used in investing activities of $21.2 million in the year ended December 31, 2015 and $17.9 million in the year ended December 31, 2014. For the year ended December 31, 2016, a total of $36.8 million change in bank deposits and $12.2 million in purchase of financial assets at fair value through profit or loss. For the year ended December 31, 2015, we invested a total of $19.5 million in bank deposits and $1.6 million in purchasing of intangible assets. For the year ended December 31, 2014, we invested a total of $17 million in bank deposits and $1.0 million in purchasing of intangible assets.

Financing activities

Net cash flow provided by financing activities for the year ended December 31, 2016 amounted to approximately $36 million, compared with approximately $54.8 million for the year ended December 31, 2015 and $24.4 million for the year ended December 31, 2014. For the year ended December 31, 2016, most of the cash from financing activities resulted from the underwritten public offering and the concurrent registered direct offering for a total net amount of $35.8 million. In 2015, most of the cash flows from financing activities resulted from the two underwritten public offerings for a total net amount of $54.7 million. In 2014, most of the cash flows from financing activities resulted from the January 2014 private placements for a total net amount of $19.4 million and from the exercise of warrants for a net amount of $5.0 million.

We did not have any material commitments for capital expenditures, including any anticipated material acquisition of plant and equipment or interests in other companies, as of December 31, 2016.

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.

	2016	2015	2014
Payroll and related expenses	0.7	0.6	0.6
Professional services	1.8	2	1.7
Share-based payments	0.8	0.9	0.9
Clinical trials, net	20.7	13.4	8.5
Intellectual property development	0.4	0.2	0.6
Other	0.8	0.7	0.4
Total	25.2	17.8	12.7

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, rate of patient recruitment 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 or our development or commercialization partners are unable to obtain or maintain FDA or other foreign regulatory clearance and approval for our therapeutic candidates or products we may sell or market, we or our commercialization partners will be unable to commercialize our therapeutic candidates or products we may sell or market."

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 substantial revenues from our projects.

D. Trend Information

We are a specialty biopharmaceutical company primarily focused primarily on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of GI and inflammatory diseases and cancer.

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. In December 2016, we were granted certain rights to promote Donnatal® in the U.S., a specialty GI product currently included in the FDA DESI review

program, which is part of our goal to build our own marketing and commercialization capabilities to support future commercialization of our therapeutic candidates.

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, 2016:

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
	(U.S. dollars in thousands)				
	(Unaudited)				
Office lease obligations	1,141	370	771	—	—
Accounts payable and accrued expenses	3,356	3,356	—	—	—
Payable in respect of intangible asset purchase	2,000	2,000	—	—	—
Total	6,497	5,726	771	—	—

The foregoing table does not include our in-license agreements with Temple University, IntelGenx Corp., Wilex, Apogee, our asset sale agreement with Giaconda Limited and our agreement with UCF or University of Minnesota, pursuant to which we are obligated to make various payments upon the achievement of agreed upon milestones or make certain royalty payments since we are unable to currently estimate the actual amount or timing of these payments. If all of the milestones are achieved over the life of each in-licensing agreement, we will be required to pay, in addition to the amounts in the above table and royalties on our net income, an aggregate amount of approximately $3.1 million for milestones achieved. All of our in-licensing agreements are terminable at-will by us upon prior written notice. See "Item 4. Information on the Company – B. Business Overview – Acquisition and License Agreements."

The foregoing table does not include our manufacturing agreements pursuant to which we are obligated to make various payments upon the achievement of agreed upon milestones. We are unable to currently estimate the actual amount or timing of these payments. If all of the milestones are achieved over the life of the manufacturing agreements, we will be required to pay, in addition to the above table and royalties on our net income, an aggregate amount of approximately $2.4 million. All of our manufacturing agreements are terminable at-will by us upon short prior written notice.

The foregoing table also does not include payments payable under our clinical services agreements, all of which are contingent upon the completion of milestones. See "Item 4. Information on the Company – B. 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	51	Chief Executive Officer and Chairman of the Board of Directors
Micha Ben Chorin	48	Chief Financial Officer
Reza Fathi, Ph.D.	62	Senior Vice President Research and Development
Gilead Raday	42	Chief Operating Officer
Adi Frish	47	Senior Vice President Business Development and Licensing
Guy Goldberg	41	Chief Business Officer
Uri Hananel Aharon	36	Chief Accounting Officer
Directors		
Dr. Shmuel Cabilly (2)	67	Director
Eric Swenden	72	Director
Dr. Kenneth Reed	63	Director
Dan Suesskind (1)	73	Director
Rick D. Scruggs	57	Director
Ofer Tsimchi (1), (2)	57	Director
Nurit Benjamini (1), (2)	50	Director
Nicolas A. Weinstein (3)	35	Board nominee

(1) Member of our audit committee that also serves as our financial statements committee.
(2) Member of our compensation committee.
(3) Mr. Weinstein has been approved as a director nominee by our board of directors, and our shareholders will vote on his election to the board of directors at the next annual meeting of our shareholders. Currently, he serves as an observer to our board of directors.

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.. Mr. Ben-Asher is currently a director at Agrea Ltd. Mr. Ben-Asher holds an LLB from the University of Leicester, U.K., an MJur. from Oxford University, U.K. and completed LLM studies at Harvard University.

Micha Ben Chorin has served as our Chief Financial Officer since March 1, 2016. From 2014 until 2016, Mr. Ben Chorin served as Chief Financial Officer of Pyramid Analytics. From 2009 until 2013 he served as CFO of Starhome B.V., from 2005 until 2009 as CFO of Winetwors, and from 1998 until 2005 Mr. Ben Chorin served as Chief Financial Officer at GVT (currently Telefonica Brazil). Mr. Ben Chorin previously served on the boards of DIC and Petroleum & Energy Infrastructures LTD. Mr. Ben Chorin holds a B.A. from Tel Aviv University and is a Certified Public Accountant.

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, from 2000-2005, Dr. Fathi served as Director of Research at Vivoquest, Inc. where he was 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.

Gilead Raday has served as our Chief Operating Officer since April 1, 2016. From December 5, 2012 until March 31, 2016, Mr. Raday served as Senior Vice President Corporate and Product Development. 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 M.Sc. in Neurobiology from the Hebrew University of Jerusalem, Israel, and an M.Phil. in Biotechnology Management from Cambridge University, U.K.

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, U.K. and an LLM in Business Law from the Bar-Ilan University, Israel.

Guy Goldberg has served as our Chief Business Officer since 2012. From 2007 to 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.

Uri Hananel Aharon has served as our Chief Accounting Officer since 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 TASE, 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 B.A. in Accounting and Economics from the Hebrew University of Jerusalem, Israel, and an M.B.A. 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 Dr. Cabilly 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 serves as a board member at several companies, including Vidac Pharma Ltd., BioKine Therapeutics Ltd., Neuroderm Ltd., Biologic Design Ltd., and Ornim Inc. Dr. Cabilly holds a B.Sc. in Biology from the Ben Gurion University of Beer Sheva, Israel, an M.Sc. in Immunology and Microbiology from the Hebrew University of Jerusalem, Israel, and a Ph.D. 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 TBC S.A. and Alterpharma 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 M.D. PC. Dr. Reed currently serves on the board of directors of Minerva Biotechnologies Corporation. Dr. Reed received his B.A from Brown University in the U.S and a M.D from the university of Medicine and Dentistry of New Jersey in the U.S. Dr. Reed is a board certified dermatologist

with the over 25 years of clinical experience since completing the Harvard Medical School Residency Program in Dermatology. Dr. Reed is also a cofounder of Early Cell, a prenatal diagnostics company, and Prescient Pharma.

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. from 1981 to 2001 and again from 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 B.A. in Economics and Political Science from the Hebrew University of Jerusalem, Israel, and an M.B.A. from University of Massachusetts. The board of directors has determined that Mr. Suesskind is a financial and accounting expert under Israeli law.

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

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

Nurit Benjamini has served as a director on our board of directors and a chairperson of our audit committee and a member of our compensation committee since February 16, 2016 and has served on our investment committee since February 22, 2017. Since December 2013, Ms. Benjamini has served as the Chief Financial Officer of TabTale Ltd. a company that develops, designs and manufactures interactive digital content to be displayed on electronic devices and websites. From 2011 to 2013, Ms. Benjamini served as the Chief Financial Officer of Wixpress Ltd. (NASDAQ: WIX); from 2007 through 2011, she served as the Chief Financial Officer of CopperGate Communications Ltd. now Sigma Designs Israel, a subsidiary of Sigma Designs Inc. (NASDAQ: SIGM); and from 2000 through 2007, she served as the Chief Financial Officer of Compugen Ltd. (NASDAQ: CGEN). Prior to that, from 1993 through 1998, Ms. Benjamini served as the Chief Financial Officer of Aladdin Knowledge Systems Ltd. (formerly NASDAQ: ALDN). Ms. Benjamini serves as an external director of BiolineRx Ltd. (NASDAQ/TASE: BLRX), and as the chairperson of its audit committee, and on the board of directors, and as chairperson of the audit committee, of Allot Communications Ltd. (NASDAQ/TASE: ALLT). Ms. Benjamini holds a B.A. in economics and business and an M.B.A. in finance, both from Bar Ilan University, Israel.

Nicolas Weinstein has served as Managing Director of Water Bear Investments LLC, a healthcare and real estate investments services company since January 2017. From 2014 to 2015, Mr. Weinstein served as country head in Chile for Abbott Laboratories / CFR Pharmaceuticals. In 2014, Mr. Weinstein served as VP Marketing & Sales of CFR Pharmaceuticals, and from 2012 to 2013, he served as VP Business Development of CFR Pharmaceuticals. From 2008 to 2010, Mr. Weinstein served as VP Marketing & Sales of CFR Pharmaceuticals. Mr. Weinstein currently leads the healthcare and venture investments of EMC2 Fund Ltd. and its partnership interests in Olive Tree Ventures Limited Partnership (Israel) and Puma Bioventures (a U.S. biotech fund). Mr. Weinstein is a director in investee companies of EMC2, including Aquila Diagnotics, Medasense, Via Surgical, Harbo and Selfpoint. Mr. Weinstein holds an M.Sc. in Finance from Universidad Adolfo Ibanez (Chile) and an MBA from the Kellogg School of Management (2012). Mr. Weinstein has been nominated to our board of directors by EMC2 Fund Ltd. pursuant to the right granted by the Company to any investor that invests at least $15 million in the Company in our December 2016 public offering to nominate one person to our board of directors, subject to various conditions described in the prospectus the Company filed with the SEC.

B. Compensation

The aggregate compensation paid, and benefits in-kind granted to or accrued on behalf of all of our directors and executive officers for their services, in all capacities, to us during the year ended December 31, 2016 was approximately $2.5 million. Out of that amount $1.6 million was paid as salary and consultants fees, $0.5 million was attributed to the value of the options granted to senior management during 2016, approximately $0.1 million was attributed to retirement plans and $0.3 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 are derived from their employment agreements and comply with our Compensation Policy for Executive Officers and Directors as approved by our shareholders on June 8, 2016 (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, 2016. The compensation detailed in the table below refers to actual compensation granted or paid to the director or officer during the year 2016.

Name and Position of director or officer	Base Salary or Other Payment (1)	Value of Social benefits (2)	Bonuses	Value of Equity Based Compensation Granted (3)	All Other Compensation (4)	Total
	Amounts in U.S.$ dollars are based on 2016 monthly average representative U.S. dollar – NIS rate of exchange					
Dror Ben-Asher, Chief Executive Officer (5)	262,454	52,084	—	338,118	18,787	671,443
Micha Ben Chorin, CFO	162,642	46,370	—	207,458	14,784	431,254
Gilead Raday, Chief Operating Officer	218,087	28,854	40,000	—	15,262	302,203
Reza Fathi, Senior Vice President Research and Development	246,000	—	—	—	21,014	267,014
Guy Goldberg, Chief Business Officer	172,419	36,454	—	—	12,525	221,398

(1) "Base Salary or Other Payment" means the aggregate yearly gross monthly salaries or other payments with respect to the Company's Executive Officers and members of the board of directors for the year 2016.

(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 2016 in exchange for the directors and officers services recognized as an expense in profit or loss and is carried to accumulated deficit under equity. The total amount recognized as an expense over the vesting period of the options.

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

(5) Mr. Ben-Asher's employment terms as the Company's Chief Executive Officer provide that Mr. Ben-Asher is entitled to a monthly base gross salary of NIS 90,000 (approximately $24,300). 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," as defined in the Israeli Securities Law 1968, or a "holder," as defined in the Israel Securities Law 1968, of 25% or more of the voting rights in the Company. In addition, in case of an "hostile takeover", all options granted to Mr. Ben-Asher will immediately vest in full.

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

Employment Agreements

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

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

Director Compensation

We currently pay our non-executive directors an annual cash fee of NIS 83,480 (approximately $22,500) and a cash fee of NIS 4,390 (approximately $1,200) per meeting (or a smaller amount in the case where they do not physically attend the meeting).

Compensation Policy

On June 8, 2016, our shareholders approved the Compensation Policy for our directors and officers in accordance with Amendment No. 20 to the Israeli Companies Law, pursuant to which we are required to determine compensation of our directors and officers and which must be approved by our shareholders every three years. The policy was previously approved by our board of directors, upon recommendation of our compensation committee.

The Compensation Policy is in effect for three years from the 2016 annual general meeting. Our 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 our 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 five persons and no more than seven persons, excluding the external directors whose appointment is required by law. The directors who are not 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 Rick Scruggs, will hold office until our annual general meeting to be held in the year 2017. The directors of the second class, currently consisting of Dr. Kenneth Reed, and Eric Swenden, will hold office until our annual general meeting to be held in the year 2018 and the directors of the third class, currently consisting of Dr. Shmuel Cabilly and Dan Suesskind, will hold office until our annual general meeting to be held in the year 2019. 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. See "Item 6. "Directors, Senior Management and Employees – C. Board Practices – Independent and External Directors – Israeli Companies Law Requirements" below for a description of the adoption by the Company of the corporate governance exemptions set forth in Regulation 5D of the Israeli Companies Regulations (Relief for Public Companies with Shares Listed for Trading on a Stock Market Outside of Israel), 5760-2000, including with respect to external directors.

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, entry 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 chief executive officer, directors or controlling shareholders (or a relative thereof) receive the approval of the compensation committee, board of directors, and shareholders, subject to limited exceptions. The appointment and terms of office of a company's officers, other than directors and the general manager (i.e., chief executive officer) are subject to the approval by first, the company's compensation committee; second, the company's board of directors, in each case subject to the company's compensation policy, and then approved by its shareholders. However, in special circumstances, they may approve the appointment and terms of office of officers inconsistent with such policy, provided that (i) they have considered those provisions that must be included in the compensation policy according to the Israeli Companies Law and (ii) shareholder approval is obtained (by a majority of shareholders that does not include the controlling shareholders of the company and any shareholders interested in the approval of the compensation). However, if the shareholders of the company do not approve a compensation arrangement with an officer inconsistent with the company's compensation policy, in special situations the compensation committee and the board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide detailed reasons for their decision. In addition, non-material amendments to the compensation of a public company's officers (other than the chief executive officer and the directors) may be approved by the chief executive officer of the company if the company's compensation policy establishes that non-material amendments within the parameters established in the compensation policy may be approved by the chief executive officer, so long as the compensation is consistent with the company's compensation policy. An amendment to the Israeli Companies Law requires that by August 11, 2013, the board and shareholders (with approval by a "special majority" as further discussed below) adopt a compensation policy applicable to the company's directors and officers 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 are 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.

The compensation paid to a public company's chief executive officer is required to be approved by, first, the company's compensation committee; second, the company's board of directors; and third, unless exempted under the regulations promulgated under the Israeli Companies Law, by the company's shareholders (by a special majority vote as discussed above with respect to the approval of director compensation). However, if the shareholders of the company do not approve the compensation arrangement with the chief executive officer, the compensation committee and board of directors may override the shareholders' decision if each of the compensation committee and the board of directors provide a detailed report for their decision. The renewal or extension of the engagement with a public company's chief executive officer need not be approved by the shareholders of the company if the terms and conditions of such renewal or extension are no more beneficial than the previous engagement or there is no substantial difference in the terms and conditions under the circumstances, and the terms and conditions of such renewal or extension are in accordance with the company's compensation policy. The compensation committee and board of directors approval should be in accordance with the company's stated compensation policy; however, in special circumstances, they may approve compensation terms of a chief executive officer that are inconsistent with such policy provided that they have considered those provisions that must be included in the compensation policy according to the Israeli Companies Law and that shareholder approval was obtained (by a special majority vote as discussed above with respect to the approval of director compensation). The compensation committee may waive the shareholder approval requirement with regards to the approval of the initial engagement terms of a candidate for the chief executive officer position, if they determine that the compensation arrangement is consistent with the company's stated compensation policy, and that the chief executive officer did not have a prior business relationship with the company or a controlling shareholder of the company and that subjecting the approval of the engagement to a shareholder vote would impede the company's ability to employ the chief executive officer candidate. The engagement with a public company's chief executive officer need not be approved by the shareholders of the company

with respect to the period from the commencement of the engagement until the next shareholder meeting convened by the company, if the terms and conditions of such engagement were approved by the compensation committee and the board of directors of the company, the terms and conditions of such engagement are in accordance with the company's compensation policy approved in accordance with the Israeli Companies Law, and if the terms and conditions of such engagement are no more beneficial than the terms and conditions of the person previously serving in such role or there is no substantial difference in the terms and conditions of the previous engagement versus the new one under the circumstances, including the scope of engagement.

We have a service contract with one of our directors, Dror Ben-Asher, that provides for benefits upon termination of his employment as director. For more information, see "Item 6. Directors, Senior Management and Employees – B. 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, except as provided below, 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.

Our board of directors has resolved to adopt the corporate governance exception set forth in Regulation 5D of the Israeli Companies Regulations (the "Regulation"). In accordance with the Regulation, a public company with securities listed on certain foreign exchanges, including the NASDAQ Stock Market, that satisfies the applicable foreign country laws and regulations that apply to companies organized in that country relating to the appointment of independent directors and composition of audit and compensation committees and have no controlling shareholder are exempt from the requirement to appoint external directors or comply with the audit committee and compensation committee composition requirements under the Israeli Companies Law. In accordance with our board of directors' resolution, pursuant to the Regulation, we intend to comply with the NASDAQ Listing Rules in connection with a majority of independent directors on the board of directors and in connection with the composition of each of the audit committee and the compensation committee, in lieu of such requirements of the Israeli Companies Law. In accordance with the transition rules set forth in the Regulation, effective as of our adoption of the exemptions under the Regulation on May 22, 2016, our external directors then in office, Mr. Ofer Tsmichi and Ms. Nurit Benjamini, were no longer classified as such under the Israeli Companies Law. The transition rules provide that such directors have the right to remain in office as our directors at their option after the exemptions under the Regulation are adopted until the earlier of such directors' original end of term of office or the second annual meeting of shareholders after the adoption of the exemption under the Regulation, which in the case of Ms. Nurit Benjamini is until the date of our annual meeting of shareholders in 2017 and in the case of Mr. Ofer Tsimchi is the earlier of April 30, 2017 or the date of our annual meeting of shareholders in 2017.

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 officer, 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 "officer" 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.

Except for the cessation of classification of directors as external directors in connection with the adoption by certain companies listed on foreign stock exchanges, including the NASDAQ Stock Market, of the corporate governance exceptions set forth in the Regulation, as described above, 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 officer 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 may 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 Exchange Act, (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 TASE 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.

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. Except in the case of companies listed on foreign stock exchanges, including the NASDAQ Stock Market, which have adopted the corporate governance exceptions set forth in the Regulation, such as us, as described under "- Independent and External Directors - Israeli Companies Law Requirements", who are exempt from the audit committee composition requirements under the Companies Law, an audit committee of a public company under the Israeli Companies Law must be comprised of at least three directors including all of the external directors.

In addition, the Israeli Companies Law provides that 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 Israeli Companies Law.

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

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

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

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

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

A recent amendment to the Israeli Companies Law, enacted on February 17, 2016, or Amendment 27, allows a company whose audit committee's composition meets the requirements set for the composition of a compensation committee (as further detailed below) to have one committee acting as both audit and compensation committees. As of the date of this Annual Report, we have not elected to have one committee acting as both the audit and the compensation committees.

Compensation Committee

According to the Israeli Companies Law, the board of directors of a public company must establish a compensation committee. Except in the case of companies listed on foreign stock exchanges, including the NASDAQ Stock Market, which have adopted the corporate governance exceptions set forth in the Regulation, such as us, as described under "-Independent and External Directors - Israeli Companies Law Requirements", who are exempt from the compensation committee composition requirements under the Companies Law, the Israeli Companies Law requires that the compensation committee must consist 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 the Israeli Companies Law requirements described above. The compensation committee chairman must be an external director and 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 Israeli Companies Law.

Our compensation committee, which consists of Mr. Ofer Tsimchi (chairman), Dr. Shmuel Cabilly and Ms. Nurit Benjamini, administers issues relating to our global compensation plan with respect to our employees, directors and consultants. Our compensation committee is responsible for making recommendations to the board of directors regarding the issuance of share options and compensation terms for our directors and officers 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 Suesskind and Ms. Nurit Benjamini assists the board in fulfilling its responsibilities with respect to our 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 our 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 Listing 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 Exchange Act 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 SEC 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 Exchange Act, 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 SEC, 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 Listing Rules, the audit committee is directly responsible for the appointment, compensation and performance of our independent auditors. In addition, the audit committee is responsible for assisting the board of directors in reviewing our annual financial statements, the adequacy of our internal controls and our compliance with legal and regulatory requirements. The audit committee also oversees our major financial risk exposures and policies for managing such potential risks, discusses with management and our independent auditor significant risks or exposure and assesses the steps management has taken to minimize such risk.

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

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 officer or a director, a relative of an interested party, or a relative of an officer or a director, nor may the internal auditor be our independent accountant or its representative. Ms. Dana Gottesman-Erlich, Partner at Risk Advisory Services Group at BDO Israel, serves as our internal auditor.

Duties of Directors and Officers and Approval of Specified Related Party Transactions under the Israeli Companies Law

Fiduciary Duties of Officers

The Israeli Companies Law imposes a duty of care and a duty of loyalty on all directors and officers of a company, including directors and executive officers. The duty of care requires a director or an officer to act with the level of care, according to which a reasonable director or officer 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 directors' or officer's approval or performed by such person by virtue of such person's position; and
- all other important information pertaining to the previous actions.

The duty of loyalty requires a director or an officer 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 director's or officer's duties in the company and such person's 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 director, officer or others; and
- disclose to the company any information or documents relating to a company's affairs which the director or officer has received due to such person's position as a director or an officer.

Under the Israeli Companies Law, subject to certain exceptions, directors' compensation arrangements require approval of the compensation committee, the board of directors and the shareholders.

The Israeli Companies Law requires that a director or an officer 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 such person, in connection with any existing or proposed transaction by the company. A personal interest of a director or an officer (which includes a personal interest of the director's or officer's relative) is in a company in which the director or officer or the director's or officer's relative is: (i) a shareholder which holds 5% or more of a company's share capital or its voting rights, (ii) a director or a general manager, or (iii) in which the director or officer 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 – in each case, regardless whether discretion with respect to how to vote lies with the person voting or not. In the case of an extraordinary transaction, the director's or the officer's duty to disclose applies also to a personal interest of the director or officer's relative.

Under the Israeli Companies 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 a director or an officer complies with the above disclosure requirement, the board of directors may approve an ordinary transaction between the company and a director or an officer, or a third party in which a director or an officer 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 officer (who 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 at 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 a director or an officer 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 a director or an officer 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 are 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 directors or officers 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 must 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 a director or an officer 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

Exemption of Officers and Directors

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 our directors and officers.

Directors' and Officers' 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 directors and officers for any liability stemming from any act performed by an officer or director in his capacity as an officer or director, as the case may be with respect to any of the following:

- a breach of such officer's or director's duty of care to us or to another person;
- a breach of such officer's or director's duty of loyalty to us, provided that such officer or director acted in good faith and had reasonable cause to assume that his act would not prejudice our interests;
- a financial liability imposed upon such officer or director in favor of another person;
- financial liability imposed on the officer or director for payment to persons or entities harmed as a result of violations in administrative proceedings as described in Section 52(54)(a)(1)(a) of the Israeli Securities Law (Party Harmed by the Breach);
- expenses incurred by such officer or director in connection with an administrative proceeding conducted in his matter, including reasonable litigation expenses, including legal fees; or
- a breach of any duty or any other obligation, to the extent insurance may be permitted by law.

In June 2016, our shareholders approved our Compensation Policy, which includes, among other things, 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 our Compensation Policy, should we sell our operations (in whole or in part) or in case of merger, spin-off or any other significant business combination involving us 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 may 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 2016 annual general meeting.

Subsequent to the approval of the terms of our Compensation Policy, our compensation committee and board of directors resolved to purchase a directors' and officers' liability insurance policy, pursuant to which the total amount of insurance covered under the policy would be $50 million This insurance was renewed in December 2016, for the period commencing on December 16, 2016 and ending on December 15, 2017. Pursuant to the foregoing approvals, we carry directors' and officers' liability insurance.

Indemnification of Officers and Directors

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 a director or an officer 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 directors and officers must be approved by our audit committee and board of directors and, in specified circumstances, by our shareholders.

Letters of Indemnification

We may provide a commitment to indemnify in advance any director or officer of ours in the course of such person's position as our director or officer, all subject to the letter of indemnification, as approved by our shareholders from time to time and in accordance with our articles of association. We may provide retroactive indemnification to any officer to the extent allowed by the Israeli Companies Law. As approved by our shareholders on July 18, 2013, 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.

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 December 31, 2016, we had 13 employees, and we also received services from 14 consultants who provide services to us in the U.S., Canada and Belgium.

	As of December 31,					
	2014		2015		2016	
	Company Employees	Consultants	Company Employees	Consultants	Company Employees	Consultants
Management and administration	9	2	11	2	11	4
Research and development	1	8	1	11	2	10

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

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

E. Share Ownership

The following table sets forth information regarding the beneficial ownership of our outstanding Ordinary Shares as of February 22, 2017, 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 170,581,594 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 peron that were currently exercisable at, or exercisable within 60 days of February 22, 2017. The Ordinary Shares issuable under these options and warrants are treated as if they were outstanding for purposes of computing the percentage ownership of the person holding these options and warrants but not the percentage ownership of any other person. None of the holders of the Ordinary Shares listed in this table have voting rights different from other holders of the Ordinary Shares.

	Number of Shares Beneficially Held	Percent of Class
Directors		
Dr. Kenneth Reed (1)	4,661,160	2.73 %
Dr. Shmuel Cabilly (2)	4,329,178	2.53 %
Eric Swenden (3)	2,468,710	1.44 %
Dan Suesskind (4)	1,179,100	*
Ofer Tsimchi (5)	330,000	*
Rick D. Scruggs	-	-
Nurit Benjamini	-	-
Executive officers		
Dror Ben-Asher (6)	6,298,780	3.62 %
Reza Fathi, Ph.D. (7)	1,451,250	*
Adi Frish (8)	973,750	*
Gilead Raday (9)	700,460	*
Guy Goldberg (10)	593,750	*
Uri Hananel Aharon (11)	377,500	*
Micha Ben Chorin (12)	75,000	—
All directors and executive officers as a group (14 persons)	23,438,638	13.01 %

* Less than 1.0%

(1) Includes options to purchase 346,103 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $0.165 and $1.48 per share, and the options expiry date range between 2017 and 2023. 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 195,000 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $1.28 and $1.48 per share, and the options expiry date range between 2021 and 2023. 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 81,250 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $1.28 and $1.48 per share, and the options expiry date range between 2021 and 2023. Includes warrants to purchase 47,500 ADSs with exercise price of $13.33 and an expiration date of December 26, 2019 purchased in the public offering that closed on December 27, 2016.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 735,000 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $0. 5 and $1.48 per share, and the options expiry date range between 2018 and 2023. 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 330,000 Ordinary Shares exercisable within 60 days of February 22, 2017. 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.

(6) Includes options to purchase 3,591,397 Ordinary Shares exercisable within 60 days of February 22, 2017 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 2023. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.
(7) Includes options to purchase 1,181,250 Ordinary exercisable within 60 days of February 22, 2017. 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.
(8) Includes options to purchase 973,750 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $0.165 and $1.56 per share, and the options expiry date range between 2017 and 2022.
(9) Includes options to purchase 700,460 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $0.165 and $1.65 per share, and the options expiry date range between 2017 and 2022.
(10) Includes options to purchase 593,750 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $0.165 and $1.56 per share, and the options expiry date range between 2017 and 2022.
(11) Includes options to purchase 347,500 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between $0.7 and $1.56 per share, and the options expiry date range between 2019 and 2022.
(12) Includes options to purchase 75,000 Ordinary Shares exercisable within 60 days of February 22, 2017. The exercise price of these options range between is $1.41 per share, and the options expiry is 2023.

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, 2017, there were 20,275,548 Ordinary Shares issuable upon the exercise of outstanding options under the 2010 Option Plan.

Administration of Our 2010 Option Plan

Our 2010 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, directors and officers 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, a merger or other change of control approved by the board of directors, 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.

Upon termination under the event of a merger or other change of control approved by the board of directors, the grantee will be entitled at the time of termination to full acceleration of all the options granted prior to the event.

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 TASE 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.

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 22, 2017, 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 170,581,594 Ordinary Shares outstanding as of such date. In determining the number of Ordinary Shares beneficially owned by a person, we include any shares as to which the person has sole or shared voting power or investment power, as well as any Ordinary Shares subject to options or warrants held by that person that were currently exercisable at, or exercisable within 60 days of February 22, 2017. 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
EMC2 Fund Ltd. (1)	21,951,230 (2)	12.34 %

(1) EMC2 Fund Ltd. ("EMC") holds the ADSs and warrants to purchase ADSs. The address of EMC is Bayside Executive Park, Building No. 1, West Bay Street, PO Box SP-63131, Nassau, the Bahamas. Based on information provided to us, EMC is controlled by Banque Pictet & Cie SA.

(2) Includes warrants to purchase 731,708 ADSs with an exercise price of $13.33 and an expiration date of December 26, 2019, purchased by EMC in a registered direct offering that closed on December 27, 2016. See "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources" for more information regarding the warrants.

On February 10, 2017, 9,945,340 ADSs (equivalent to 99,453,400 Ordinary Shares, or approximately 58% of our total issued and outstanding Ordinary Shares), were held of record by three record holders in the U.S., of which one holder had a U.S. address. As of February 22, 2017, there was one shareholder of record of our Ordinary Shares, which was located

in Israel. The number of record holders is not representative of the number of beneficial holders of our ADSs or Ordinary Shares because many of the ADSs and Ordinary Shares are held by brokers or other nominees.

B. Related Party Transactions

December 2016 Public Offering

In our underwritten public offering which closed on December 27, 2016, Mr. Eric Swenden, one of our directors, purchased 95,000 ADSs and warrants to purchase 47,500 ADSs. The terms of the issuance as well as the discount received by the underwriters for these shares were the same as those offered to the public. In the concurrent registered direct offering, EMC purchased 1,463,415 ADSs and warrants to purchase 731,708 ADSs at the same price as the public offering price. For more information on the underwritten public offering, please see "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources".

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, 2016.

ITEM 9. THE OFFER AND LISTING

A. Offer and Listing Details

Our Ordinary Shares have been trading on the TASE under the symbol “RDHL” since February 2011.

Ordinary Shares

The following table sets forth, for the periods indicated, the reported high and low closing prices of our Ordinary Shares on the TASE 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**
2016	6.05	3.32	1.58	0.86
2015	7.80	4.34	2.03	1.12
2014	6.80	3.00	1.96	0.78
2013	4.29	3.23	1.15	0.92
2012	4.19	1.71	1.08	0.45
Quarter				
2016				
Fourth quarter	5.51	3.73	1.45	0.98
Third quarter	6.05	4.21	1.58	1.09
Second quarter	5.30	3.90	1.41	1.41
First quarter	5.14	3.32	1.31	0.86
2015				
Fourth quarter	5.42	4.34	1.39	1.12
Third quarter	7.10	4.62	1.88	1.19
Second quarter	7.80	5.52	2.03	1.41
First quarter	6.16	4.89	1.57	1.26
Most Recent Six Months				
February 2017 (through February 22, 2017)	3.72	3.53	0.99	0.95
January 2017	4.17	3.57	1.08	0.94
December 2016	4.44	3.73	1.17	0.98
November 2016	4.74	4.33	1.24	1.12
October 2016	5.51	4.69	1.45	1.22
September 2016	5.84	5.50	1.55	1.46
August 2016	6.05	5.17	1.60	1.36

On February 22, 2017, the last reported closing price of our Ordinary Shares on the TASE was NIS 3.53 per share, or $0.95 per share (based on the exchange rate reported by the Bank of Israel for such date). On February 22, 2016 the exchange rate of the NIS to the U.S. dollar was $1.00 = NIS 3.71, as reported by the Bank of Israel.

ADSs

Our ADSs have been trading on the NASDAQ Capital Market under the symbol “RDHL” since December 27, 2012.

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

	U.S.$ Price per ADS	
Annual	**High**	**Low**
2016	16.29	8.21
2015	19.79	11.05
2014	19.20	8.03
2013	13.60	8.31
Quarter		
2016		
Fourth quarter	14.47	9.65
Third quarter	16.29	10.80
Second quarter	13.79	10.00
First quarter	12.61	8.21
2015		
Fourth quarter	13.72	11.05
Third quarter	18.46	12.16
Second quarter	19.79	14.03
First quarter	15.92	12.52
Most Recent Six Months		
February 2017 (through February 22, 2017)	9.95	9.33
January 2017	10.88	9.62
December 2016	11.43	9.65
November 2016	12.19	10.91
October 2016	14.47	11.92
September 2016	15.24	13.89
August 2016	16.29	14.55

On February 22, 2017, the last reported price of our ADSs on the NASDAQ Capital Market was $9.42 per ADS.

B. Plan of Distribution

Not applicable.

C. Markets

Our Ordinary Shares are listed and traded on the TASE, 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 will increase or as a result of it a person will 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 are 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 a director or an officer 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 will be allowed to participate and vote on this matter, but an approval of the transaction by the shareholders in the general meeting will 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 report to the board of directors their resolutions or recommendations on a regular basis, as 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 will not affect the validity of any resolution of a committee, pursuant to which we acted, vis-à-vis another person, who was not aware of the cancellation thereof. Decisions or recommendations of the committee of the board which require the approval of the board of directors will be brought to the directors' attention a reasonable time prior to the discussion at the board of directors.

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

Description of Securities

Ordinary Shares

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

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

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

Notices. Under the Israeli Companies Law and our articles of association, we are required to publish notices in two Hebrew-language daily newspapers or our website at least 21 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 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 and no more than seven, including the external directors whose appointment is required by law. 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 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, are to be paid pro rata to the amount paid or credited as paid on account of the nominal value of shares held by the shareholders. In the event of our liquidation, the liquidator may, with the general meeting's approval, distribute parts of our property in specie among the shareholders and he may, with similar approval, deposit any part of our property with trustees in favor of the shareholders as the liquidator, with the approval mentioned above deems fit.

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

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

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

Acquisitions under Israeli Law

Full Tender Offer

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

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

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

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

If the shareholders who did not respond or accept the tender offer hold at least 5% of the issued and outstanding share capital of the company or of the applicable class, the acquirer may not acquire shares of the company that will increase its

holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

The description above regarding a full tender offer will 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 must abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

An officer in a target company who, in his or her capacity as an officer, 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 officer acted in good faith and had reasonable grounds to believe he or she was acting for the benefit of the company. However, officers 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 must refrain from making a subsequent tender offer for the purchase of shares of the target company and may not execute a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer.

Merger

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

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

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

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

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

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

Anti-takeover Measures

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

C. Material Contracts

For a description of other material agreements, please see "Item 4. Information on the Company – B. Business Overview.

D. Exchange Controls

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

E. Taxation

Israeli Tax Considerations

General

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

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

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

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax on their taxable income at the rate of 25% for the 2016 tax year (to be reduced to 24% in 2017 and to 23% in 2018 and thereafter).

Taxation of Shareholders

Capital Gains

Capital gains tax is imposed on the disposition of capital assets by an Israeli resident and on the disposition 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 disposition. 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 (25% in 2016, to be reduced to 24% in 2017 and to 23% in 2018 and thereafter), and a marginal tax rate of up to 50% in 2016 for individuals, including an 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 (this condition will

not apply to shares purchased on or after January 1, 2009) and (ii) the seller does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, non-Israeli resident corporations will not be entitled to the foregoing exemption if Israeli residents: (i) have a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the income or profits of such non-Israeli corporation, whether directly or indirectly. In addition, such exemption would not be available to a person whose gains from selling or otherwise disposing of the securities are deemed to be business income.

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

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

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

Dividends

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

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

Excess Tax

Individual 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 a certain threshold in a tax year ((NIS 810,720 for 2016 and NIS 640,000 for 2017 and thereafter linked to the Israeli Consumer Price Index) will be subject to an additional tax at the rate of 2% in

2016 (to be increased to 3% in 2017 and thereafter) on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

Foreign Exchange Regulations

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

U.S. Federal Income Tax Considerations

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

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

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

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

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

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

- an individual who is a citizen or resident of the U.S.;

- a corporation (or other entity taxable as a corporation for U.S. federal income tax purposes) created or organized in the U.S. or under the laws of the U.S. or any political subdivision thereof;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) if (a) a court within the U.S. 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 U.S. 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 "Item 10. Additional Information – E. Taxation – U.S. Federal Income Tax Considerations – Passive Foreign Investment Companies" below, the gross amount of any distribution, including the amount of any Israeli taxes withheld from such distribution, see "Item 10. Additional Information – E. Taxation – 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, then 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 "Item 10. Additional Information – E. Taxation – U.S. Federal Income Tax Considerations – 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 "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – 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 "Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – 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 "Item 10. Additional Information – E. Taxation – 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, must be included in gross income (as ordinary income) for the current tax year; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to.

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

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

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

The mark-to-market election is available only for "marketable stock," which is stock that is traded in other than de minimis quantities on at least 15 days during each calendar quarter, or regularly traded, on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. Any trades that have as their principal purpose meeting this requirement will be disregarded. The ADSs are listed on the NASDAQ Capital Market 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 U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. 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 ''Item 10. Additional Information – Taxation — U.S. Federal Income Tax Considerations – 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 Exchange Act, applicable to foreign private issuers, and under those requirements we file reports with the SEC. Those other reports or other information may be inspected without charge at the SEC'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 SEC at such address, at prescribed rates. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. Our filings with the SEC are also available to the public through the SEC's website at *http://www.sec.gov*.

As a foreign private issuer, we are exempt from the rules under the Exchange Act, related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act, to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to comply with the informational requirements of the Exchange Act, and, accordingly, file current reports on Form 6-K, annual reports on Form 20-F and other information with the SEC.

In addition, since our Ordinary Shares are traded on the TASE, we have filed Hebrew language periodic and immediate reports with, and furnish information to, the TASE 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 TASE 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, 2016:

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	27	68	53,786	(68)	(27)
Bank deposits	4	9	55	(9)	(4)
Accounts receivable (except prepaid expenses)	3	7	1,541	(7)	(3)
Accounts payable and accrued expenses	(3)	(6)	(3,356)	6	3
Total loss	31	78		(78)	(31)

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 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 SEC 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 us in the reports that we file or submit under the Exchange Act, is accumulated and communicated to our management, including our 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 Chief Financial Officer, have concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15(d) - 15(e) of the Exchange Act) 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 Chief Financial Officer, 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 Chief Financial Officer, we assessed the effectiveness of our internal control over financial reporting as of December 31, 2016 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, 2016.

(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, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM16. [RESERVED]

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

Our board of directors has determined that Ofer Tsimchi, Dan Suesskind and Nurit Benjamini are audit committee financial experts. Mr. Tsimchi, Mr. Suesskind and Ms. Benjamini are independent directors for the purposes of the NASDAQ Listing 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://files.shareholder.com/downloads/AMDA-1C0OBF/2136056036x0x622354/AB22671F-9FAF-4EF6-8552-4F9A31E4B64F/Business-Conduct-and-Ethics.pdf .

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Paid to Independent Registered Public Accounting Firm

The following table sets forth, for each of the years indicated, the aggregate fees billed by our independent registered public accounting firm for professional services.

	Year Ended December 31,	
Services Rendered	**2016**	**2015**
	(U.S. dollars in thousands)	
Audit (1)	122	118
Audit related services (2)	64	110
Tax (3)	—	7
Total	186	235

(1) Audit fees consist of services that would normally be provided in connection with statutory and regulatory filings or engagements, including services that generally only the independent accountant can reasonably provide.
(2) Audit related services relate to work regarding prospectus supplements and ongoing consultation.
(3) Tax fees relate to tax compliance, planning and advice.

Audit Committee Pre-Approval Policies and Procedures

Our audit committee's specific responsibilities in carrying out its oversight of the quality and integrity of the accounting, auditing and reporting practices of the Company include the approval of audit and non-audit services to be provided by the external auditor. The audit committee approves in advance the particular services or categories of services to be provided to the Company during the following yearly period and also sets forth a specific budget for such audit and non-audit services. Additional non-audit services may be pre-approved by the audit committee.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

Not applicable.

ITEM 16F. CHANGE IN REGISTRANT'S CERTIFYING ACCOUNTANT

Not applicable.

ITEM 16G. CORPORATE GOVERNANCE

NASDAQ Stock Listing Rules and Home Country Practices

As a foreign private issuer, we are permitted to follow Israeli corporate governance practices instead of NASDAQ Listing 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:

- *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; and
- *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 Listing Rules related to corporate governance. We also comply with Israeli corporate governance requirements under the Israeli Companies Law as applicable to us.

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 123.

Glossary of Industry Terms

Certain standards and other terms specific to our industry that are used in this Annual Report are defined below:

API - active pharmaceutical ingredient - the ingredient in a pharmaceutical drug that is biologically active.

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 FDA must be met.

Bioequivalence Clinical Study - a study the data from which is submitted to the FDA 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 FDA, which must be met.

cGMP - Current Good Manufacturing Practice - Standards, procedures and guidelines designed for production quality control.

CMC - chemistry, manufacturing and controls of pharmaceutical products.

CRL - Complete Response Letter – the FDA will send the applicant of an NDA a complete response letter if they determine that they will not approve an application or abbreviated application in its present form.

CRO - Contract Research Organization, also called a **clinical research organization** is a service organization that provides outsourced pharmaceutical research services.

DESI - Drug Efficacy Study Implementation program of the FDA - the DESI program was created, in part, to require the FDA to conduct a retrospective evaluation of the effectiveness of drug products that were approved as safe between 1938 and 1962 through the new drug approval process. According to the DESI program, drugs approved before October 10, 1962, were reviewed to evaluate whether there was substantial evidence of their effectiveness.

Diffuse large B-cell lymphoma (DLBCL) - a B-cell type of lymphoma. With DLBCL, the cancer cells appear very large and scattered throughout (diffuse) all of the lymph node. Lymphoma is the most common blood cancer. Lymphoma occurs when cells of the immune system called lymphocytes, a type of white blood cell, grow and multiply uncontrollably. Cancerous lymphocytes can travel to many parts of the body, including the lymph nodes, spleen, bone marrow, blood, or other organs, and form a mass called a tumor.

DSMB - Data and Safety Monitoring Board - an independent group of experts that advises the study investigators.

GCP - Good Clinical Practices - requirements for the conduct of research involving human subjects.

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 FDA to a drug before allowing its use in humans, so that experimental clinical trials may be conducted.

IRB - Institutional Review Board - Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects.

ITT - intention-to-treat – intention-to-treat analysis means all of the patients who were enrolled and randomized into a clinical study are included in the analysis.

MAA - Marketing Authorization Application - 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.

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 suspected as the cause of Crohn disease in humans.

NDA - New Drug Application - an application by drug sponsors to the Food and Drug Administration (FDA) for approval of a new pharmaceutical for sale and marketing in the U.S.

NOOH - Notice of Opportunity Hearing - The Notice of Opportunity for Hearing provides an individual with the opportunity for a hearing on a regulatory action, including a proposed action (such as debarment), before a presiding officer designated by the FDA Commissioner.

NTM - Nontuberculous Mycobacteria – a class of Mycobacteria also known as environmental mycobacteria, atypical mycobacteria and mycobacteria other than tuberculosis (MOTT).

Ondansetron - 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.

PK - pharmacokinetics - the study of the absorption, distribution, metabolism, and excretion of drugs in the body.

QIDP - Qualified Infectious Disease Product - designation granted under the FDA's Generating Antibiotic Incentives Now Act, which is intended to encourage development of new antibiotic drugs for the treatment of serious or life-threatening infections that have the potential to pose a serious threat to public health**.**

Rizatriptan™ - a serotonin 5-HT 1B/1D receptor agonist of the triptan class of drugs.

Sphingosine kinase-2 (SK2) - an enzyme catalyzes the phosphorylation of sphingosine to generate sphingosine 1-phosphate. There are two isotypes of sphingosine enzyme, SK1 and SK2. Both isotypes have a key role in variety of disease, including the development of a range of solid tumors and are promising anti-cancer therapeutic targets.

Stability Testing - as part of the cGMP regulations, the FDA requires that drug products bear an expiration date determined by appropriate stability testing. The stability of drug products needs to be evaluated over time in the same container-closure system in which the drug product is marketed.

TNFα - Tumor necrosis factor alpha is a cell-signaling protein (cytokine) involved in systemic inflammation.

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

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REDHILL BIOPHARMA LTD.
2016 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. as of December 31, 2016 and 2015 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, 2016. 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, 2016 and 2015 and the results of its operations, changes in equity and cash flows for each of the three years in the period ended December 31, 2016, in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

Tel-Aviv, Israel
February 22, 2017

/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		
		2016	2015	2014
		U.S. dollars in thousands		
REVENUES:				
Licensing revenue	17	100	—	7,000
Other revenue		1	3	14
TOTAL REVENUES		101	3	7,014
COST OF REVENUE		—	—	1,050
RESEARCH AND DEVELOPMENT EXPENSES, net	18	25,241	17,771	12,700
GENERAL, ADMINISTRATIVE AND BUSINESS DEVELOPMENT EXPENSES	19	5,403	4,134	4,011
OTHER EXPENSES (INCOME)		—	100	(100)
OPERATING LOSS		30,543	22,002	10,647
FINANCIAL INCOME		1,548	1,124	319
FINANCIAL EXPENSES		375	212	383
FINANCIAL EXPENSES (INCOME), net	20	(1,173)	(912)	64
LOSS AND COMPREHENSIVE LOSS FOR THE YEAR		29,370	21,090	10,711
LOSS PER ORDINARY SHARE (U.S. dollars):	21			
Basic		0.23	0.19	0.12
Diluted		0.24	0.19	0.13

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

REDHILL BIOPHARMA LTD.

STATEMENTS OF FINANCIAL POSITION

	Note	December 31	
		2016	2015
		U.S. dollars in thousands	
CURRENT ASSETS:			
Cash and cash equivalents	5	53,786	21,516
Bank deposits		55	36,622
Financial assets at fair value through profit or loss	6	12,313	—
Prepaid expenses and receivables	7	1,661	2,372
		67,815	60,510
NON-CURRENT ASSETS:			
Bank deposits		137	134
Fixed assets	8	165	124
Intangible assets	9	6,095	6,060
		6,397	6,318
TOTAL ASSETS		74,212	66,828
CURRENT LIABILITIES:			
Accounts payable and accrued expenses	11	3,356	3,514
Payable in respect of intangible asset purchase	12a(6)	2,000	2,000
		5,356	5,514
NON-CURRENT LIABILITIES:			
Derivative financial instruments	15	6,155	1,237
TOTAL LIABILITIES		11,511	6,751
COMMITMENTS	12		
EQUITY:			
Ordinary shares	14	441	343
Additional paid-in capital		150,838	120,621
Warrants		1,057	1,057
Accumulated deficit		(89,635)	(61,944)
TOTAL EQUITY		62,701	60,077
TOTAL LIABILITIES AND EQUITY		74,212	66,828

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

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:					
Share-based compensation to employees and service providers	—	—	—	1,753	1,753
Exercise of warrants and options into ordinary shares, net	11	5,696	(702)		5,005
Issuance of ordinary shares and warrants, net of expenses	55	15,927	1,057	—	17,039
Warrants expiration	—	694	(694)	—	—
Comprehensive loss	—	—	—	(10,711)	(10,711)
BALANCE AT DECEMBER 31, 2014	240	65,461	1,528	(42,218)	25,011
BALANCE AT JANUARY 1, 2015	240	65,461	1,528	(42,218)	25,011
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2015:					
Share-based compensation to employees and service providers	—	—	—	1,364	1,364
Exercise of options into ordinary shares	*	108	—	—	108
Issuance of ordinary shares, net of expenses	103	54,581	—	—	54,684
Warrants expiration		471	(471)		—
Comprehensive loss	—	—	—	(21,090)	(21,090)
BALANCE AT DECEMBER 31, 2015	343	120,621	1,057	(61,944)	60,077
BALANCE AT JANUARY 1, 2016	343	120,621	1,057	(61,944)	60,077
CHANGES DURING THE YEAR ENDED DECEMBER 31, 2016:					
Share-based compensation to employees and service providers	—	—	—	1,679	1,679
Issuance of ordinary shares, net of expenses	96	29,956	—	—	30,052
Exercise of options into ordinary shares	2	261	—	—	263
Comprehensive loss	—	—	—	(29,370)	(29,370)
BALANCE AT DECEMBER 31, 2016	441	150,838	1,057	(89,635)	62,701

* Represents amount less than $1 thousand.

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

REDHILL BIOPHARMA LTD.

STATEMENTS OF CASH FLOWS

	Year ended December 31		
	2016	2015	2014
	U.S. dollars in thousands		
OPERATING ACTIVITIES:			
Comprehensive loss	(29,370)	(21,090)	(10,711)
Adjustments in respect of income and expenses not involving cash flow:			
Share-based compensation to employees and service providers	1,679	1,364	1,753
Depreciation	44	36	27
Write-off of intangible assets	—	100	—
Cost out-licensing of intangible assets	—	—	50
Unrealized gains on derivative financial instruments	(1,152)	(888)	(200)
Fair value gains on financial assets at fair value through profit or loss	(67)	—	—
Revaluation of bank deposits	(274)	(69)	(29)
Issued cost in respect of warrants	368	—	—
Exchange differences in respect of cash and cash equivalents	(39)	150	237
	559	693	1,838
Changes in assets and liability items:			
Decrease (increase) in prepaid expenses and receivables	711	702	(2,586)
Increase (decrease) in accounts payable and accrued expenses	(158)	1,869	(770)
	553	2,571	(3,356)
Net cash used in operating activities	(28,258)	(17,826)	(12,229)
INVESTING ACTIVITIES:			
Purchase of fixed assets	(85)	(14)	(70)
Purchase of intangible assets	(35)	(1,620)	(1,035)
Change in investment in current bank deposits	36,838	(29,500)	(7,000)
Purchase of non-current bank deposit	—	(58)	(10,000)
Purchase of financial assets at fair value through profit or loss	(12,246)	—	—
Maturity of non-current bank deposits	—	10,000	—
Proceeds from sale of financial assets at fair value through profit or loss	—	—	243
Net cash provided by (used in) investing activities	24,472	(21,192)	(17,862)
FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares and warrants, net of expenses	35,754	54,684	19,364
Exercise of warrants and options into ordinary shares, net of expenses	263	108	5,005
Net cash provided by financing activities	36,017	54,792	24,369
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	32,231	15,774	(5,722)
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	39	(150)	(237)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	21,516	5,892	11,851
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	53,786	21,516	5,892
SUPPLEMENTARY INFORMATION ON INTEREST RECEIVED IN CASH	408	236	118
Supplementary information on investing activities not involving cash flows - Purchase of intangible assets	—	1,925	75

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

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 1 - GENERAL:

a. General

RedHill Biopharma Ltd. (the "Company") was incorporated in Israel on August 3, 2009. The Company is a specialty biopharmaceutical company primarily focused on the development and commercialization of late clinical-stage, proprietary, orally-administered, small molecule drugs for the treatment of gastrointestinal and inflammatory diseases and cancer. The Company also has a U.S. co-promotion agreement granting the Company certain rights to promote Donnatal® in the U.S., a prescription oral adjunctive drug marketed in the U.S. for gastrointestinal conditions.

In February 2011, the Company listed its securities on the Tel-Aviv Stock Exchange ("TASE"). Since December 2012, the Company's American Depositary Shares ("ADSs") have been listed on the NASDAQ Capital Market ("NASDAQ").

The Company's registered address is at 21 Ha'arba'a St, Tel-Aviv, Israel.

The Company is engaged in the research and development of most of its therapeutic candidates and to date has out-licensed on an exclusive world-wide basis only one of its therapeutic candidates and had two additional regional exclusive out-licensing transactions with another therapeutic candidate. Accordingly, there is no assurance that the Company's business will generate positive cash flow. Through December 31, 2016, 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 and Donnatal®, out-licensing certain programs and raising additional capital. The Company's current cash resources are not sufficient to complete the research development and commercialization of all of the Company's therapeutic candidates and Donnatal®. Management expects that the Company will incur more losses as it continues to focus its resources on advancing these products based on a prioritized plan that will result in negative cash flows from operating activities. The Company believes its existing capital resources should be sufficient to fund its current and planned operations for at least the next 12 months.

If the Company is unable to commercialize or further out-license its therapeutic candidates and Donnatal®, 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 these products, 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 22, 2017.

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, 2016 and 2015 and for each of the three years in the period ended on December 31, 2016 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.

d. Fixed assets

Fixed assets items are initially recognized at acquisition cost. Fixed assets items are stated at cost less accumulated depreciation.

Depreciation is computed by the straight- line method, to reduce the cost of fixed assets to their residual value over their estimated useful lives as follows:

	%
Computers	33
Office furniture and equipment	8-15

Leasehold improvements are depreciated by the straight-line method over the shorter of the term of the lease or the estimated useful life of the improvements.

e. Research and development:

1) Research and development assets acquired by the Company, the development of which has not been completed yet, are stated at cost and are not amortized; these assets are tested for impairment

once a year. At the time these assets will be available for use, they will be amortized by the straight line method over their useful lives.

2) Research expenses are charged to profit or loss as incurred. An intangible asset arising from development of the Company's therapeutic 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; and
- adequate technical, financial and other resources to complete the development and to use or sell the intangible asset are available and costs associated with the intangible asset during development can be measured reliably.

Other development costs that do not meet the above criteria are recognized as expenses as incurred. Development costs previously recognized as an expense are not recognized as an asset in a subsequent period.

As of December 31, 2016, the Company has not yet capitalized development costs.

3) Amounts paid to purchase intellectual property of therapeutic candidates are capitalized and recorded as intangible assets. Amounts due for future payment based on contractual agreements are accrued upon reaching the relevant milestones.

4) Research and development costs for the performance of pre-clinical, clinical trials and manufacturing by subcontractors are recognized as expenses when incurred.

f. Impairment of non-financial assets

Depreciable assets are tested for impairment if any events have occurred or changes in circumstances have taken place which might indicate that their carrying amounts may not be recoverable. Research and development assets, the development of which has not been completed yet, are not amortized and are tested for impairment on an annual basis.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Nonfinancial assets that were subject to impairment are reviewed for possible reversal of the impairment recognized in respect thereof at each date of statement of financial position.

g. Financial assets:

1) Classification

The financial assets of the Company are classified into the following categories: financial assets at fair value through profit or loss, 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.

b) Loans and receivables

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They are included in current assets, except for those with maturities greater than 12 months after the statement of financial position date (for which they are classified as noncurrent assets). The loans and receivables of the Company are comprised of prepaid expenses and receivables, cash and cash equivalents and bank deposits in the statement of financial position.

2) Recognition and measurement

Regular purchases and sales of financial assets are recognized on the settlement date, which is the date on which the asset is delivered to the Company or delivered by the Company. Investments are initially recognized at fair value plus transaction costs, for all financial assets not recorded at fair value through profit or loss.

Financial assets measured at fair value through profit or loss are initially recognized at fair value, and transaction costs are expensed into profit or loss. Financial assets are derecognized when the rights to receive cash flows from the investments have expired or have been transferred and the Company has transferred substantially all risks and rewards of ownership. Financial assets at fair value through profit or loss are subsequently recorded at fair value. Loans and receivables are measured in subsequent periods at amortized cost using the effective interest method.

Gains or losses arising from changes in the fair value of financial assets at fair value through profit or loss are presented in the statement of comprehensive loss under "financial expenses (income), net".

h. Trade payables

Trade payables are obligations to pay for goods or services that have been acquired from suppliers in the ordinary course of business. Accounts payable are classified as current liabilities if payment is due within one year or less, otherwise they are presented as noncurrent liabilities.

Trade payables are recognized initially at fair value and subsequently measured at amortized cost using the effective interest method.

i. Warrants

Receipts in respect of warrants are classified as equity to the extent that they confer the right to purchase a fixed number of shares for a fixed exercise price. Warrants that confer the right to net share settlement do not qualify for equity classification and are classified as derivative liabilities (see j below).

j. Derivative financial instruments

The derivative financial instruments of the Company represent warrants.
These derivative financial instruments are carried at fair value, with changes in their fair value recognized in profit or loss. The issuance costs of such instruments were directly charged to profit or loss.

k. Share capital

The Company's ordinary shares are classified as the Company's share capital. Incremental costs directly attributed to issuance of new shares or warrants are presented under equity as a deduction from the proceeds of issuance.

l. Employee benefits:

1) Pension and retirement benefit obligations

In any matter related to payment of pension and severance pay to employees in Israel to be dismissed or to retire from the Company, the Company operates in accordance with labor laws.

Labor laws and agreements in Israel and the Company's practice require the Company to pay severance pay and/or pensions to employees in Israel dismissed or retiring from their employer in certain circumstances.

The Company has a severance pay plan in accordance with Section 14 of the Israeli Severance Pay Law with the plan treated as a defined contribution plan. According to the plan, the Company regularly makes payments to severance pay or pension funds without having a legal or constructive obligation to pay further contributions if the fund does not hold sufficient assets to pay all employees in Israel the benefits relating to employee service in the current and prior periods. Contributions for severance pay or pension are recognized as employee benefit expenses when they are due commensurate with receipt of work services from the employee and no further provision is required in the financial statements.

2) Vacation and recreation pay

Under Israeli law, each employee in Israel is entitled to vacation days and recreation pay, both computed on an annual basis. The entitlement is based on the period of employment. The Company records a liability and expenses vacation and recreation pay based on the benefit accumulated by each employee.

m. Share-based payments

The Company operates a number of equity-settled, share-based compensation plans to employees (as defined in IFRS 2 "Share-Based Payments") and service providers. As part of the plans, the Company grants employees and service providers, from time to time and at its discretion, options to purchase Company shares. The fair value of the employee and service provider services received in exchange for the grant of the options is recognized as an expense in profit or loss and is recorded as accumulated

deficit within equity. The total amount recognized as an expense over the vesting period of the options (the period during which all vesting conditions are expected to be met) is determined by reference to the fair value of the options granted at date of grant.

Vesting conditions are included in the assumptions about the number of options that are expected to vest. The total expense is recognized over the vesting period, which is the period over which all of the specified vesting conditions are to be satisfied.

At the end of each reporting period, the Company revises its estimates of the number of options that are expected to vest based on the nonmarket vesting conditions. The Company recognizes the impact of the revision to original estimates, if any, in profit or loss, with a corresponding adjustment to accumulated deficit.

When exercising options, the Company issues new shares. The proceeds, less direct-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; and
- the costs incurred or to be incurred in respect of the sale can be measured reliably.

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 potential 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.

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

IFRS 9, 'Financial instruments', addresses the classification, measurement and recognition of financial assets and financial liabilities. The complete version of IFRS 9 was issued in July 2014. It replaces the guidance in IAS 39 that relates to the classification and measurement of financial instruments. IFRS 9 retains but simplifies the mixed measurement model and establishes three primary measurement categories for financial assets: amortized cost, fair value through other comprehensive income and fair value through profit or loss. The basis of classification depends on the entity's business model and the contractual cash flow characteristics of the financial asset. Investments in equity instruments are required to be measured at fair value through profit or loss with the irrevocable option at inception to present changes in fair value in other comprehensive income. Further, the expected credit losses model replaces the incurred loss impairment model used in IAS 39. For financial liabilities, there were no changes to classification and measurement except for the recognition of changes in the Company's own credit risk in other comprehensive income for liabilities designated at fair value through profit or loss.

The standard is effective for accounting periods beginning on or after 1 January, 2018. Early adoption is permitted. The Company is currently assessing the impact of IFRS 9.

International Financial Reporting Standard No. 15 "Revenue from Contracts with Customers" (hereafter - IFRS 15)

IFRS 15 amends revenue recognition requirements and establishes principles for reporting information about the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. The standard replaces IAS 18 Revenue and IAS 11 Construction Contracts and related interpretations. The standard is effective for annual periods beginning on or after January 1, 2018. The Company is currently assessing the impact of adopting IFRS 15.

International Financial Reporting Standard No. 16 "Leases" (hereafter - IFRS 16)

IFRS 16 defines a lease as a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration. Under IFRS 16 lessees have to recognize a lease liability reflecting future lease payments and a 'right-of-use asset' for almost all lease contracts.

The standard replaces the current guidance in IAS 17. The standard is effective for annual periods beginning on or after January 1, 2019. The Company is currently assessing the impact of adopting IFRS 16.

NOTE 3 - CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS:

Estimates and judgments are continually evaluated and are based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances.

The Company makes judgments and estimates and assumptions concerning the future. The resulting accounting estimates will, by definition, seldom equal the related actual results. The material judgments, estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the following financial year are in respect of impairment of intangible assets.

The Company reviews once a year or when indications of impairment are present, whether research and development assets are impaired, see also note 2f.

The Company makes judgments to determine whether indications are present that require reviewing impairment of these intangible assets.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amounts of each asset are based on the Company's estimates as to the development of the therapeutic 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 Chief Financial Officer 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 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.

(a) Market risks

Foreign exchange risk: The Company might be exposed to foreign exchange risk as a result of making payments to employees or service providers and investment of some liquidity in currencies other than the U.S. dollar (i.e. the Functional Currency). The Company manages the

foreign exchange risk by aligning the currencies for holding liquidity with the currencies of expected expenses, based on the expected cash flows of the Company. Had the Functional Currency of the Company been stronger by 5% against the NIS, assuming all other variables remained constant, the Company would have recognized an additional expense of $78,000, $12,000 and $125,000 in profit or loss for the years ended, December 31, 2016, 2015 and 2014, respectively, the foreign exchange risks associated with these balances are immaterial.

(b) Credit and interest risks

Credit and interest risks arise from cash and cash equivalents, deposits with banks, financial assets at fair value through profit or loss, as well as receivables. A substantial portion of liquid instruments of the Company are invested in short-term deposits in highly-rated banks. The Company estimates that since the liquid instruments are mainly invested for the short term and with highly-rated institutions, the credit and interest risks associated with these balances are immaterial.

(c) Liquidity risk

Prudent liquidity risk management requires maintaining sufficient cash and the availability of funding through an adequate amount of committed credit facilities. Management monitors rolling forecasts of the Company's liquidity reserve (comprising of cash and cash equivalents, deposits, and financial assets through profit or loss). 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 therapeutic candidates or Donnatal® 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, 2016 and 2015, the Company's non-derivative financial liabilities include accounts payable, accrued expenses and payable in respect of intangible asset purchase for a period of less than 1 year.

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 and to reduce the cost of capital.

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.

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

	Level 1	Level 3	Total
	U.S. dollars in thousands		
December 31, 2016:			
Assets -			
Financial assets at fair value through profit or loss	12,313	—	12,313
Liabilities -			
Derivative financial instruments	—	6,155	6,155
December 31, 2015:			
Liabilities -			
Derivative financial instruments	—	1,237	1,237

The following table represents the change in derivative liabilities measured at level 3 for the years ended December 31, 2016 and 2015:

	Derivative financial instruments	
	Year ended December 31	
	2016	2015
	U.S. dollars in thousands	
Balance at beginning of the year	1,237	2,125
Proceeds received during the reported year	6,070	—
Amounts recognized in profit or loss	(1,152)	(888)
Balance at the end of the year	6,155	1,237

The fair value of the above-mentioned derivative financial liabilities that are not traded in an active market is determined by using valuation techniques. The Company uses its judgment to select a variety of methods and make assumptions that are mainly based on market conditions existing at the end of each reporting period.

For more information regarding the derivatives, see note 15.

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NOTES TO THE FINANCIAL STATEMENTS (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, 2016:			
Cash and cash equivalents	—	53,786	53,786
Bank deposits	—	55	55
Receivables (except prepaid expenses)	—	1,541	1,541
Financial assets at fair value through profit or loss	12,313	—	12,313
	12,313	55,382	67,695
As of December 31, 2015:			
Cash and cash equivalents	—	21,516	21,516
Bank deposits	—	36,756	36,756
Receivables (except prepaid expenses)	—	2,260	2,260
	—	60,532	60,532

	Financial liabilities at fair value through profit or loss	Financial liabilities at amortized cost	Total
	U.S. dollars in thousands		
As of December 31, 2016:			
Accounts payable and accrued expenses	—	3,356	3,356
Derivative financial instruments	6,155	—	6,155
Payable in respect of intangible asset purchase	—	2,000	2,000
	6,155	5,356	11,511
As of December 31, 2015:			
Accounts payable and accrued expenses	—	3,514	3,514
Derivative financial instruments	1,237	—	1,237
Payable in respect of intangible asset purchase	—	2,000	2,000
	1,237	5,514	6,751

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

c. Composition of financial instruments by currency:

	U.S. dollar	Other currencies	Total
	U.S. dollars in thousands		
As of December 31, 2016:			
Assets:			
Cash and cash equivalents	51,936	1,850	53,786
Bank deposits	—	55	55
Financial assets at fair value through profit or loss	12,313	—	12,313
Receivables (except prepaid expenses)	1,078	463	1,541
	65,327	2,368	67,695
Liabilities:			
Accounts payable and accrued expenses	3,226	129	3,356
Payable in respect of intangible asset purchase	2,000	—	2,000
Derivative financial instruments	6,155	—	6,155
	11,382	129	11,511
	53,946	2,239	56,185
As of December 31, 2015:			
Assets:			
Cash and cash equivalents	20,282	1,234	21,516
Bank deposits	36,605	150	36,756
Receivables (except prepaid expenses)	2,064	196	2,260
	58,951	1,580	60,532
Liabilities:			
Accounts payable and accrued expenses	3,465	49	3,514
Payable in respect of intangible asset purchase	2,000	—	2,000
Derivative financial instruments	1,237	—	1,237
	6,702	49	6,751
	52,249	1,531	53,781

NOTE 5 - CASH AND CASH EQUIVALENTS:

	December 31	
	2016	2015
	U.S. dollars in thousands	
Cash in bank	53,772	5,990
Short-term bank deposits	14	15,526
	53,786	21,516

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

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

These financial assets as of December 31, 2016 represent a portfolio of U.S. dollar denominated marketable securities, which is managed and valued by the Company based on the fair value of all portfolio securities.

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

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 is based on their exchange market price at the end of the reporting date trading day.

NOTE 7 - PREPAID EXPENSES AND RECEIVABLES:

	December 31	
	2016	2015
	U.S. dollars in thousands	
Advances to suppliers	1,049	2,040
Discount from Service Provider	230	178
Prepaid expenses	120	112
Account receivable	101	—
Government institutions	161	42
	1,661	2,372

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	
	2016	2015	2016	2015	2016	2015
	U.S. dollars in thousands					
Office furniture and equipment (including computers)	203	151	101	76	102	75
Leasehold improvements	132	99	69	50	63	49
	335	250	170	126	165	124

NOTE 9 - INTANGIBLE ASSETS:

The intangible assets represent R&D assets with respect to intellectual property rights of the therapeutic 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	
	2016	2015
	U.S. dollars in thousands	
Cost:		
Balance at beginning of year	6,160	2,615
Additions during the year	35	3,545
Balance at end of year	6,195	6,160
Write off charge – balance at end of year	(100)	(100)
	6,095	6,060

In 2015, the Company recognized loss from writing off the initial $100,000 paid to a Danish company for the exclusive rights to a therapeutic candidate intended to treat congestive heart failure, left atrium dysfunction and high blood pressure. As the Company put on hold additional investments in the therapeutic candidate development, the above-mentioned amount exceeds the forecasted recoverable amount. Consequently, the Company decided to write off the entire amount and recorded a loss in the Statement of Comprehensive Loss under Other Expenses.

For further details regarding the intangible assets, see note 12.

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 2016, 2015 and 2014 were $121,000, $95,000 and $88,000, respectively. Of those amounts for 2016, approximately 68% were charged to general administrative and business development expenses and 32% to research and development expenses. Of those amounts for 2015 and 2014, approximately 60% were charged to general, administrative and business development expenses and 40% to research and development expenses.

NOTE 11 - ACCOUNTS PAYABLE AND ACCRUED EXPENSES:

	December 31	
	2016	2015
	U.S. dollars in thousands	
Trade payables	60	119
Accrued expenses	2,903	3,070
Employees and employees institutions	295	268
Government institutions	98	57
	3,356	3,514

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

NOTE 12 - COMMITMENTS:

a. Agreements to purchase intellectual property and U.S. rights to promote:

1) On May 2, 2010, the Company entered into an agreement with a U.S. publically-traded company that grants the Company an exclusive license to use rights relating to a therapeutic 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 therapeutic candidate, less certain deductible amounts as detailed in the agreement, during a period which is the shorter of: (1) expiry of the last patent granted under the license; (2) ten years from the beginning of marketing the therapeutic 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, 2016, 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 above mentioned therapeutic candidate. The Company therefore terminated the agreement with the U.S. company and licensed the patents directly from a U.S. university, the original owner of the patents. Under the agreement, the Company agreed to pay the U.S. university certain future payments.

2) On August 26, 2010, the Company entered into an agreement with IntelGenx Corp, a Canadian-based company which is traded in the U.S. and Canada, to co-develop RIZAPORT®, a therapeutic candidate for the treatment of acute migraines. Under the agreement, the Company paid the Canadian company up-front and milestone payments in the aggregate amount of $800,000, and undertook under the agreement to transfer additional amounts of up to $500,000 based on achieving milestones as agreed between the parties. In addition, the Company undertook to participate in additional therapeutic candidate research and development costs. Under the agreement, after recovery of certain costs and expenses, the Company will pay 60% royalties on sublicense revenues, less certain deductible amounts as detailed in the agreement, to the Canadian company for the first $2 million of such revenues. For revenues beyond the $2 million, the Company will pay royalties at 20% - 40 of the Company's revenues from the therapeutic candidate, after recovery of certain costs and expenses as detailed in the agreement. The 20% rate also applies until the Company recovers additional fees covered by the Company as detailed in the agreement. The agreement is for an indefinite period and is subject to certain termination conditions. Through December 31, 2016, the Company paid the Canadian company for the license of the therapeutic candidate under the agreement a total of approximately $800,000. In addition, through December 31, 2016, the Company participated in the therapeutic candidate research and development costs in the amount of approximately $1.3 million that was recorded in the statement of comprehensive loss under research and development expenses.

3) On August 11, 2010, the Company entered into an agreement with an Australian company in an asset purchase agreement to acquire intellectual property of the Australian company relating to three therapeutic candidates for the treatment of gastrointestinal conditions. Pursuant to the purchase agreement, the Company paid the Australian company an initial amount of $500,000 and undertook to pay future payments in the range of 7% - 20% of the Company revenues generated from the therapeutic candidates, less certain deductible amounts as detailed in the agreement. Through December 31, 2016, the Company paid the Australian company a total of $1.5 million. See also note 17 in connection with the license agreement for one of the therapeutic candidates.

4) On June 30, 2014, the Company entered into an agreement with a German publicly-traded company that grants the Company the exclusive worldwide (excluding China, Hong Kong, Taiwan and Macao) development and commercialization rights for all indications to an oncology therapeutic candidate. Under the terms of the agreement, the Company paid to the German company an upfront payment in the amount of $1 million and agreed to pay the German company potential tiered royalties on revenues, less certain deductible amounts as detailed in the agreement, ranging from mid-teens up to 30%. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2016, the Company paid the German company total amount of approximately $1 million.

5) On August 13, 2014, the Company entered into a binding exclusive option agreement with a private German company in relation to an oncology therapeutic candidate. Under the terms of the agreement, the Company has an option to acquire the worldwide exclusive rights of an oncology therapeutic candidate for all indications (excluding pancreatic cancer indication in South Korea). The option was extended in August 2016 for an additional nine-month period. During the option period, the Company may, at its discretion, conduct development activities with the therapeutic candidate. The total payment, for both the option and the acquisition of the rights, should the Company elect to exercise the option, will be $100,000, as well as potential milestone payments and tiered royalties on revenues, less certain deductible amounts as detailed in the agreement, ranging from single-digit to mid-teens. Through December 31, 2016, the Company paid a total amount of $45,000 in consideration of the option period. In February 2017, the Company provided notice of termination of the exclusive option agreement.

6) On March 30, 2015, the Company entered into an agreement with a U.S.-based private company that granted the Company the exclusive worldwide development and commercialization rights for all indications to an oncology therapeutic candidate, and additional intellectual property rights, targeting multiple inflammatory-GI and oncology disease indications. Under the terms of the agreement, the Company undertook to pay the U.S. Company an upfront payment in the amount of $1.5 million and an additional amount of $2 million which will be paid on the earlier of (i) a specific date or (ii) reaching a specific development milestone. In addition, the Company undertook to pay up to $2 million in potential development milestone payments, and potential tiered royalties on revenues, less certain deductible amounts as detailed in the agreement, starting in the low double-digits. Such potential royalties are due until the later of (i) the expiration of the last to expire licensed patent that covers the product in the relevant country; and (ii) the expiration of regulatory exclusivity in the relevant country. Through December 31, 2016, the Company paid the U.S. Company the initial amount of $ 1.5 million and recognized an amount of $2 million as a current liability.

7) On December 30, 2016, the Company entered into an exclusive co-promotion agreement with a subsidiary of Concordia, an international specialty pharmaceutical company focused on generic and legacy pharmaceutical products and orphan drugs.

   Under the exclusive commercialization agreement, the Company will be responsible for certain promotional activities related to Donnatal® in the U.S., Concordia will continue to be responsible for the manufacturing and supply of Donnatal® in all territories. The Company and Concordia will share the revenues generated from the promotion of Donnatal® by the Company based on an agreed upon split between them. There are no upfront or milestone payments under the agreement. The initial term of the agreement is three years.

b. Operating lease agreement

The Company entered into an operating lease agreement for the offices it uses. The agreement will expire on January 31, 2020. The projected yearly rental expenses are approximately $370,000 per year, of which we sublease office space to a third party for approximately $86,000 per year.

As of December 31, 2016, an amount of $137,000 was deposited with a bank to secure the lease payments.

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 13 - 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 2014 and 2015 was 26.5%.

In January 2016, a law was approved to reduce the corporate tax rate in 2016 to 25%.

On December 22, 2016, the Israeli Budgetary Law for 2017 and 2018 was approved, among other changes, reduces the regular corporate tax rate from 25% to 24% in 2017 and 23% in 2018 and thereafter.

c. **Carryforward losses**

The balance of carryforward losses as of December 31, 2016 is $71 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, 2016 and 2015, were $28 million and $21 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 2011 are hence considered final

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 14 - 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	
	2016	2015
	In thousands	
Authorized	300,000	200,000
Issued and paid	164,974	127,114

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, 2016 was $10.46 per

ADS on the NASDAQ and $1.05 per share on the TASE (based on the exchange rate reported by the Bank of Israel for such date).

On February 16, 2016, a special general meeting of shareholders approved the increase of the authorized share capital of the Company to 300,000,000 ordinary shares.

2) Exercise of options

During 2015, the Company received notifications of exercise with respect to options that had been issued to employees and a consultant of the Company. Accordingly, the Company issued 338,750 ordinary shares for $108,000.

During 2016, the Company received notifications of exercise with respect to options that had been issued to employees and consultants of the Company. Accordingly, the Company issued 725,790 ordinary shares for $263,000.

3) In February 2015, the Company completed an underwritten public offering in the U.S. of an aggregate of 1,150,000 ADSs at a price of $12.50 per ADS for gross proceeds to the Company of $14.4 million. Net proceeds to the Company from the offering, following discounts, commissions and expenses amounting to $1.2 million, were approximately $13.2 million.

As a result of the offering, a price protection right, provided by the Company to investors who participated in January 2014 private placement, was no longer valid. The change in the fair value of the price protection right of $542,000 was recognized as financial income in the statement of comprehensive loss in 2015.

4) In July 2015, the Company completed an underwritten public offering in the U.S. of an aggregate of 2,739,143 ADSs at a price of $16.25 per ADS generating gross proceeds to the Company of approximately 44.5$ million. Net proceeds to the Company from the offering, following underwriting discounts and other offering expenses of approximately $3 million, were approximately $41.5 million.

5) In December 2016, the Company completed an underwritten public offering and a registered direct offering in the U.S. of an aggregate of 3,713,415 ADSs and warrants to purchase 1,856,708 ADSs

for gross proceeds to the Company of $38.1 million. Net proceeds to the Company from the offering, following discounts, commissions and expenses amounting to $2.3 million, were approximately $35.8 million. As part of the offering, one of the Company's directors, purchased 95,000 ADSs and warrants to purchase 47,500 ADSs for a total consideration of $1 million, see also note 22b below.

In addition, as part of the public offering, the underwriters received an option to purchase 337,500 ADSs and warrants to purchase 168,750 ADSs. On December 27, 2016, the underwriters partially exercised their option and purchased warrants to purchase 168,750 ADSs.

The warrants were classified as a financial liability due to a net settlement provision. These derivatives were recognized and subsequently measured at fair value through profit or loss. The consideration, net of issue expenses, was allocated to the various issued instruments. Out of the gross consideration, amount of $6.1 million was allocated to the warrants. The remainder of approximately $32 million was allocated to ADSs. Issuance expenses were allocated both to the liability instruments and to the equity component. Expenses allocated to the liability instruments, in amount of $0.4 million, were recorded directly to the statement of comprehensive loss, and expenses in the amount of $1.9 million allocated to the equity component were recorded against share premium.

For information regarding the terms of the warrants, see note 15b below.

For more information regarding the proceeds to the Company following the partial exercise by the underwriters of their option, see note 23 below.

b. **Warrants**

The warrants issued under investment agreements from January 2014 were exercisable into 4,183,496 ordinary shares. The warrants had a three-year term and were exercisable at an exercise price of $1.4 per ordinary share. In January 2017, the warrants expired along with any right or claim of the holders.

NOTE 15 - DERIVATIVE FINANCIAL INSTRUMENTS:

a. Warrants issued in 2014

The warrants issued under an investment agreement from January 2014, were classified as a financial liability due to a net settlement provision. These warrants were exercisable into 357,896 ADSs and had a three-year term.

In January 2017, warrants exercisable into 252,632 ADSs were exercised, resulting in proceeds to the Company of approximately $2.63, million and the remaining unexercised warrants expired along with any right or claim of the holders. For more information regarding the exercise of the warrants, see note 23 below.

The fair value of the warrants was computed using the Black and Scholes option pricing model. The fair value of the warrants as of December 31, 2015, was based on the price of an ADS on December 31, 2015 and based on the following parameters: risk-free interest rate of 0.66% and an average standard deviation of 49.55%. The fair value of the warrants as of December 31, 2016, was based on the price of an ADS on December 31, 2016 and based on the following parameters: risk-free interest rate of 0.1% and an average standard deviation of 40.35%.

b. Warrants issued in 2016

The warrants issued under the offering, as described in note 14a(5) above, were classified as a financial liability due to a net settlement provision. These warrants are exercisable into 2,025,458 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 $13.33 per ADS.

The fair value of the warrants is computed using the Black and Scholes option pricing model. The fair value of the warrants upon issuance was computed based on the price of an ADS and based on the following parameters: risk-free interest rate of 1.56% and an average standard deviation of 53.13%. The fair value of the warrants as of December 31, 2016, is based on the price of an ADS on December 31, 2016 and based on the following parameters: risk-free interest rate of 1.48% and an average standard deviation of 52.94%.

NOTE 16 - SHARE-BASED PAYMENTS:

On May 30, 2010, a general meeting of shareholders approved the option plan of the Company for 2010 (the "Option Plan"), after being approved by the board of directors. It was resolved in 2015 to increase the Option Plan to allow the Company to allocate 30,000,000 options to employees, consultants 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 2016:

	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		
April 2016	590,000	—	590,000	1.41	400
June 2016	—	1,500,000	1,500,000	1.28	725
June 2016 (3)	—	150,000	150,000	1.48	105
	590,000	1,650,000	2,240,000		1,125

1) The options will vest as follows: for employees and consultants of the Company who had provided services exceeding one year to the Company as of the grant date, the options will vest in 16 equal quarterly installments over a four-year period. For employees and consultants of the Company who had not provided services to the Company exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over the following three years in 12 equal quarterly installments. The options will be exercisable, either in full or in part, from the vesting date until the end of 7 years from the date of grant.

2) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $1.28 - $1.41, expected volatility: 52.52% - 53.09%, risk-free interest rate: 1.51% - 1.57% and expected useful life to exercise: seven years.

3) In June 2016, the Company annual general meeting of shareholders approved the acceleration of 150,000 unvested options of Aliza Rotbard, of blessed memory, a former external director of the Company. Each option is exercisable into one ordinary share at an exercise price of $1.48 per share and will expire in November 2017. The allocated expenses, in the amount of $105 thousand were recorded directly to the statement of comprehensive loss under general and administrative expenses.

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

b. Following is information on options granted in 2015:

Date of grant	Number of options granted: According to option plan of the company: Other than directors (1)	Number of options granted: According to option plan of the company: Total	Exercise price to 1 ordinary share ($)	The fair value of options on date of grant in U.S.$ thousands (2)
May 2015	300,000	300,000	1.61	218
September 2015	2,375,072	2,375,072	1.56	1,392
	2,675,072	2,675,072		1,610

* 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 exceeding one year to the Company as of the grant date, the options will vest in 16 equal quarterly installments over a four-year period. For employees and consultants of the Company who had not provided services to the Company exceeding one year as of the grant date, the options will vest as follows: 1/4 of the options will vest one year following the grant date and the rest over the following three years in 12 equal quarterly installments. The options will be exercisable, either in full or in part, from the vesting date until the end of 7 years from the date of grant.

2) The fair value of the options was computed using the binomial model and the underlying data used was mainly the following: price of the Company's ordinary share: $1.3 - $1.56, expected volatility: 51.75% - 53.3%, risk-free interest rate: 1.87% - 1.92% and expected useful life to exercise: seven years.

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

	Year ended December 31: 2016: Number of options	2016: Weighted average of exercise price	2015: Number of options	2015: Weighted average of exercise price
Outstanding at beginning of year	20,511,338	$ 0.88	18,325,016	$ 0.78
Exercised	(725,790)	$ 0.36	(338,750)	$ 0.32
Expired	—		(150,000)	$ 1.48
Granted	2,240,000	$ 1.33	2,675,072	$ 1.57
Outstanding at end of year	22,025,548	$ 0.95	20,511,338	$ 0.88
Exercisable at end of year	15,168,938	$ 0.85	15,493,449	$ 0.68

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

December 31, 2016: Number of options outstanding at end of Year	Exercise price range	Weighted average of remaining useful life	December 31, 2015: Number of options outstanding at end of year	Exercise price range	Weighted average of remaining useful life
22,025,548	$ 0.17-$1.61	3.8	20,511,338	$ 0.17-$1.61	3.6

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

Year ended December 31		
2016	2015	2014
U.S. dollars in thousands		
1,679	1,364	1,753

The remaining compensation expenses as of December 31, 2016 are $1.4 million and will be expensed in full by May 2020.

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 17 - REVENUES:

a) On February 27, 2014, the Company entered into an exclusive agreement by which Salix Pharmaceuticals, Inc. ("Salix"), which was later acquired by Valeant Pharmaceuticals International, Inc., or Valeant, licensed the worldwide exclusive rights to one of the Company's therapeutic candidates, an encapsulated formulation for bowel preparation, and rights to other purgative developments. Under the license agreement, Salix paid an upfront payment of $7 million with subsequent potential milestone payments up to a total of $5 million. Salix has also agreed to pay the Company tiered royalties on net sales, ranging from low single-digit up to low double-digits. As there was no continuing managerial involvement of the Company under the agreement with Salix to develop any product based on the license and related intellectual property granted to Salix, the upfront payment of $7 million was recognized in 2014 as revenue in the statement of comprehensive loss.

Following the agreement with Salix, and pursuant to the purchase agreement from August 11, 2010, between the Company and an Australian company from which it purchased the rights sold to Salix, the Company paid to the Australian company $1 million in 2014. The amount paid was recognized as cost of revenue in the statement of comprehensive loss.

b) In 2016, the Company and its co-development partner, IntelGenx Corp., entered into exclusive license agreements granting to third parties the right to register and commercialize RIZAPORT® in two territories, and a right of first refusal for additional territories. Under the license agreements, the Company and IntelGenx Corp. are entitled to receive an upfront payment and additional milestone payments upon the achievement of certain predefined regulatory and commercial targets, as well as tiered royalties.

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 18 - RESEARCH AND DEVELOPMENT EXPENSES, net**:**

	Year ended December 31		
	2016	2015	2014
	U.S. dollars in thousands		
Payroll and related expenses	652	621	573
Professional services	1,816	1,953	1,685
Share-based payments	841	842	951
Clinical and pre-clinical trials	21,013	13,611	9,187
Intellectual property development	428	216	556
Other	772	713	382
Discount from service provider*	(281)	(185)	(634)
	25,241	17,771	12,700

* Discount provided to the Company by its Canadian service provider due to certain Canadian authorities' incentives programs.

NOTE 19 – GENERAL, ADMINISTRATIVE AND BUSINESS DEVELOPMENT EXPENSES:

	Year ended December 31		
	2016	2015	2014
	U.S. dollars in thousands		
Payroll and related expenses	1,383	986	943
Share-based payments	838	522	802
Professional services	2,338	2,050	1,662
Office related expenses, net	380	173	187
Other	464	403	417
	5,403	4,134	4,011

NOTE 20 - FINANCIAL EXPENSES (INCOME), net**:**

	Year ended December 31		
	2016	2015	2014
	U.S dollars in thousands		
Financial income:			
Fair value gain on derivative financial instruments	1,152	888	200
Fair value gain on financial assets at fair value through profit or loss	80	—	—
Gain from changes in exchange rates	34	—	—
Interest from bank deposits	282	236	119
	1,548	1,124	319
Financial expenses:			
Loss from changes in exchange rates	—	200	361
Issued cost in respect of warrants	368	—	—
Other	7	12	22
	375	212	383
Financial expenses (income) - net	(1,173)	(912)	64

REDHILL BIOPHARMA LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 21 - 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		
	2016	2015	2014
Loss (U.S. dollars in thousands)	29,370	21,090	10,711
Weighted average number of ordinary shares outstanding during the period (in thousands)	128,514	110,814	86,610
Basic loss per share (U.S. dollars)	0.23	0.19	0.12

b. Diluted

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding assuming conversion of all dilutive potential ordinary shares, which is calculated using the Treasury Method. The Company has two categories of dilutive potential ordinary shares: warrants issued to investors and options issued to employees and service providers. The effect of options issued to employees and service providers is anti-dilutive.

	Year ended December 31		
	2016	2015	2014
Loss (U.S. dollars in thousands)	29,370	21,090	10,711
Adjustment for financial income of warrants	1,208	346	463
Loss used to determine diluted loss per share	30,578	21,436	11,174
Weighted average number of ordinary shares outstanding during the period (in thousands)	128,514	110,814	86,610
Adjustment for warrants	295	901	612
Weighted average number of ordinary shares for diluted loss per share (in thousands)	128,809	111,715	87,222
Diluted loss per share (U.S. dollars)	0.24	0.19	0.13

NOTE 22 - RELATED PARTIES:

a. Key management in 2016 includes members of the Board of Directors and the Chief Executive Officer

	Year ended December 31		
	2016	2015	2014
	U.S. dollars in thousands		
Key management compensation:			
Salaries and other short-term employee benefits	576	776	628
Post-employment benefits	32	58	60
Share-based payments	504	382	726
Other long-term benefits	11	27	31

b. Balances with related parties:

	December 31	
	2016	2015
	U.S. dollars in thousand	
Current liabilities -		
Credit balance in "accounts payable	174	264
Non-current liabilities -		
Derivative financial instruments	144	-

NOTE 23 - EVENTS SUBSEQUENT TO DECEMBER 31, 2016:

a. In January 2017, the Company received notifications of exercise with respect to share options that had been issued to employees, consultants and directors of the Company. Accordingly, the Company issued 1,750,000 ordinary shares for $605 thousand.

b. On January 3, 2017, the underwriters for the Company's 2016 underwritten public offering partially exercised their option and purchased 133,104 ADSs. Following the partial exercise of the underwriters' option, the underwritten public offering and the concurrent registered direct offering totaled 3,846,519 ADSs and warrants to purchase 2,025,458 ADSs, representing aggregate gross proceeds from both offerings combined of approximately $39.4 million before deducting underwriting discounts and commissions, placement agent fees and other offering expenses.

c. In January 2017, the Company received notifications of exercise with respect to the exercise of warrants that had been issued as part of a private placement. Accordingly, the Company issued 2,526,320 ordinary shares for approximately $2.63 million. The remaining unexercised warrants to purchase 5,236,136 ordinary shares issued as part of private placements expired along with any right or claim whatsoever of the holders thereof.

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) (incorporated by reference to Exhibit 1.1 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
2.1	Form of Deposit Agreement among the Registrant, the Bank of New York Mellon, as Depositary, and all Owners and Holders from time to time of American Depositary Shares issued hereunder (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
2.2	Form of American Depositary Receipt (incorporated by reference to Exhibit 1 to the Registration Statement on Form F-6 filed by The Bank of New York Mellon with the Securities and Exchange Commission on December 6, 2012).
4.1*	Co- Development and Commercialization Agreement, dated August 26, 2010, by and between the Registrant and IntelGenx Corp. (incorporated by reference to Exhibit 4.3 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.2*	Side Letter Agreement, dated January 31, 2013, by and between the Registrant and IntelGenx Corp (incorporated by reference to Exhibit 4.4 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2014).
4.3*	Asset Purchase Agreement, dated August 11, 2010, by and between the Registrant and Giaconda Limited (RHB-104, 105, 106) (incorporated by reference to Exhibit 4.4 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.4*	Amendment to Asset Purchase Agreement by and between the Registrant and Giaconda Limited (RHB-104, 105, 106) dated February 27, 2014 (incorporated by reference to Exhibit 4.4 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.5*	License Agreement, dated September 15, 2011, by and between the Registrant and University of Central Florida Research Foundation (incorporated by reference to Exhibit 4.5 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated October 26, 2012).
4.6*	License Agreement, dated February 27, 2014, by and between the Registrant and Salix Pharmaceuticals, Inc. (later acquired by Valeant Pharmaceuticals International, Inc.) (incorporated by reference to Exhibit 4.6 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.7*	Exclusive License Agreement, dated March 30, 2015, by and between the Registrant and Apogee Biotechnology Corp (incorporated by reference to Exhibit 4.7 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.8*	Clinical Services Agreement, dated June 15, 2011, by and between the Registrant and 7810962 Canada Inc. and amendment (regarding RHB-104) (incorporated by reference to Exhibit 4.15 to Draft Registration Statement on Form DRS disseminated with the Securities and Exchange Commission, dated December 3, 2012).
4.9	Change Order #4.1 dated August 9, 2015 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.12 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).

4.10*	Change Order #5 dated May 21, 2015 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.13 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.11†	Change Order #5.1 dated March 3, 2016 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc.
4.12†	Change Order #6 dated June 22, 2016 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc.
4.13†	Change Order #6.1 dated August 31, 2016 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc.
4.14†	Change Order #7 dated November 16, 2016 to the Clinical Services Agreement, dated June 15, 2011 by and between the Registrant and 7810962 Canada Inc.
4.15*	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).
4.16*	Third Amendment to Clinical Services Agreement, dated December 7, 2014, by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.14 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.17*	Fourth Amendment to Clinical Services Agreement, dated December 17, 2014, by and between the Registrant and 7810962 Canada Inc. (incorporated by reference to Exhibit 4.15 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.18*	Clinical Trials Global Master Service Agreement, dated December 27, 2012 by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) (incorporated by reference to Exhibit 4.22 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.19	Global Master Service Agreement amendment, dated June 20, 2014 by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) (incorporated by reference to Exhibit 4.23 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.20	Amendment No. 2 dated May 13, 2015 to the Clinical Trials Global Master Service Agreement, dated December 27, 2012 by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) (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, 2016).
4.21*	Master Agreement Work Order, dated May 13, 2014, by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) (incorporated by reference to Exhibit 4.24 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.22*	Amendment No. 1 dated December 30, 2015 to the Master Agreement Work Order, dated May 13, 2014, by and between the Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104). (incorporated by reference to Exhibit 4.21 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).
4.23*	Change Specification Form by and between Registrant and Q Squared Solutions LLC (f/k/a Quest Diagnostics) (regarding RHB-104) dated June 6, 2015. (incorporated by reference to Exhibit 4.22 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 25, 2016).

4.24†	Exclusive Commercialization Agreement, dated December 30, 2016, by and between Registrant and Concordia Pharmaceuticals Inc.
4.25	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).
4.26	2010 Stock Option Plan, as amended (incorporated by reference to Exhibit 4.27 of the Annual Report on Form 20-F filed with the Securities and Exchange Commission on February 26, 2015).
4.27	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).
4.28	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).
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/ Micha Ben Chorin
Name: Micha Ben Chorin
Title: Chief Financial Officer

Date: February 23, 2017

Confidential

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

Change Order 5.1 to Clinical Services Agreement

Client's study drug RHB-104

This Change Order 5.1 ("**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 5320 13th Avenue, Montreal, Quebec, H1X 2X8, Canada ((hereinafter "MANAGER");

WHEREAS, "SPONSOR" mandated "MANAGER" to enter into a subcontract with inVentiv Health Clinical to act as a CRO for its Study (as defined in the Clinical Services Agreement);

Is hereby made effective as of February 26, 2016 ("**Effective Date**") and the parties hereby agree as follows:

1. Change Order 5.1 to Clinical Services Agreement.

   This Change Order constitutes an amendment to the Clinical Services Agreement pursuant to section 3.0 therein. As such, this Change Order is subject in all respects to the terms and provisions of the Clinical Services Agreement.

2. Scope of Work

   In addition to the Services to be provided in the above-referenced Clinical Services Agreement, the pass through expenses will be modified in accordance with the Summary of Changes attached hereto and incorporated herein as Exhibit A.

3. Compensation

   Under this Change Order, inVentiv Health Clinical's Pass-through Costs have increased by the amount of USD [****]. The total costs of the Clinical Services Agreement have increased to USD [****].

Payment due to inVentiv Health Clinical for the Change Order shall be made pursuant to the Agreement.

4. Project Period

The term of this Change Order shall commence on the date of its execution and shall continue until the Services as described in the Clinical Services Agreement are completed, unless this Change Order or corresponding Clinical Services Agreement are terminated early in accordance with the Clinical Services Agreement.

By their signatures below, the parties hereto agree to the terms of this Change Order and represent that they are authorized to enter into this Change Order on behalf of their respective companies.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd.	For 7810962 Canada
/s/ Micha Ben Chorin	/s/ Alain Guimond
Name: Micha Ben Chorin	Name: Alain Guimond
Title: CFO	Title: V-P R&D
Date: March 3, 2016	Date: 01-March-2016

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

Date: March 3, 2016

Study Assumption Changes

Changes to the parameters and assumptions for the study are defined below. Unless otherwise noted, activities will be performed according to the original contract.

Change Order 5.1 for 7810962 Canada Inc. /Red Hill Biopharma Ltd.

1.1 Revised Costs

Costs for this study are presented below in two categories, pass-through costs and professional fees.

1.1.1 Pass-Through Costs

Pass-through costs are in US dollars and include those expenses listed below. inVentiv Health Clinical will invoice Client for actual costs in these areas, it being understood that any pass-through costs in excess of the amounts set out below will require the Client's prior written approval. inVentiv Health Clinical will use its best efforts to keep actual costs to reasonable levels through adherence to inVentiv Health Clinical's travel policy and prudent negotiation with outside providers. Pass-through costs are presented in the table below:

Task	Current (USD)	Change Order #5.1	Assumption Changes influencing the change in the budget	Additional comments
Site Visit Travel	$[****]	$[****]	No change	
Investigators' Meeting Organisation	$[****]	$[****]	No change	
Kick-off Meeting Travel/Attendance	$[****]	$[****]	No change	
Shipping/Photocopying	$[****]	$[****]	No change	
Translation	$[****]	$[****]	No change	
Regulatory Fees	$[****]	$[****]	No change	
Ethics Committee Fees	$[****]	$[****]	No change	
EDC Studies/3G Cards	$[****]	$[****]	No change	
DSMB member fees	$[****]	$[****]	No change	
EDC Fees (Oracle)	$[****]	$[****]	Oracle has quoted $[****]to implement and execute the Quest Data integration to Inform DB and the Oracle Contract is being extended by [****] months for a cost of $[****]	
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	

1.1.3 Professional Fees

Based on the parameters and assumptions outlined in the original proposal, inVentiv Health Clinical fees are categorised by major activity in the table below and in USD:

Task	Current (US Dollars)	Change Order #5.1	Assumption Changes influencing the change in the budget	Additional comments
Pre-study Activities				
Case Report Form Preparation/Review	$[****]	$[****]	No Change	
Data Management Plan Preparation/Review	$[****]	$[****]	No Change	
Informed Consent Preparation/Review	$[****]	$[****]	No Change	
IRB/Ethics Committee Interactions	$[****]	$[****]	No Change	
Investigators' Meetings	$[****]	$[****]	No Change	
Investigator Site Contract	$[****]	$[****]	No Change	
Investigator Recruitment	$[****]	$[****]	No change	
Project Feasibility	$[****]	$[****]	No change	
Project Plan Preparation/Review	$[****]	$[****]	No Change	
Protocol Preparation/Review	$[****]	$[****]	No Change	
Randomization Schedule Preparation	$[****]	$[****]	No Change	
Study-Specific Form Preparation	$[****]	$[****]	No Change	
Training - Project-Specific	$[****]	$[****]	No Change	
Translations	$[****]	$[****]	No Change	
PROMIS	$[****]	$[****]	No Change	
Monitoring/Site Management				
Data Clean-up	$[****]	$[****]	No Change	
Investigator Grant Administration	$[****]	$[****]	No Change	

Task	Current (US Dollars)	Change Order #5.1	Assumption Changes influencing the change in the budget	Additional comments
Laboratory Report Review	$[****]	$[****]	No Change	
Serious/Significant Adverse Event Management	$[****]	$[****]	No Change	
Site Management	$[****]	$[****]	No Change	
Remote Monitoring of Site Data	$[****]	$[****]	No Change	
Site Visits - Pre-study Visits	$[****]	$[****]	No Change	
Site Visits - Initiation Visits	$[****]	$[****]	No Change	
Site Visits - Routine Visits conducted on site	$[****]	$[****]	No Change	
Site Visits - Close-out Visits at each site at Study End	$[****]	$[****]	No Change	
Study Master File/Project File Set-up and Maintenance	$[****]	$[****]	No Change	
Patient/Site Recruitment	$[****]	$[****]	No Change	
Client/CRO meeting	$[****]	$[****]	No Change	
Regulatory				
Regulatory Documentation Preparation/Review	$[****]	$[****]	No Change	
Project Management /Project Tracking				
Financial Project Management	$[****]	$[****]	No Change	
Project Management	$ [****]	$ [****]	No Change	
Project Tracking / Communications	$[****]	$[****]	No Change	
Vendor Management	$[****]	$[****]	No Change	.
Data Management				
Database Archiving	$[****]	$[****]	No change	
Data Cleanup (DM)	$[****]	$[****]	No Change	
Data Management: Database Quality Control Inspection	$[****]	$[****]	No Change	
Database Design	$[****]	$[****]	No Change	
Dictionary Coding	$[****]	$[****]	No Change	
Edit Check Programming	$[****]	$[****]	No Change	

Task	Current (US Dollars)	Change Order #5.1	Assumption Changes influencing the change in the budget	Additional comments
Electronic Data Import	$[****]	$[****]	No Change	
Case Report Form Data/Document Transfers	$[****]	$[****]	No Change	
EDC Fees	$[****]	$[****]	No Change	
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				
Project Team Meetings - Internal Meetings	$ [****]	$ [****]	No Change	
Project Team Meetings - Client Teleconferences	$[****]	$[****]	No Change	
Project Team Meetings - Kick-off Meeting	$[****]	$[****]	No Change	
Total Direct Costs	**$**[****]	**$**[****]		

Total Costs

Category	Total Costs($)		
	Current Contract (USD)	Change in Scope # 5.1 (USD)	Revised Total (USD)
Pass-Through Costs	$[****]	$[****]	$[****]
Investigator Grants Costs	$[****]	$[****]	$[****]
Professional Fees	$[****]	$[****]	$[****]
Discount	-$[****]	$[****]	-$[****]
Revised Professional Fees	$[****]	$[****]	$[****]
Grand Total	$[****]	$[****]	$[****]

1. PAYMENT TERMS

A. Service Fees:

Exhibit B
inVentiv Health Clinical
Milestone Payment Schedule
7810962 Canada Inc. (11ISB001)

Milestone	Original Agreement	CO#2 with Discount	CO#3 with Discount	CO#4 with Discount	CO#5	Total (USD) with Discount	Invoice #	Invoice Amount	Paid Amount
Upon Execution of Contract	250,249					250,249	11ISB001-001	250,249	250,249
Upon Execution of CO#3			904,042			904,042	11ISB001-064	904,042	904,042
Upon Execution of CO#4				119,480		119,480	11ISB001-065	119,480	119,480
Upon Execution of CO#5					349,419	349,419			
Completion of Investigator Meeting						0			
50% of Site Initiation Visits completed						0			
Last Site Initiation Visits completed						0			
Database Release (eCRF release) to Production						0			
First Patient In US Trial	250,249	-250,249				0			
First Patient In European Trial	250,249	-250,249				0			
Last Patient In US Trial	344,865	-344,865				0			
Last Patient In European Trial	344,865	-344,865				0			
First Patient In		421,712				421,712	11ISB001-034/11ISB001-042	421,712	421,712
Last Patient in		576,327	300,000			876,327			
	1,440,477	**-192,189**	**1,204,042**	**119,480**	**349,419**	**2,921,229**			
26-week Subject Treatment Period Ends:						0			
DBL for all patients completing 26-weeks completed		412,620	280,000			692,620			
Study Unblinded after analysis of efficacy part completed						0			
Delivery of Draft Tables, Listings and Graphs						0			
Delivery of Final Tables, Listings and Graphs						0			
Delivery of Final 26 CSR US Trial	750,746	-750,746				0			
Delivery of Final 26 CSR European Trial	750,746	-750,746				0			
	1,501,492	-1,088,872	280,000			692,620			
52-week Subject Treatment Period ends:						0			
DBL for all patients completed		232,364	200,000			432,364			
Delivery of Draft Tables, Listings and Graphs						0			
Delivery of Final Tables, Listings and Graphs						0			
Delivery of Final 52 CSR US Trial	261,441	-261,441				0			
Delivery of Final 52 CSR European Trial	261,442	-261,441				1			
Delivery of Final CSR		124,981				124,981			
Database Lock						0			
Delivery of Draft CRF US Trial	261,432	0				261,432	11ISB001-023	261,432	261,432
Delivery of Draft CRF European Trial	261,432	-261,432				0			
	1,045,747	**-426,969**	**200,000**			**818,778**			
Total Milestones	**3,987,716**	**-1,708,030**	**1,684,042**			**4,432,627**		**1,956,915**	**1,956,915**

Quarterly Project Management Fee (10 Quarters starting June 16, 2011, ending December 15, 2013: 183,590 USD per quarter) Only Invoiced for 7 quarters	1,835,894	-598,157				1,237,737	See below	1,237,737	1,054,147
Monthly Fees for Hold Period: (9 Monthlies starting April 2012, ending December 2012: 15,000 USD per month) Only Invoiced for 6 months		90,000				90,000	11ISB001-017	90,000	90,000
Quarterly Project Management Fee: (8 Quarterly Payments starting January 2014: $173,477.50 USD per quarter) Only invoiced for 4 quarters		1,387,820	-693,909			693,911	See below	693,911	
Quarterly Project Management Fee: (4 Quarterly Payments starting January 2015: $244,147.50 USD per quarter)			976,590			976,590	See below	732,443	
Total Milestone Payments[1]	**5,823,610**	**-828,367**	**1,966,723**			**7,430,865**		**3,978,563**	**3,101,062**

[1] - Professional fees are net of the 5% discount applied to Original Agreement and CO#1-#4

Quarterly Payments			
3rd Quarter 2011	11ISB001-002	183,590.00	183,590
4th Quarter 2011	11ISB001-006	183,590.00	183,590
1st Quarter 2012	11ISB001-008	183,590.00	183,590
1st Quarter 2012 (Reconciled for Amendment #1)	11ISB001-017 & 19	(47,393.00)	(47,393)
1st Quarter 2013	11ISB001-022	183,590.00	183,590
2nd Quarter 2013	11ISB001-027	183,590.00	183,590
3rd Quarter 2013	11ISB001-032	183,590.00	183,590
4th Quarter 2013	11ISB001-032	183,590.00	183,590
1st Quarter 2014	11ISB001-042	173,477.50	173,478
2nd Quarter 2014	11ISB001-045	173,477.50	173,478
3rd Quarter 2014	11ISB001-053	173,477.50	173,478
4th Quarter 2014	11ISB001-058	173,478.00	173,478
1st Quarter 2015	11ISB001-064	244,147.50	244,148
2nd Quarter 2015	0030014002	244,147.50	
3rd Quarter 2015		244,147.50	
4th Quarter 2015			

2. Pass Through Costs:

(a) CO#2: Twenty percent (20%) of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling $[****], 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: Twenty percent (20%) 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) 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.
(d) CO#5: This is a one-time payment of $[****] (exclusive of funds for investigator grants), that will be due and payable upon execution of this Agreement.
(e) Actual pass-through expenses, as provided in the expenses estimate, will be billed as incurred by inVentiv Health Clinical
(f) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

3. Investigator Grants:

(a) Twenty percent (20%) of the estimated total of the grant payments of the study, totaling $[****], will be invoiced upon commencement of services. Prepayment for Investigator Grants (to be drawn down once paid and replenished once 75% depleted). This process to continue until the end of the study.
(b) inVentiv Health Clinical will submit invoices in advance for estimated amounts to be paid to investigators during the next quarter to ensure that adequate funds are available to pay investigator grants
(c) inVentiv Health Clinical will not make payments to investigators without having sufficient funds available in advance.
(d) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

4. Payment Conditions:

(a) For all Services, pass through expenses and investigator grants invoiced, payments are due net thirty (30) days from invoice date as set forth in Terms, Item 2 of the Agreement. In the event of a dispute, all undisputed portions of the invoice(s) are due within the above stated terms
(b) Payments shall be made in the currency identified above and shall be made free of any applicable local withholding taxes, charges or remittance fees. Invoices will be inclusive of applicable taxes as determined by local laws and regulations
(c) inVentiv Health Clinical reserves the right to charge interest against any unpaid overdue balance at the rate of one and a half percent (0.5%) per month
(d) All services and pass-through payments should be sent via wire or ACH

Confidential

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

Change Order 6.1 to Clinical Services Agreement

Client's study drug RHB-104

This Change Order 6.1 ("**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 5320 13th Avenue, Montreal, Quebec, H1X 2X8, Canada ((hereinafter "MANAGER");

WHEREAS, "SPONSOR" mandated "MANAGER" to enter into a subcontract with inVentiv Health Clinical to act as a CRO for its Study (as defined in the Clinical Services Agreement);

Is hereby made effective as of July 28, 2016 ("**Effective Date**") and the parties hereby agree as follows:

1. Change Order 6.1 to Clinical Services Agreement.

   This Change Order constitutes an amendment to the Clinical Services Agreement pursuant to section 3.0 therein. As such, this Change Order is subject in all respects to the terms and provisions of the Clinical Services Agreement.

2. Scope of Work

   In addition to the Services to be provided in the above-referenced Clinical Services Agreement, inVentiv Health Clinical will perform additional Services for Client's study drug RHB-104, in accordance with the Summary of Changes attached hereto and incorporated herein as Exhibit A.

3. Compensation

   Under this Change Order, inVentiv Health Clinical's Professional Fees have increased by the amount of USD [****]. The total costs of the Clinical Services Agreement have increased to USD [****].

Payment due to inVentiv Health Clinical for the Services provided under this Change Order shall be made pursuant to the Agreement and the revised unit Payment Schedule attached hereto and incorporated herein as Exhibit B.

4. Project Period

The term of this Change Order shall commence on the date of its execution and shall continue until the Services as described in the Clinical Services Agreement are completed, unless this Change Order or corresponding Clinical Services Agreement are terminated early in accordance with the Clinical Services Agreement.

By their signatures below, the parties hereto agree to the terms of this Change Order and represent that they are authorized to enter into this Change Order on behalf of their respective companies.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd.		For 7810962 Canada
/s/ Dror Ben-Asher	/s/ Micha Ben Chorin	/s/ Alain Guimond
Name: Dror Ben-Asher	Micha Ben Chorin	Name: Alain Guimond
Title: CEO	CFO	Title: V-P R&D
Date: August 31, 2016_____		Date: 30-August-2016

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 6.1 for 7810962 Canada Inc. /Red Hill Biopharma Ltd.

Overview of major level changes

- The fee to add [****]to the DCRA team is $[****]- There are [****]hrs in the [****]month period from [****] through to [****]. The hourly rate is $[****]/hr.
- Number of DCRAs changed from [****] to [****].

1.1 Revised Costs

Costs for this study are presented below in two categories, pass-through costs and professional fees.

1.1.1 Pass-Through Costs

Pass-through costs are in US dollars and include those expenses listed below. inVentiv Health Clinical will invoice Client for actual costs in these areas, it being understood that any pass-through costs in excess of the amounts set out below will require the Client's prior written approval. inVentiv Health Clinical will use its best efforts to keep actual costs to reasonable levels through adherence to inVentiv Health Clinical's travel policy and prudent negotiation with outside providers. Pass-through costs are presented in the table below:

Task	Current (USD)	Change Order #6.1	Assumption Changes influencing the change in the budget	Additional comments
Site Visit Travel	$[****]	$[****]	No change	
Investigators' Meeting Organization	$[****]	$[****]	No change	
Kick-off Meeting Travel/Attendance	$[****]	$[****]	No change	
Shipping/Photocopying	$[****]	$[****]	No change	
Translation	$[****]	$[****]	No change	
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 (USD)**	**Change Order #6.1**	**Assumption Changes influencing the change in the budget**	**Additional Comments**
	$[****]	$[****]	No Change	Estimate only. Will be paid based on actual costs as approved by the Client.

1.1.3 Professional Fees

Based on the parameters and assumptions outlined in the original proposal, inVentiv Health Clinical fees are categorised by major activity in the table below and in USD:

Task	**Current (US Dollars)**	**Change Order #6.1**	**Assumption Changes influencing the change in the budget**	**Additional comments**
Pre-study Activities				
Case Report Form Preparation/Review	$[****]	$[****]	No change	No change
Data Management Plan Preparation/Review	$[****]	$[****]	No change	No change
Informed Consent Preparation/Review	$[****]	$[****]	No change	No change
IRB/Ethics Committee Interactions	$[****]	$[****]	No change	No change
Investigators' Meetings	$[****]	$[****]	No change	No change
Investigator Site Contract	$[****]	$[****]	No change	No change
Investigator Recruitment	$[****]	$[****]	No change	No change
Project Feasibility	$[****]	$[****]	No change	No change
Project Plan Preparation/Review	$[****]	$[****]	No Change	No change

Task	Current (US Dollars)	Change Order #6.1	Assumption Changes influencing the change in the budget	Additional comments
Protocol Preparation/Review	$[****]	$[****]	No change	No change
Randomization Schedule Preparation	$[****]	$[****]	No change	No change
Study-Specific Form Preparation	$[****]	$[****]	No change	No change
Training - Project-Specific	$[****]	$[****]	No change	No change
Translations	$[****]	$[****]	No change	No change
PROMIS	$[****]	$[****]	No change	No change
Monitoring/Site Management				
Data Clean-up	$[****]	$[****]	No change	No change
Investigator Grant Administration	$[****]	$[****]	No change	No change
Laboratory Report Review	$[****]	$[****]	No change	No change
Serious/Significant Adverse Event Management	$[****]	$[****]	No change	No change
Site Management	$[****]	$[****]	No change	No change
Remote Monitoring of Site Data	$[****]	$[****]	No change	No change
Site Visits - Pre-study Visits	$[****]	$[****]	No change	No change
Site Visits - Initiation Visits	$[****]	$[****]	No change	No change
Site Visits - Routine Visits conducted on site	$[****]	$[****]	No change	No change
Site Visits - Routine Visits conducted on site – Dedicated NA CRA Program-[****]CRAs	$[****]	$[****]	No change	No change
Site Visits - Routine Visits conducted on site-Dedicated NA CRA Program-[****] CRA	$[****]	$[****]	Dedicated NA CRA Program	Adding [****] Dedicated Sr. CRA- $[****]/hr X [****]hrs ([****] hrs over a year X [****] months)
Site Visits - Close-out Visits at each site at Study End	$[****]	$[****]	No change	No change
Study Master File/Project File Set-up and Maintenance	$[****]	$[****]	No change	No change

Task	Current (US Dollars)	Change Order #6.1	Assumption Changes influencing the change in the budget	Additional comments
Patient/Site Recruitment	$[****]	$[****]	No change	No change
Client/CRO meeting	$[****]	$[****]	No change	No change
Regulatory				
Regulatory Documentation Preparation/Review	$[****]	$[****]	No change	No change
Project Management /Project Tracking				
Financial Project Management	$[****]	$[****]	No change	No change
Project Management	$ [****]	$ [****]	No change	No change
Project Tracking / Communications	$[****]	$[****]	No change	No change
Vendor Management	$[****]	$[****]	No change	No change
Data Management				
Database Archiving	$[****]	$[****]	No change	No change
Data Cleanup (DM)	$[****]	$[****]	No change	No change
Data Management: Database Quality Control Inspection	$[****]	$[****]	No change	No change
Database Design	$[****]	$[****]	No change	No change
Dictionary Coding	$[****]	$[****]	No change	No change
Edit Check Programming	$[****]	$[****]	No change	No change
Electronic Data Import	$[****]	$[****]	No change	No change
Case Report Form Data/Document Transfers	$[****]	$[****]	No change	No change
EDC Fees	$[****]	$[****]	No change	No change
Statistical Analysis and Table Generation				
Electronic Data Transfer	$[****]	$[****]	No change	No change

Task	Current (US Dollars)	Change Order #6.1	Assumption Changes influencing the change in the budget	Additional comments
Interim Analysis/Report Preparation and Review	$[****]	$[****]	No change	No change
Statistical Analysis Plan Preparation/Review	$[****]	$[****]	No change	No change
Table Generation	$[****]	$[****]	No change	No change
Table/Listings Review	$[****]	$[****]	No change	No change
Clinical Study Report				
Clinical Study Report Preparation/Review	$[****]	$[****]	No change	No change
Team Meetings				
Project Team Meetings - Internal Meetings	$ [****]	$ [****]	No change	No change
Project Team Meetings - Client Teleconferences	$[****]	$[****]	No change	No change
Project Team Meetings - Kick-off Meeting	$[****]	$[****]	No change	No change
Total Direct Costs	**$**[****]	**$**[****]		

Total Costs

Category	Total Costs($)		
	Current Contract (USD)	Change in Scope # 6.1 (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:

Exhibit B
inVentiv Health Clinical
Milestone Payment Schedule
7810962 Canada Inc. (11ISB001)

Milestone	Original Agreement	CO#2 with Discount	CO#3 with Discount	CO#4 with Discount	CO#5	CO#6	CO#6.1	Total (USD) with Discount	Invoice #	Invoice Amount	Paid Amount
Upon Execution of Contract	250,249							250,249	11ISB001-001	250,249	250,249
Upon Execution of CO#3			904,042					904,042	11ISB001-064	904,042	904,042
Upon Execution of CO#4				119,480				119,480	11ISB001-065	119,480	119,480
Upon Execution of CO#5					349,419			349,419	0030018998	349,419	349,419
Upon Execution of CO#6						424,093		424,093			
Completion of Investigator Meeting								0			
50% of Site Initiation Visits completed								0			
Last Site Initiation Visits completed								0			
Database Release (eCRF release) to Production								0			
First Patient In US Trial	250,249	-250,249						0			
First Patient In European Trial	250,249	-250,249						0			
Last Patient In US Trial	344,865	-344,865						0			
Last Patient In European Trial	344,865	-344,865						0			
First Patient In		421,712						421,712	11ISB001-034/11ISB001-042	421,712	421,712
Last Patient in		576,327	300,000					876,327			
	1,440,477	-192,189	**1,204,042**	**119,480**	**349,419**	**424,093**	**0**	**3,345,322**			
26-week Subject Treatment Period Ends:								0			
DBL for all patients completing 26-weeks completed		412,620	280,000					692,620			
Study Unblinded after analysis of efficacy part completed								0			
Delivery of Draft Tables, Listings and Graphs								0			
Delivery of Final Tables, Listings and Graphs								0			
Delivery of Final 26 CSR US Trial	750,746	-750,746						0			
Delivery of Final 26 CSR European Trial	750,746	-750,746						0			
	1,501,492	-1,088,872	**280,000**					**692,620**			
52-week Subject Treatment Period ends:								0			
DBL for all patients completed		232,364	200,000					432,364			
Delivery of Draft Tables, Listings and Graphs								0			
Delivery of Final Tables, Listings and Graphs								0			
Delivery of Final 52 CSR US Trial	261,441	-261,441						0			
Delivery of Final 52 CSR European Trial	261,442	-261,441						1			
Delivery of Final CSR		124,981						124,981			
Database Lock								0			
Delivery of Draft CRF US Trial	261,432	0						261,432	11ISB001-023	261,432	261,432
Delivery of Draft CRF European Trial	261,432	-261,432						0			
	1,045,747	-426,969	**200,000**	**0**	**0**	**0**	**0**	**818,778**			
Total Milestones	**3,987,716**	-1,708,030	**1,684,042**	**119,480**	**349,419**	**424,093**	**0**	**4,856,720**		**2,306,334**	**2,306,334**

Quarterly Project Management Fee (10 Quarters starting June 16, 2011, ending December 15, 2013: 183,590 USD per quarter) **Only Invoiced for 7 quarters**	**1,835,894**	**-598,157**						**1,237,737**	See below	1,237,737	1,237,737
Monthly Fees for Hold Period: (9 Monthlies starting April 2012, ending December 2012: 15,000 USD per month) **Only Invoiced for 6 months**		**90,000**						**90,000**	11ISB001-017	90,000	90,000
Quarterly Project Management Fee: (8 Quarterly Payments starting January 2014: $173,477.50 USD per quarter) **Only invoiced for 4 quarters**		**1,387,820**	**-693,909**					**693,911**	See below	**693,911**	**693,911**
Quarterly Project Management Fee: (4 Quarterly Payments starting January 2015: $244,147.50 USD per quarter)			**976,590**					**976,590**	See below	**976,590**	**976,590**
Quarterly Fees for Dedicated CRA Program (4 Quarters Starting July 2016: $141,364.29 USD per quarter)						**565,457**		**565,457**			
Quarterly Fees for Dedicated CRA Program (3 Quarters Starting July 2016: $59,985 USD per quarter)							**179,955**	**179,955**			
Total Milestone Payments[1]	**5,823,610**	**-828,367**	**1,966,723**	**119,480**	**349,419**	**989,550**	**179,955**	**8,600,370**		**5,304,572**	**5,304,572**

[1] **- Professional fees are net of the 5% discount applied to Original Agreement and CO#1-#4**

Quarterly Payments			
3rd Quarter 2011	11ISB001-002	183,590.00	183,590
4th Quarter 2011	11ISB001-006	183,590.00	183,590
1st Quarter 2012	11ISB001-008	183,590.00	183,590
1st Quarter 2012 (Reconciled for Amendment #1)	11ISB001-017 & 19	(47,393.00)	(47,393)
1st Quarter 2013	11ISB001-022	183,590.00	183,590
2nd Quarter 2013	11ISB001-027	183,590.00	183,590
3rd Quarter 2013	11ISB001-032	183,590.00	183,590
4th Quarter 2013	11ISB001-032	183,590.00	183,590
1st Quarter 2014	11ISB001-042	173,477.50	173,478
2nd Quarter 2014	11ISB001-045	173,477.50	173,478
3rd Quarter 2014	11ISB001-053	173,477.50	173,478
4th Quarter 2014	11ISB001-058	173,478.00	173,478
1st Quarter 2015	11ISB001-064	244,147.50	244,148
2nd Quarter 2015	0030014002	244,147.50	244,148
3rd Quarter 2015	0030017725	244,147.50	244,148
4th Quarter 2015	0030017726	244,147.50	244,148
3rd Quarter 2016		141,364.29	
4rd Quarter 2016		201,349.29	
1st Quarter 2017		201,349.29	
2nd Quarter 2017		201,349.29	

2. Pass Through Costs:

(a) CO#2: Twenty percent (20%) of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling $[****], was invoiced 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: Twenty percent (20%) of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling $[****], was invoiced 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) CO#4: This is a one-time payment of $[****] (exclusive of funds for investigator grants), that was invoiced upon execution of this Agreement.

(d) CO#5: This is a one-time payment of $[****] (exclusive of funds for investigator grants), that was invoiced upon execution of this Agreement.

(e) CO#6: This is a quarterly payment of [****]for ([****]) Quarters beginning with 1st payment invoiced on or after [****]. First payment invoiced on [****].

(f) CO#6.1: This is a Quarterly payment of [****]for ([****]) Quarters beginning with 1st payment to be invoiced on [****]or upon execution of this Agreement if the executed date is later than [****].

(g) Actual pass-through expenses, as provided in the expenses estimate, will be billed as incurred by inVentiv Health Clinical

(h) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

3. Investigator Grants:

(a) Twenty percent (20%) of the estimated total of the grant payments of the study, totaling $[****], was invoiced upon commencement of services. Prepayment for Investigator Grants (to be drawn down once paid and replenished once 75% depleted). This process to continue until the end of the study.

(b) inVentiv Health Clinical will submit invoices in advance for estimated amounts to be paid to investigators during the next quarter to ensure that adequate funds are available to pay investigator grants

(c) inVentiv Health Clinical will not make payments to investigators without having sufficient funds available in advance.

(d) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

4. Payment Conditions:

(a) For all Services, pass through expenses and investigator grants invoiced, payments are due net thirty (30) days from invoice date as set forth in Terms, Item 2 of the Agreement. In the event of a dispute, all undisputed portions of the invoice(s) are due within the above stated terms

(b) Payments shall be made in the currency identified above and shall be made free of any applicable local withholding taxes, charges or remittance fees. Invoices will be inclusive of applicable taxes as determined by local laws and regulations

(c) inVentiv Health Clinical reserves the right to charge interest against any unpaid overdue balance at the rate of one and a half percent (1.5%) per month

(d) All services and pass-through payments should be sent via wire or ACH

Confidential

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

Change Order 6 to Clinical Services Agreement

Client's study drug RHB-104

This Change Order 6 ("**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 507 Place D'Armes , Suite 1101, Montreal, Quebec, H2Y 2W8, Canada (hereinafter "**MANAGER**");

WHEREAS, "SPONSOR" mandated "MANAGER" to enter into a subcontract with inVentiv Health Clinical to act as a CRO for its Study (as defined in the Clinical Services Agreement);

Is hereby made effective as of May 25, 2016 ("**Effective Date**") and the parties hereby agree as follows:

1. Change Order 6 to Clinical Services Agreement.

   This Change Order constitutes an amendment to the Clinical Services Agreement pursuant to section 3.0 therein. As such, this Change Order is subject in all respects to the terms and provisions of the Clinical Services Agreement.

2. Scope of Work

   In addition to the Services to be provided in the above-referenced Clinical Services Agreement, Manager will cause inVentiv Health Clinical to perform additional Services for Sponsor's study drug RHB-104, in accordance with the Summary of Changes attached hereto and incorporated herein as Exhibit A.

3. Compensation

   Under this Change Order, inVentiv Health Clinical's Professional Fees have increased by the amount of USD [****]. The total costs of the Clinical Services Agreement have increased to USD [****].

Payment due to inVentiv Health Clinical for the Services provided under this Change Order shall be made pursuant to the Agreement and the revised unit Payment Schedule attached hereto and incorporated herein as Exhibit B.

4. Project Period

The term of this Change Order shall commence on the date of its execution and shall continue until the Services as described in the Clinical Services Agreement are completed, unless this Change Order or corresponding Clinical Services Agreement are terminated early in accordance with the Clinical Services Agreement.

By their signatures below, the parties hereto agree to the terms of this Change Order and represent that they are authorized to enter into this Change Order on behalf of their respective companies.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd.		7810962 Canada Inc.
/s/ Dror Ben-Asher	/s/ Micha Ben Chorin	/s/Alain Guimond
Name: Dror Ben-Asher Title: CEO	Micha Ben Chorin CFO	Name: Alain Guimond Title: V-P R&D
Date: June 22, 2016		Date: 20-June-2016

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 6 for 7810962 Canada Inc. /Red Hill Biopharma Ltd.

Overview of major level changes

- [****]: [****] Dedicated CRAs starts [****] = $[****]/hour * [****] hours X [****] CRAs = $[****] ([****] hours comes from the [****]hours/year / 12mths * [****]mths) ; [****] Dedicated CRA starts [****]=$[****]/hour * [****] hours X [****] CRA=$[****] ([****] hours comes from the [****] hours/year / 12 months * [****] month)
  [****]= $[****]/hour *[****] hours *[****] CRAs = $[****]
  [****]= $[****]/hour * [****] hours ([****] hours comes from [****] hours/year/ 12 months * [****] months ([****])) * [****] CRAs= $[****]
- The flat rate of $[****] used in the above costing represents a discount to normal and customary rates for the purpose of offsetting inflation costs paid by 7810962 Canada Inc. for the period of [****]through [****]. Future change orders are subject to prevailing rates.

1.1 Revised Costs

Costs for this study are presented below in two categories, pass-through costs and professional fees.

1.1.1 Pass-Through Costs

Pass-through costs are in US dollars and include those expenses listed below. inVentiv Health Clinical will invoice Client for actual costs in these areas, it being understood that any pass-through costs in excess of the amounts set out below will require the Client's prior written approval. inVentiv Health Clinical will use its best efforts to keep actual costs to reasonable levels through adherence to inVentiv Health Clinical's travel policy and prudent negotiation with outside providers. Pass-through costs are presented in the table below:

Task	Current (USD)	Change Order #6	Assumption Changes influencing the change in the budget	Additional comments
Site Visit Travel	$[****]	$[****]	No change	
Investigators' Meeting Organization	$[****]	$[****]	No change	
Kick-off Meeting Travel/Attendance	$[****]	$[****]	No change	
Shipping/Photocopying	$[****]	$[****]	No change	
Translation	$[****]	$[****]	No change	
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)**	**Change Order #6**	**Assumption Changes influencing the change in the budget**	**Additional comments**
Pre-study Activities				
Case Report Form Preparation/Review	$[****]	$[****]	No change	No change
Data Management Plan Preparation/Review	$[****]	$[****]	No change	No change
Informed Consent Preparation/Review	$[****]	$[****]	No change	No change
IRB/Ethics Committee Interactions	$[****]	$[****]	No change	No change
Investigators' Meetings	$[****]	$[****]	No change	No change
Investigator Site Contract	$[****]	$[****]	No change	No change
Investigator Recruitment	$[****]	$[****]	No change	No change
Project Feasibility	$[****]	$[****]	No change	No change
Project Plan Preparation/Review	$[****]	$[****]	No Change	No change
Protocol Preparation/Review	$[****]	$[****].	No change	No change
Randomization Schedule Preparation	$[****]	$[****]	No change	No change
Study-Specific Form Preparation	$[****]	$[****]	No change	No change
Training - Project-Specific	$[****]	$[****]	No change	No change
Translations	$[****]	$[****]	No change	No change

Task	Current (US Dollars)	Change Order #6	Assumption Changes influencing the change in the budget	Additional comments
PROMIS	$[****]	$[****]	No change	No change
Monitoring/Site Management				
Data Clean-up	$[****]	$[****]	No change	No change
Investigator Grant Administration	$[****]	$[****]	No change	No change
Laboratory Report Review	$[****]	$[****]	No change	No change
Serious/Significant Adverse Event Management	$[****]	$[****]	No change	No change
Site Management	$[****]	$[****]	No change	No change
Remote Monitoring of Site Data	$[****]	$[****]	No change	No change
Site Visits - Pre-study Visits	$[****]	$[****]	No change	No change
Site Visits - Initiation Visits	$[****]	$[****]	No change	No change
Site Visits - Routine Visits conducted on site	$[****]	$[****]	No change	No change
Site Visits - Routine Visits conducted on site	$[****]	$[****]	Dedicated NA CRA Program	[****]: [****] Dedicated CRAs starts [****] = $[****]/hr * [****]hrs X [****] CRAs = $[****] ([****]hrs comes from the [****]hrs/year / 12mths * [****]mths) ; [****] Dedicated CRA starts [****]=$[****]/hr * [****] hrs X [****] CRA=$[****] ([****] hrs comes from the [****] hrs/year / 12 mths * [****] mth) [****] = $[****]/hr *[****]hrs *[****] CRAs = $[****] [****] = $[****]/hr * [****]hrs * [****] CRAs= $[****]
Site Visits - Close-out Visits at each site at Study End	$[****]	$[****]	No change	No change
Study Master File/Project File Set-up and Maintenance	$[****]	$[****]	No change	No change
Patient/Site Recruitment	$[****]	$[****]	No change	No change

Task	Current (US Dollars)	Change Order #6	Assumption Changes influencing the change in the budget	Additional comments
Client/CRO meeting	$[****]	$[****]	No change	No change
Regulatory			No change	No change
Regulatory Documentation Preparation/Review	$[****]	$[****]	No change	No change
Project Management /Project Tracking			No change	No change
Financial Project Management	$[****]	$[****]	No change	No change
Project Management	$ [****]	$ [****]	No change	No change
Project Tracking / Communications	$[****]	$[****]	No change	No change
Vendor Management	$[****]	$[****]	No change	No change
Data Management				
Database Archiving	$[****]	$[****]	No change	No change
Data Cleanup (DM)	$[****]	$[****]	No change	No change
Data Management: Database Quality Control Inspection	$[****]	$[****]	No change	No change
Database Design	$[****]	$[****]	No change	No change
Dictionary Coding	$[****]	$[****]	No change	No change
Edit Check Programming	$[****]	$[****]	No change	No change
Electronic Data Import	$[****]	$[****]	No change	No change
Case Report Form Data/Document Transfers	$[****]	$[****]	No change	No change
EDC Fees	$[****]	$[****]	No change	No change
Statistical Analysis and Table Generation			No change	No change

Task	Current (US Dollars)	Change Order #6	Assumption Changes influencing the change in the budget	Additional comments
Electronic Data Transfer	$[****]	$[****]	No change	No change
Interim Analysis/Report Preparation and Review	$[****]	$[****]	No change	No change
Statistical Analysis Plan Preparation/Review	$[****]	$[****]	No change	No change
Table Generation	$[****]	$[****]	No change	No change
Table/Listings Review	$[****]	$[****]	No change	No change
Clinical Study Report			No change	No change
Clinical Study Report Preparation/Review	$[****]	$[****]	No change	No change
Team Meetings			No change	No change
Project Team Meetings - Internal Meetings	$[****]	$ [****]	No change	No change
Project Team Meetings - Client Teleconferences	$[****]	$[****]	No change	No change
Project Team Meetings - Kick-off Meeting	$[****]	$[****]	No change	No change
Total Direct Costs	**$**[****]	**$**[****]		

Total Costs

Category	Total Costs($)		
	Current Contract (USD)	Change in Scope # 6 (USD)	Revised Total (USD)
Pass-Through Costs [1]	$[****]	$[****]	$[****]
Investigator Grants Costs	$[****]	$[****]	$[****]
Professional Fees	$[****]	$[****]	$[****]
Discount	-$[****]	$[****]	-$[****]
Revised Professional Fees	**$**[****]	**$**[****]	**$**[****]
Grand Total	**$**[****]	**$**[****]	**$**[****]

1 Subsequent to the execution of CO#5.1 between 7810962 Canada Inc. and RedHill Biopharma Ltd., additional EDC Fees in the amount of $[****]were included in CO#5.1 between inVentiv Health and 7810962 Canada Inc, therefore the current actual contracted amount for pass-through is $[****]

Exhibit B Payment Schedule

1. PAYMENT TERMS

A. Service Fees:

Exhibit B
inVentiv Health Clinical
Milestone Payment Schedule
7810962 Canada Inc. (11ISB001)

Milestone	Original Agreement	CO#2 with Discount	CO#3 with Discount	CO#4 with Discount	CO#5	CO#6	Total (USD) with Discount	Invoice #	Invoice Amount	Paid Amount
Upon Execution of Contract	250,249						250,249	11ISB001-001	250,249	250,249
Upon Execution of CO#3			904,042				904,042	11ISB001-064	904,042	904,042
Upon Execution of CO#4				119,480			119,480	11ISB001-065	119,480	119,480
Upon Execution of CO#5					349,419		349,419	0030018998	349,419	349,419
Upon Execution of CO#6						424,093	424,093			
Completion of Investigator Meeting							0			
50% of Site Initiation Visits completed							0			
Last Site Initiation Visits completed							0			
Database Release (eCRF release) to Production							0			
First Patient In US Trial	250,249	-250,249					0			
First Patient In European Trial	250,249	-250,249					0			
Last Patient In US Trial	344,865	-344,865					0			
Last Patient In European Trial	344,865	-344,865					0			
First Patient In		421,712					421,712	11ISB001-034/11ISB001-042	421,712	421,712
Last Patient in		576,327	300,000				876,327			
	1,440,477	**-192,189**	**1,204,042**	**119,480**	**349,419**	**424,093**	**3,345,322**			
26-week Subject Treatment Period Ends:							0			
DBL for all patients completing 26-weeks completed		412,620	280,000				692,620			
Study Unblinded after analysis of efficacy part completed							0			
Delivery of Draft Tables, Listings and Graphs							0			
Delivery of Final Tables, Listings and Graphs							0			
Delivery of Final 26 CSR US Trial	750,746	-750,746					0			
Delivery of Final 26 CSR European Trial	750,746	-750,746					0			
	1,501,492	**-1,088,872**	**280,000**				**692,620**			
52-week Subject Treatment Period ends:							0			
DBL for all patients completed		232,364	200,000				432,364			
Delivery of Draft Tables, Listings and Graphs							0			
Delivery of Final Tables, Listings and Graphs							0			
Delivery of Final 52 CSR US Trial	261,441	-261,441					0			
Delivery of Final 52 CSR European Trial	261,442	-261,441					1			
Delivery of Final CSR		124,981					124,981			
Database Lock							0			
Delivery of Draft CRF US Trial	261,432	0					261,432	11ISB001-023	261,432	261,432
Delivery of Draft CRF European Trial	261,432	-261,432					0			
	1,045,747	**-426,969**	**200,000**	**0**	**0**	**0**	**818,778**			
Total Milestones	**3,987,716**	**-1,708,030**	**1,684,042**	**119,480**	**349,419**	**424,093**	**4,856,720**		**2,306,334**	**2,306,334**

Quarterly Project Management Fee (10 Quarters starting June 16, 2011, ending December 15, 2013: 183,590 USD per quarter) **Only Invoiced for 7 quarters**	1,835,894	-598,157					1,237,737	See below	1,237,737	1,237,737
Monthly Fees for Hold Period: (9 Monthlies starting April 2012, ending December 2012: 15,000 USD per month) **Only Invoiced for 6 months**		90,000					90,000	11ISB001-017	90,000	90,000
Quarterly Project Management Fee: (8 Quarterly Payments starting January 2014: $173,477.50 USD per quarter) Only **invoiced for 4 quarters**		1,387,820	-693,909				693,911	See below	693,911	693,911
Quarterly Project Management Fee: (4 Quarterly Payments starting January 2015: $244,147.50 USD per quarter)			976,590				976,590	See below	976,590	976,590
Quarterly Fees for Dedicated CRA Program (4 Quarters Starting July 2016: $141,364.29 USD per quarter)						565,457	565,457			
Total Milestone Payments[1]	**5,823,610**	**-828,367**	**1,966,723**	**119,480**	**349,419**	**989,550**	**8,420,415**		**5,304,572**	**5,304,572**

[1] **- Professional fees are net of the 5% discount applied to Original Agreement and CO#1-#4**

Quarterly Payments			
3rd Quarter 2011	11ISB001-002	183,590.00	183,590
4th Quarter 2011	11ISB001-006	183,590.00	183,590
1st Quarter 2012	11ISB001-008	183,590.00	183,590
1st Quarter 2012 (Reconciled for Amendment #1)	11ISB001-017 & 19	(47,393.00)	(47,393)
1st Quarter 2013	11ISB001-022	183,590.00	183,590
2nd Quarter 2013	11ISB001-027	183,590.00	183,590
3rd Quarter 2013	11ISB001-032	183,590.00	183,590
4th Quarter 2013	11ISB001-032	183,590.00	183,590
1st Quarter 2014	11ISB001-042	173,477.50	173,478
2nd Quarter 2014	11ISB001-045	173,477.50	173,478
3rd Quarter 2014	11ISB001-053	173,477.50	173,478
4th Quarter 2014	11ISB001-058	173,478.00	173,478
1st Quarter 2015	11ISB001-064	244,147.50	244,148
2nd Quarter 2015	0030014002	244,147.50	244,148
3rd Quarter 2015	0030017725	244,147.50	244,148
4th Quarter 2015	0030017726	244,147.50	244,148

2. Pass Through Costs:

(a) CO#2: Twenty percent (20%) of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling $[****], 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: Twenty percent (20%) 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) 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.

(d) CO#5: This is a one-time payment of $[****] (exclusive of funds for investigator grants), that will be due and payable upon execution of this Agreement.

(e) Actual pass-through expenses, as provided in the expenses estimate, will be billed as incurred by inVentiv Health Clinical

(f) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

3. Investigator Grants:

(a) Twenty percent (20%) of the estimated total of the grant payments of the study, totaling $[****], will be invoiced upon commencement of services. Prepayment for Investigator Grants (to be drawn down once paid and replenished once 75% depleted). This process to continue until the end of the study.

(b) inVentiv Health Clinical will submit invoices in advance for estimated amounts to be paid to investigators during the next quarter to ensure that adequate funds are available to pay investigator grants

(c) inVentiv Health Clinical will not make payments to investigators without having sufficient funds available in advance.

(d) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

4. Payment Conditions:

(a) For all Services, pass through expenses and investigator grants invoiced, payments are due net thirty (30) days from invoice date as set forth in Terms, Item 2 of the Agreement. In the event of a dispute, all undisputed portions of the invoice(s) are due within the above stated terms

(b) Payments shall be made in the currency identified above and shall be made free of any applicable local withholding taxes, charges or remittance fees. Invoices will be inclusive of applicable taxes as determined by local laws and regulations

(c) inVentiv Health Clinical reserves the right to charge interest against any unpaid overdue balance at the rate of one-half percent (0.5%) per month

(d) All services and pass-through payments should be sent via wire or ACH

Confidential

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

Change Order 7 to Clinical Services Agreement

Client's study drug RHB-104

This Change Order 7 ("**Change Order**") to the Clinical Services Agreement signed 15 June 2011 ("**Clinical Services Agreement**"), is by and among:

(1) RedHill Biopharma Ltd., having its principal 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 5320 13th Avenue, Montreal, Quebec, H1X 2X8, Canada (hereinafter "**MANAGER**")

WHEREAS, "SPONSOR" mandated "MANAGER" to enter into a subcontract with inVentiv Health Clinical to act as a CRO for its Study (as defined in the Clinical Services Agreement);

Is hereby made effective as of October 7, 2016 ("**Effective Date**") and the parties hereby agree as follows:

1. Change Order 7 to Clinical Services Agreement.

   This Change Order constitutes an amendment to the Clinical Services Agreement pursuant to section [****] therein. As such, this Change Order is subject in all respects to the terms and provisions of the Clinical Services Agreement.

2. Scope of Work

   In addition to the Services to be provided in the above-referenced Clinical Services Agreement, Manager will cause inVentiv Health Clinical to perform additional Services for Client's study drug RHB-104, in accordance with the Summary of Changes attached hereto and incorporated herein as Exhibit A.

3. Compensation

   Under this Change Order, inVentiv Health Clinical's Professional Fees have increased by the amount of USD $[****][****] and pass-through expenses have increased by the amount of USD $[****]. The total costs of the Clinical Services Agreement have increased to USD $[****].

Payment due to inVentiv Health Clinical for the Services provided under this Change Order shall be made pursuant to the Clinical Services Agreement and the revised unit Payment Schedule attached hereto and incorporated herein as Exhibit B.

4. Project Period

The term of this Change Order shall commence on the date of its execution and shall continue until the Services as described in the Clinical Services Agreement are completed, unless this Change Order or corresponding Clinical Services Agreement are terminated early in accordance with the Clinical Services Agreement.

In the event that the Study is completed in advance of the timelines set forth in this Agreement as amended and in the event that sites are closed or put on administrative hold due to inactivity and the amount of sites is reduced (along with other management activities driven by the number of sites), the parties will engage in good faith discussions to determine whether there were any costs incurred for which Manager was compensated in advance requiring a reimbursement from Manager to Client.

By their signatures below, the parties hereto agree to the terms of this Change Order and represent that they are authorized to enter into this Change Order on behalf of their respective companies.

ACCEPTED AND AGREED TO:

RedHill Biopharma Ltd		For 7810962 Canada
/s/ Micha Ben Chorin	/s/ Dror Ben-Asher	/s/ Alain Guimond
Name: Micha Ben Chorin	Dror Ben-Asher	Name: Alain Guimond
Title: CFO	CEO	Title: VP of Research and Development
Date: November 16, 2016		Date: 11-Nov-2016

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 7 for 7810962 Canada Inc. /Red Hill Biopharma Ltd.

Overview of major level changes

Study Timelines increased with LPI on [****][****]
Monthly InForm Data Transfers to BioForum through to [****]
DSMB Member Replacement and Contract Revisions
Data Management, Medical Monitoring, and Pharmacovigilance for [****] sites in [****]
CDAI eCRF revisions and Report Generation
Addition of [****] North American Sites
Adding Vendors Bioforum and MWB Consulting
DCRA Program Start-up and Conference Calls through to [****]
CRA Vendor Teleconferences with CSSi, Quest, iCardiac, Spectrum, IWRS, & ALGO,
Investigator Contract Amendments for PKs, PI and site name changes, extended patient safety follow-up
SAE increase from [****] to [****]
Israeli Site Transfer to Cato_Israel
Study Coordinator Turnover - InForm Set-Up
Pre DDW NA Investigator Meeting
Protocol Amendment #9
F2F Sponsor Meetings 10-11SEP2015, 25-26Feb2016
Oracle Vendor Contract Extension to [****] [****]
Sponsor Audit
Advertising Initiatives with Study Kik, CSSi Retention Materials, Quebec Recruitment Materials
Investigator Brochures and Confirmation Letters
DSUR listing - [****] updates
Vendor Management - Spectrum IP replacement and Quest lab manual follow-up
Increase Clinical and Data Managers to [****]from [****]
Increase CMPL to [****]from [****]

Category	Current Contract	CO7	Rationale for change
Study Start- Up period	[****] months + [****] month [****]	[****]months + [****]month [****]	Investigator Recruitment extended to [****]as per client
Enrolment period	[****] months	[****]	Recruitment extended to [****]as per client
Stats Timeline	[****] weeks	[****] weeks	no change
# of countries	[****]	[****]	Addition of [****]
# of sites	[****]	[****]	Per client add [****]NA sites and [****]sites in [****]. [****]sites for Data Management, Medical Monitoring, and Pharmacovigilance. [****]sites for iVH clinical to open and [****] to maintain open
# Subjects Randomized	[****]	[****]	Per client request
# of subjects for DM, MM & PVG	[****]	[****]	No change
# of CRF pages/book	[****]	[****]	eCRF pages added and revised as per client direction
# of unique CRF pages	[****]	[****]	eCRF pages added and revised as per client direction
# of PSVs	[****]	[****]	Additional sites, therefore additional PSVs,
# of SIVs	[****]	[****]	Added [****] sites to NA
# of RMVs	[****]	[****]	Removed [****]RMVs for Israeli sites
# of COVs	[****]	[****]	Removed [****]COVs for Israel; Added [****]sites to NA
# of internal meetings	[****]	[****]	Increased timelines lead to increased number of internal meetings.
# of client telecons	[****]	[****]	Increased timelines lead to increased number of client teleconferences. Also includes teleconferences for 1:1 calls between iVH Sr. Director & RHB Product Manager; weekly Touch Base calls; DCRA calls with RHB, Vendor teleconferences. Please see details in Professional Fees table.
Client Meetings	[****]	[****]	North American CRA Meeting in Montreal on [****]September 2015; PM-Sr. Director Meeting on 25 February 2016; CRA Meeting on 26 February 2016
Investigator Meeting	[****]	[****]	Investigator Meeting on 21 May 2016
# of vendors	[****]	[****]	iCardiac, Quest, AST, CDEIS central reader, EDC, DSMB (5 DSMB members considered equivalent to 1 vendor); Novotech, CATO, Bioforum, MWB
# of edit checks	[****]	[****]	eCRF pages added and revised as per client direction requires more edit check
# of imports	[****]	[****] [****]	Increased timelines mean there are increased monthly imports
# of SAEs	[****]	[****]	Timeline extension means more SAEs. Currently [****]SAEs to date
# of SAE Narratives	[****]	[****]	Timeline extension means more SAEs. Currently [****]SAEs to date
IVRS	Not Included	Not Included	
eCRF Changes	Included for Protocol Amendment 8	Requested by sponsor for CDAI and Study Medication eCRFs	Please see Professional Fees table
Clinical and Data Manager Allocation	[****] FTE	[****] FTE	Manager at [****]for 2013 and then at [****]FTE for 2014 and 2015. Remainder of the study at [****]FTE
CMPL Allocation	[****] FTE	[****] FTE	CMPL at [****]FTE for 2014 and 2015. Remainder of the study at [****]FTE

1.1 Revised Costs

Costs for this study are presented below in two categories, pass-through costs and professional fees.

1.1.1 Pass-Through Costs

Pass-through costs are in US dollars and include those expenses listed below. inVentiv Health Clinical will invoice Client for actual costs in these areas, it being understood that any pass-through costs in excess of the amounts set out below will require the Client's prior written approval. inVentiv Health Clinical will use its best efforts to keep actual costs to reasonable levels through adherence to inVentiv Health Clinical's travel policy and prudent negotiation with outside providers. Pass-through costs are presented in the table below:

Task	Current (USD)	Change Order #7	Assumption Changes influencing the change in the budget	Additional comments
Site Visit Travel	$[****] [****]	$[****] [****]	No change	
Investigators' Meeting Organization	$[****]	$[****]	No change	
Kick-off Meeting Travel/Attendance	$[****]	$[****]	No change	
Shipping/Photocopying	$[****]	$[****]	No change	
Translation	$[****]	$[****]	No change	
Regulatory Fees	$[****]	$[****]	No change	
Ethics Committee Fees	$[****]	$[****]	No change	
EDC Studies/3G Cards	$[****]	$[****]	No change	
DSMB member fees	$[****]	$[****]	Increased DSMB member hourly rate to $[****] from $[****]	
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 (USD)**	**Change Order #7**	**Assumption Changes influencing the change in the budget**	**Additional Comments**
	$[****]	$[****]	No Change	Estimate only. Will be paid based on actual costs as approved by the Client.

1.1.3 Professional Fees

Based on the parameters and assumptions outlined in the original proposal, inVentiv Health Clinical fees are categorised by major activity in the table below and in USD:

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Pre-study Activities				
Case Report Form Preparation/Review	$[****]	$[****]	Updated the CDAI eCRF and added diary eCRF page	Manager (DM) (NA) [****]hours at [****][****] Manager (DM) (NA) [****] hours at [****] Manager (DM) (NA) [****] hours at [****] Data Analyst (API[****]hrs @ [****] Data Analyst (API) [****] hrs @ [****] Manager (PM) (NA) [****]hr @[****] Manager (DM) NA - [****] hrs @[****]
Data Management Plan Preparation/Review	$[****]	$[****]	Changes to the eCRF as above and at least yearly updates for 2016, 2017, and 2018	Manager (DM & PM) (NA) [****] hours for [****] Manager (DM & PM) (NA) [****] hours for [****] Manager (DM & PM)(NA) [****]hours for [****] Manager (DM & PM) (NA[****] hours for [****] Manager (DSPM) NA [****] hours @ [****] Manager (DM) (NA) - [****][****]hour @ [****] DM Manager (NA) = [****] hrs @ [****] Manager (NA) (DSPM) - [****] hr @ [****] Manager (NA) (PM) [****][****]hr @ [****]
Informed Consent Preparation/Review	$[****]	$[****]	Started up [****] additional sites in NA and Israel and Protocol v9 will require updated site consents.	Regulatory Associate II (NA) [****]hrs at [****] Regulatory Associate II (NA)10 hours at [****] GSSU Mgr (NA)= [****] hrs @ [****] for Master ICF and country-specific consents for USA, Canada, Attention to local site ICF review as needed Manager (NA)(PM[****]hrs @ [****] GSSU SS Specialist = [****] hrs @ [****] for [****][****] ICFs

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
IRB/Ethics Committee Interactions	$[****]	$[****] [****]	Added [****] sites in NA and [****] sites in Israel; Protocol v9 will require updated site consent; Annual and other periodic reviews in 2016, 2017, 2018; Submissions for Investigator Brochures in 2016, 2017, 2018 and protocol clarification letters dated [****]; DSURs in 2016, 2017, 2018.	[****] hrs for Regulatory Associate II (GSSU Specialist) (API) for work in [****]at [****] [****] hrs for Regulatory Associate II (GSSU Specialist) at [****] ([****] hrs/site for [****] sites added in 2015) Regulatory Associate II (GSSU Specialist)(NA) [****]hrs at [****], Regulatory Associate II (GSSU Specialist)(NA) [****]hrs at [****] Regulatory Associate II (GSSU Specialist)(NA) [****][****]hrs at [****] Regulatory Associate II (GSSU Specialist) 6 hrs at [****] for ([****] new sites added in 2015) Regulatory Associate II (GSSU Specialist) [****]hrs at [****] for [****] new sites in 2016 GSSU SS specialist (NA) = [****] hrs @ [****]; averages two hours/site for [****][****] sites Regulatory Associate (NA) [****] hrs @ [****] Regulatory Associate II (API) - [****] hrs @ [****] Regulatory Associate II (NA) - [****][****] hrs @ [****] Regulatory Associate II (NA) - [****] hrs @ [****] Safety Associate I (NA) [****] hrs @ [****] Safety Associate I (NA) [****] hrs @ [****] Safety Associate I (NA) [****] hrs @ [****]
Investigators' Meetings	$[****]	$[****]	Pre DDW NA Investigator Meeting on [****]May2016	Sr. CRAs (NA) - [****] hrs @ [****] (Non- DCRAs) - travel CMPL (LCRA) (NA)- [****] hrs @ [****] - travel Manager (NA)(PM[****]hrs @ [****] - travel Manager (NA) (DM) - [****] hrs @ [****] – travel Sr. CRAs (NA) - [****] hrs @ [****] (Non- DCRAs) attendance and prep CMPL (LCRA) (NA)- [****]hrs @ [****] attendance and prep Manager (NA)(PM) [****]hrs @ [****] attendance and prep Manager (NA) (DM) - [****] hrs @ [****] attendance and prep
Investigator Site Contract	$[****] [****]	$[****]	Additional contracts for [****]more NA sites; Investigator contract amendments for PI turnover, site name changes, PI safety follow-up, CDAI rework, and patient imbursement for PK samples; Protocol v9 changes will require site contract amendments.	Sr. Contract Associate (NA) [****] - [****] hrs (3 site contracts) Sr. Contract Associate (NA) [****] [****] hrs (10 contracts) Sr. Grant & Contract Associate (NA) [****] hours ([****]contract amendments at [****] hrs each) at [****] Manager (PM) (NA) [****][****]hrs@ [****] Paralegal (NA) [****] hrs @ [****] Sr. Grants and Contracts Associate (NA) [****] hours @ [****] Paralegal (NA) [****) hour @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
				Paralegal (NA) [****][****]hrs @ [****] Sr. Grants Associate (NA) [****] hours @ [****] Sr.Grants & Contract Associate (NA) - [****] hrs @ [****] Sr. Grants & Contract Associate (NA) [****] hrs @ [****] Sr. Contracts Associate (NA) = [****] hours @ [****] averages [****]hours/ contract for [****][****] contracts and includes tracking; filing; updating the Grants Profiles Manager, Clinical Research [****]hours @ [****] Sr. Grants Associate (NA) [****][****] hrs @ [****] ([****] hr/site) Contracts Associate (NA) [****] hr @ [****] Paralegal (NA) - [****][****]hr @ [****] Manager (NA[****][****]hr @ [****] Sr. Grant & Contracts Associate (NA) - [****] hrs @ [****] Paralegal (NA) - v hr @ [****] Project Manager (NA) [****][****][****]hrs @ [****]
Investigator Recruitment	$[****]	$[****]	Outreach to [****] sites in NA in 2014 and 2015.	Manager (PM) (NA) [****] hrs at [****] Manager (PM) (NA) [****] hrs at [****]
Project Feasibility	$[****]	$[****]	No change	No change
Project Plan Preparation/Review	$[****]	$[****]	Project plans yearly updates for 2016, 2017, 2018 and review by the team.	Sr. CRA (NA) [****] hr at [****] Sr. CRA (NA) [****] hr at [****] Sr. CRA (NA) [****] hr at [****] CRA I (NA) [****] hr at [****] CRA I (NA) [****] hr at [****] CRA I (NA) [****] hr at [****] Manager (PM) (NA) - [****]hrs at [****] Manager (PM) (NA) [****]hrs at [****] Manager (PM) (NA) [****][****] hrs at [****] CMPL (LCRA) (NA) [****] hrs at [****] CMPL (LCRA) (NA) [****]hrs at [****] CMPL (LCRA) (NA) [****]hrs at [****] Safety Associate (NA) [****]hrs at [****] Safety Associate (NA) [****]hrs at [****] Safety Associate (NA) [****]hrs at [****] Sr. Medical Director (NA) [****] hours at [****] Sr. Medical Director (NA) [****] hours at [****] Sr. Medical Director (NA) [****] hours at [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Protocol Preparation/Review	$[****]	$[****] [****][****]	Protocol v9 will need input from the Project Manager and Medical Director, with team review of the finalized version	Data Analyst (API) [****] hr @ [****] Sr. Data Analyst (API) [****] hr @ [****] Manager (DM) (NA) [****] hours @ [****] Manager (DSPM) (NA) [****] hours @ [****] Manager (PM) (NA) -[****]hours @ [****] Medical Director (NA) [****] hrs @ [****] Medical Director (WE) [****] hrs @ [****] CMPL (LCRA) (NA) [****][****][****]hours @ [****] Sr. CRA (NA) [****] hrs @ [****] CRA I (NA) 2 hrs @ [****] Sr Regulatory Associate (NA) [****] hr @ [****] Reg Affairs Associate (NA) [****] hr @ [****] Director Reg Affairs (NA) [****] hr @ [****] Safety Associate (NA) [****] hr @ [****] Principal Statistician (NA) [****] hr @ [****] Principal Statistician (API) [****] hr @ [****]
Randomization Schedule Preparation	$[****]	$[****]	No change	No change
Study-Specific Form Preparation	$[****]	$[****]	Preparation and revision of the CDAI calculation tool	Manager (PM) (NA) [****],[****][****]hours Manager (PM) (NA) [****],[****]hours
Training - Project-Specific	$[****]	$[****]	CDAI Training to sites; non-dCRAs, and CRO teams; Study Rationale Presentation Training for non-dCRAs and attendance by CMPL and PM; Study training by CMPL, Medical Director, and PM for CRA hired in 2015 specially for the dCRA program; F2F training session at InSymbiosis office for CRA I on 26Feb2016; Training for Protocol v9	DM Manager (NA) [****] hours @ [****] (7 1-hr sessions ([****] CRA Sessions (NA, Novotech, Cato) + [****] Site Sessions) + [****]hr prep) Sr. CRA NA - [****] hours @ [****] (Attend 1-hr session X [****] CRAs); Manager (PM) (NA) [****]hours @ [****] ([****] hr prep, [****] X [****]-hr sessions, [****] hrs follow-up) CMPL (LCRA) (NA)- [****]hours @ [****]([****] hrs presentation and [****] hrs prep) Training CRAs and Site Teleconferences Sr. CRA (API) [****] hrs @ [****] Manager (PM) (NA) [****]hrs @ [****] CMPL (LCRA (NA) [****]hr hrs @ [****] Sr. CRA (NA) [****]hrs @ [****] CMPL (LCRA (NA[****][****]hours @ [****] PM (NA) [****]hours @ [****] Medical Director (WE) [****] hours @ [****] [****]hrs Manager (PM) (NA) @ [****] [****] hrs CMPL (LCRA) (NA) @[****] [****] hrs CRA I (NA) @ [****] [****] hrs Sr. CRA (NA) @ [****] [****]hrs Manager (NA)(DM) @ [****] PM (NA) [****] hrs @ [****] CRA I (NA) [****] hrs @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Translations	$[****]	$[****]	Protocol v9 Consent translation	Manager (NA) (PM) [****] hr @ [****]
PROMIS/CTMS	$[****]	$[****]	Increase in project timelines increases the time for Clinical Trial Management Systems oversight by Data Management	Manager DM (NA) - [****] [****] hrs Manager DM (NA) - [****] [****] hrs Manager DM (NA) - [****] [****] hrs Manager DM (NA) - [****] [****][****] hrs
Monitoring/Site Management				
Data Clean-up	$[****]	$[****]	Increased the number of eCRF pages from [****]to [****]by adding more unique pages and randomizing [****]subjects for iVH to [****]from [****]. Extensive clean-up of reworked CDAI entries;	Sr. CRA (NA) - [****] [****] hrs Sr. CRA (NA) - [****] - [****] hrs Sr. CRA (NA) [****] - [****][****] hrs; CRA I (NA) [****] - [****] hrs CRA I (NA) [****] - [****] hrs CRA I (NA) [****] - [****] hrs
Investigator Grant Administration	$[****]	$[****]	Removal of [****]payments to Israeli PIs from current agreement amount of [****]= [****][****]. Added Investigator grant payments in 2016, 2017, and 2018 and adding 14 more sites in NA for total of [****]payments; Also includes processing [****]retroactive patient PK stipends; and CDAI rework.	Sr. CRA, API - [****] Subtract ([****]) hrs Sr. CRA, API - [****] Subtract ([****]) hrs Sr. CRA, API - [****] Subtract ([****]) hrs Technical Assistant, API - [****] Subtract ([****]) hrs Technical Assistant, API - [****] Subtract ([****]) hrs Technical Assistant, API - [****] Subtract ([****][****]) hrs Manager (Investigator Grants) (NA) [****] hrs at [****] Manager (Investigator Grants) (NA) [****] hrs at [****] Manager (Investigator Grants) (NA) [****] hrs at [****] Sr Grant &Contracts Associate (NA) [****] hrs at [****] Sr Grant &Contracts Associate (NA) [****] hrs at [****] Sr Grant &Contracts Associate (NA) [****] hrs at [****] Grant &Contracts Associate II (NA) [****] hrs at [****] Grant &Contracts Associate II (NA) [****] hrs at [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
				Grant &Contracts Associate II (NA) [****] hrs at [****] Grant &Contracts Associate I (NA) [****] hrs at [****] Grant &Contracts Associate I (NA) [****] hrs at [****] Grant &Contracts Associate I (NA) [****] hrs at [****] Technical Assistant (Investigator Grants) (NA) [****] hrs at [****] Technical Assistant (Investigator Grants) (NA) [****][****] hrs at [****] Technical Assistant (Investigator Grants) (NA) [****][****][****] hrs at [****] Manager (PM) (NA) [****] hrs at [****] Manager (PM) (NA) [****][****] hrs at [****] Manager (PM) (NA) [****] hrs at [****] Sr. Grants Associate (NA) - [****] hours at [****] Sr. Grants Associate (NA) [****] hrs @ [****] Manager (Grants) (NA) [****] hrs @ [****] Manager (PM) (NA) [****] hrs @ [****]
Laboratory Report Review	$[****][****]	$[****]	Review of laboratory results for an additional [****] years	Medical Monitor (WE) [****] hrs at [****] Medical Monitor (WE) [****][****] hrs at [****] Medical Monitor (WE) [****][****] hrs at [****]
Serious/Significant Adverse Event Management	$[****]	$[****][****]	Increase from [****]to [****]SAEs over the course of the study. The number of SAEs increases with increased study duration.	Sr. Medical Director (NA) [****][****][****] hrs Sr. Medical Director (NA) [****][****] hrs Sr. Medical Director (NA) [****][****] hrs Sr. Medical Director (NA) [****][****] hrs Manager (PV) (NA) [****] hrs @ [****] Manager (PV) (NA) [****] hrs @ [****] Manager (PV) (NA) [****][****] hrs@ [****] Manager (PV) (NA) [****][****] hrs @ [****] Manager (PM) (NA) [****][****] hrs Manager (PM) (NA) [****] [****][****] hrs Manager (PM) (NA) [****][****] hrs Manager (PM) (NA) [****][****] hrs Safety Associate II (NA) [****][****] hrs Safety Associate II (NA) [****] [****] hrs Safety Associate II (NA) [****] [****] hrs Safety Associate II (NA) [****][****] hrs Sr. CRA(NA) [****][****] hrs (Reflects Non-DCRAs) Sr. CRA(NA) [****][****] hrs (Reflects Non-DCRAs) Sr. CRA(NA) [****][****] hrs (Reflects Non-DCRAs) Sr. CRA(NA) [****][****][****] hrs Technical Assistant (NA) [****] [****] hrs Technical Assistant (NA) [****] [****] hrs Technical Assistant (NA) [****] [****] hrs Technical Assistant (NA) [****] [****] hrs

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Site Management	$[****]	$[****][****]	Site management in previous contract expired [****]. The number of site management months has increased from [****]in previous contract to [****]in CO7 with a revised completion date of [****]based on database lock of [****]. This is based on [****] sites for iVH clinical over the [****]period.	Sr. Med Director (APA) [****], [****][****] sites for [****]wks. - [****]hours Sr. Med Director (APA) [****] - [****] sites for 12.69 wks. - [****]hrs CRA I (NA) [****][****] hrs @ [****] CRA I (NA) [****] hrs @ [****] CRA I (NA) [****] hrs @ [****] Sr. CRA (NA) = [****] sites for 46 hrs @ [****] Sr. CRA (NA) = [****]hrs @ [****] Sr. CRA (NA) [****] hrs @[****] Sr. CRA (NA) = [****] hrs @ [****] CMPL (LCRA) (NA) - [****]hrs @ [****] CMPL (LCRA) (NA) - [****][****]hrs @ [****] CMPL (LCRA) - [****]hrs @ [****] CMPL (LCRA) - [****]hrs @ [****] Sr. Med Director (NA) [****]hrs @ [****] Sr. Med Director (NA) [****]hrs @ [****] Sr. Med Director (NA) [****]hrs @ [****] Sr. Med Director (NA) [****]hrs @ [****] Manager (PM) (NA) [****]hrs @ [****] Manager (PM) (NA) [****]hrs @ [****] Manager (PM) (NA) [****]hrs @ [****] Manager (PM)(NA) [****]hrs @ [****] Technical Assistant (NA) - [****]- [****] sites for [****]wks-[****] hrs; Technical Assistant (NA) - [****]-[****] sites for [****][****] wks. [****] hrs; Technical Assistant (NA) - [****]-[****] sites for [****][****] wks. [****] hrs; Technical Assistant (NA) - [****]-[****] sites for [****] wks. [****][****]hrs; Sr. Med Director (WE) [****]hrs at [****] Sr. Med Director (WE) [****][****]hrs at [****] Sr. Med Director (WE) [****]hrs at [****] Sr. Med Director (WE) [****]hrs at [****]
Remote Monitoring of Site Data	$[****]	$[****]	The number of remote monitoring weeks increased from [**** to [****) by extending the study. Remote monitoring is [****][****] hrs/subject/ week. iVH will reconcile at the end of the study for subject weeks actually used	Remote Monitoring Sr. CRA (NA) = [****]hrs @ [****] Remote Monitoring Sr. CRA (NA) = [****][****]hrs @ [****] Remote Monitoring Sr. CRA (NA) = [****] hrs @ [****] Remote Monitoring Sr. CRA (NA) [****] hrs @ [****] Remote Monitoring CRA I (NA) [****]hrs @ [****] Remote Monitoring CRA I (NA) [****] hrs @ [****] Remote Monitoring CRA I (NA) [****] hrs @ [****] ([****][****] hr/site/week)

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Site Visits - Pre-study Visits	$[****]	$[****]	Increased the number of PSVs from [****] to [****] . Two PSVs were performed in 2015 and one PSV was performed in 2016 by non-dCRAs. dCRAs will perform additional PSVs if required in 2016. Unused visits will be credited to the client at the end of patient enrolment	Sr. CRA NA [****] hrs @ [****] Sr. CRA NA [****] hours @ [****]
Site Visits - Initiation Visits	$[****]	$[****]	Increased the number of SIVs from [****] to [****]. Non-dCRA would perform [****] SIVs. dCRAs would perform [****] SIVs. Unused visits will be credited to the client at the end of patient enrolment	Sr. CRA (NA) [****] hrs @ [****] (Non-DCRA)
Site Visits - Routine Visits conducted on site	$[****]	$[****]	Removed [****] visits for the Sr. CRA API and SDV CDAI Worksheet revisions for Sr. CRAs X2 and CRA I. Total RMVs tor NA = [****].	Sr. CRA, API - [****] Subtract ([****][****]) hrs Sr. CRA, API -[****] Subtract ([****]) hrs Sr. CRA, API - [****] Subtract ([****]) hrs Sr. CRA (NA) [****] hours @ [****] CRA I (NA) [****] hours @ [****] CMPL (LCRA) (NA) [****] hrs @[****] CDAI Diary review and worksheet revisions
Site Visits - Routine Visits conducted on site – Dedicated NA CRA Program-3 CRAs	$[****]	$[****]	No change	No change
Site Visits - Routine Visits conducted on site-Dedicated NA CRA Program-1 CRA	$[****]	$[****]	Dedicated NA CRA Program	No change
Site Visits - Close-out Visits at each site at Study End	$[****]	$[****]	Removed [****] close-out visits for Sr. CRA in Israel. Adding [****]more NA sites increases the number of close-out visits from [****]to [****]. Unused visits will be credited to the client at the end of the study.	Remove [****]visits for API CRA Subtract ([****] hrs) @ [****] Add [****]NA sites at [****]s - RS CRA (NA) - [****] - [****] hrs – Initiated sites increased from [****]to [****]
Study Master File/Project File Set-up and Maintenance	$[****]	$[****]	Study Master File/Project File Set-up and Maintenance in previous contract expired [****]. The number of Study Master File/Project File Set-up and Maintenance months has increased from [****] in previous contract to [****]	Sr. CRA (NA) [****] hrs @ [****] Sr. CRA (NA) [****][****] hrs @ [****] Sr. CRA (NA) [****] hrs @ [****] Sr. CRA (NA) [****][****] hrs @ [****] CRA I (NA) [****][****] hrs @ [****] CRA I (NA) [****] hrs @ [****] CRA I (NA) [****] hrs @ [****] CMPL (LCRA) [****][****] hrs @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
			in CO7 with a revised completion date of [****]based on database lock of [****]. Also includes filing documents for additional IRB submissions and approvals, site correspondence, acknowledgement forms for [****]additional NA sites, Protocol v9, Investigator Brochures, patient recruitment materials, protocol clarification letters, and investigator turnover documents.	CMPL (LCRA) [****] hrs @ [****] CMPL (LCRA) [****][****] hrs @ [****] CMPL (LCRA) [****] hrs @ [****] Manager (PM) (NA) [****] hrs @ [****] Manager (PM) (NA) [****] hrs @ [****] Manager (PM) (NA) [****] hrs @ [****] Manager (PM) (NA) [****]hrs @ [****] Regulatory Associate II (NA) [****]hrs @ [****] Regulatory Associate II (NA) [****] hrs @ [****] ([****] site start-up ([****]hrs 2016) + IBv11 filing ([****]5hr in 2016) Regulatory Associate II (NA) [****] hrs @ [****] (IB v12) Regulatory Associate II (NA) [****] hrs @ [****] (IB v13) Technical Assistant (NA) [****] hrs @ [****] Technical Assistant (NA) [****][****] hrs @ [****] Technical Assistant (NA) [****][****] hrs @ [****] Technical Assistant (NA) [****] hrs @ [****] LCRA (NA) [****] hrs @ [****] LCRA (NA) [****] hrs @ [****] TA (NA) hours @ [****] GSSU Specialist (NA) [****] hrs @ [****][****] hrs/site X [****]sites filing of submission forms; IRB protocol v9 approvals; approved Protocol v9 ICFs: CMPL (LCRA) (NA) - [****] hrs @ [****]
Patient/Site Recruitment	$[****]	$[****]	No change	No change
Client/CRO meeting	$[****]	$[****]	F2F meeting on 25Feb2016 to discuss CO 6.0 and CO 7.0 and meet new CRA I. F2F CRA meeting in Montreal on 10-11 Sep2015 for dCRA Program Kick-off	[****] hr PM (NA) @ [****] [****] hrs Sr. Director (NA) @ [****] [****] hrs PM (NA) @ [****] [****] Sr. Director (NA) @ [****] [****] hrs CRA I (NA) @ [****] Sr. CRA (API) - [****] hrs @ [****] Sr. CRA (NA) - [****] hrs @ [****] for [****]CRAs in Sep2015. CRA II (NA) - [****][****]hrs @ [****] CMPL (LCRA) (NA) - [****] hrs @ [****] Manager (PM) (NA) [****] hrs @ [****]
Sponsor Audit	[****]	$[****]	RHB contracted with 3rd party to audit to investigator sites	Lead CRA (NA) [****][****] hrs Manager,(PM) (NA) - [****][****] hrs Sr. CRA (NA)- [****] [****][****] hrs
Regulatory				
Regulatory Documentation Preparation/Review	$[****] [****]	$[****]	Four new site start-ups in Israel and [****] site start-ups in NA in 2015. [****] NA site start-ups in 2016.	Add [****]hrs for Regulatory Associate II (API) (GSSU Specialist) for [****] more site start-ups @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
			Unused site start-ups will be credited to the client at the end of recruitment. Also includes submission of one updated Investigator Brochure/year in 2016, 2017, 2018. Also includes submission of Protocol v9 to central and local NA IRBs. Also includes updated documents for PI turnover such as IRB notification, FDA Form 1[****]2, Financial Disclosure, clinicaltrial.gov consents, etc.	Regulatory Associate II (NA) [****] hrs @ [****] ([****] hrs for [****] site start-up in 2012;) Regulatory Associate II (NA) [****] hrs @ [****]; ([****] hrs ([****] site startups in 2013 + [****] hrs IBv[****] docs)) Regulatory Associate II (NA) [****] hours @ [****]for IBv12 Regulatory Associate II (NA) [****] hrs @ [****] for IBv13 LCRA (NA) [****] hours @ [****] Regulatory Associate II (NA) [****] hrs @ [****] for Protocol v9
Investigator Brochure Prep/Rev	[****]	$[****]	Medical Director review of two Investigator Brochures released in 2014; one Investigator Brochures release in each of 2015, 2016	Sr. Medical Director (NA) = [****] hours @[****] Sr. Medical Director (WE) = [****] hours @ [****] Sr. Medical Director (NA) = [****] hours @ [****] Sr. Medical Director (WE) = [****] hours @[****] Medical Director (APA) = [****] hrs @ [****] Sr. Medical Director (NA) = [****] hours @ [****] Sr. Medical Director (WE) = [****] hours @ [****] Medical Director (APA) = [****] hrs @ [****]
Project Management /Project Tracking				
Financial Project Management	$[****]	$[****]	Financial Project Management in previous contract expired [****]. The number of Financial Project Management months has increased from [****][****] in previous contract to [****][****] in CO7 with a revised completion date of [****]based on the CSR finalized by [****]	Manager (NA) (PM) [****] hrs at [****] Manager (NA) (PM) [****][****] hrs at [****]; Manager (NA) (PM) [****] hrs at [****]; Manager (NA) (PM) [****] hrs at [****]; Project Budget Analyst (NA) [****] hrs at [****] Project Budget Analyst (NA) [****] hrs at [****] Project Budget Analyst (NA) [****] hrs at [****] Project Budget Analyst (NA) [****] hrs at [****] Director (DM) (NA) - [****] - [****] hrs Director (DM) (NA) - [****] - [****][****] hrs Director (DM) (NA) - [****] - [****][****] hrs Director (DM) (NA) - [****] - [****][****] hrs Manager (DSPM) (NA) - [****] - [****] hrs Manager (DSPM) (NA) - [****] - [****][****] hrs Manager (DSPM) (NA) - [****] - [****][****] hrs Manager (DSPM) (NA) - [****] - [****][****] hrs Director (Biostats) (NA) - [****] - [****] hrs Director (Biostats) (NA) - [****] - [****] hrs Director (Biostats) (NA) - [****] - [****] hrs Director (Biostats) (NA) - [****] - [****] hrs

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Project Management	$ [****]	$[****]	Project Management in previous contract expired [****]. The number of Project Management months has increased from [****][****]in previous contract to [****][****]in CO7 with a revised completion date of [****]based on the CSR finalized by [****]. Also includes oversight for the CDAI listing and CDAI eCRF pages updates; oversight for the central lab results integration into the eCRF; oversight for the DSUR; updating the Oracle agreements to provide the InForm database platform	Sr. Med Director (NA) [****] - [****] hrs Sr. Med Director (NA) [****] - [****] hrs Sr. Med Director (NA) [****] - [****] hrs Sr. Med Director (NA) [****] - [****] hrs Sr. Director (NA) [****] - [****][****][****] hrs Sr. Director (NA) [****] - [****]hrs Sr. Director (NA) [****] - [****] hrs Manager (PM) (NA) - [****][****] hrs Manager (PM) (NA) - [****] [****] hrs Manager (PM) (NA) - [****] [****] hrs Manager (PM) (NA) - [****][****] hrs CMPL (LCRA) (NA) - [****] [****][****] hrs CMPL (LCRA) (NA) - [****] –[****] hrs CMPL (LCRA) (NA) - [****] -[****] hrs CMPL (LCRA) (NA) - [****] -[****]hrs Director (DM) (NA) - [****] [****] hrs Director (DM) (NA) - [****] - [****][****] hrs Director (DM) (NA) - [****] - [****][****] hrs Director (DM) (NA) - [****] - [****] hrs Managers X 2 (DSPM and DM) (NA) - [****] for [****] hrs Managers X 2 (DSPM and DM) (NA) - [****] for [****] hrs Managers X 2 (DSPM and DM) (NA) - [****] for [****] hrs Managers X 2 (DSPM and DM) (NA) - [****] for [****] hrs Principal Statistician (NA) - [****] [****] hrs Principal Statistician (NA) - [****] [****][****] hrs Principal Statistician (NA) - [****] [****][****] hrs Principal Statistician (NA) - [****] [****][****] hrs Manager (DSPM) = [****][****] hr @ [****] Manager (NA) (DSPM II) [****] hr @ [****] Manager (NA) (DSPM) = [****]hr @ [****] Manager (NA) (PM) [****] hrs @ [****] CMPL (NA) - [****][****] hrs @ [****] Manager (PM) (NA) [****] hrs @ [****] Manager, Medical Coding (NA) = [****] hrs @ [****] Manager (DSPM)(NA) = [****] hrs @ [****] GSSU Specialist (NA) = [****] hr @ [****] ([****] hr/ site X [****] sites Manager (NA)(PM) [****][****] hrs @ [****] Manager (NA) (DSPM) = [****] hrs @ [****] Manager (NA) (DM) = [****] hrs @ [****] Manager (DSPM) (NA) = [****] hr @ [****]
Project Tracking / Communications	$[****]	$[****]	Project Tracking /Communications in previous contract expired [****]. The	Sr. Data Analyst (API) - [****] for [****] hrs Sr. Data Analyst (API) - [****] for [****] hrs Sr. Data Analyst (API) - [****] for [****] hrs

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
			number of Project Tracking /Communications months has increased from [****] in previous contract to [****] in CO7 with a revised completion date of [****]based on the CSR finalized by [****]	Sr. Data Analyst (API) - [****] for [****][****] [****] hrs Database Programmer (API) - [****] for [****] hrs Database Programmer (API) - [****] for [****] hrs Database Programmer (API) - [****] for [****] hrs Database Programmer (API) - [****] for [****][****] hrs Manager (NA) (PM) [****] hrs at [****] Manager (NA) (PM) [****][****] hrs at [****] Manager (NA) (PM) [****] hrs at [****] Manager (NA) (PM) [****] hrs at [****] Technical Assistant (NA) - [****] Technical Assistant (NA) - [****] hrs @[****] Technical Assistant (NA) - [****] hrs @[****] Technical Assistant (NA) - [****] hrs @[****] CRA I (NA) [****] sites for [****] wks.; [****]hrs @ [****] CRA I (NA) [****] hrs @ [****] CRA I (NA) [****] sites for [****] wks. in 2015;[****]hrs @ [****] CMPL (LCRA) (NA) [****] hrs at [****] CMPL (LCRA) (NA) [****] hrs at [****] CMPL (LCRA) (NA) [****] hrs at [****] CMPL (LCRA) (NA) .[****] hrs at [****] Sr. CRA (NA) [****] sites for [****][****] wks.; [****]hrs @ [****]; Sr. CRA (NA) [****] hrs @ [****] Sr. CRA (NA) [****] hrs @ [****] Sr. CRA (NA) [****] hrs @ [****] Manager (DSPM) (NA) [****] hrs @ [****] Manager (DSPM) (NA) [****] hrs @ [****] Manager (DSPM) (NA) [****][****] hrs @ [****] Manager (DSPM) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****][****] hrs @ [****] [****][****] hrs PM (NA) @ [****] [****] hrs CMPL (LCRA) (NA) @ [****] [****] hrs Regulatory Associate II (NA) @ [****] CMPL (LCRA) (NA) - [****] hrs @ [****]
Vendor Management	$[****]	$[****]	Vendor Management in previous contract expired [****]. The number of Vendor Management months has increased from [****] in previous contract to [****] in CO7 with a revised completion date of [****]. Includes [****]a month InForm Data Transfers to BioForum from [****]to	Manager (PM) (NA) [****] hrs at [****] Manager (PM) (NA) [****] hrs at [****] Manager (PM) (NA) [****] hrs at [****] Manager (PM)(NA) [****] hrs at [****] Manager (DM) (NA)= [****] hr @ [****] Manager (DM) (NA)= [****] hr @ [****] Manager (DM) (NA)= [****] hr @ [****] Manager (PM) (NA) [****] hours @ [****] ([****][****] hrs per replacement site X[****] and end RRD; [****] min/ amendment X [****])

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
			[****]; Replacement of [****]DSMB members requiring contracts and one contract amendment:; Print orders for hard-copy documents related to Protocol v9 revisions: CRA and CMPL site follow-up on behalf of the vendors in December 2014/January 2015 for study medication replacement and receipt of the updated laboratory manual and supplies.	Manager (PM) (NA) [****][****] hours @ [****] ([****]and end [****] agreement) Paralegal (NA) [****] hours @ [****] (end RRD, [****] new agreements, [****] amendments) Paralegal (NA) [****] hours @ [****] Sr. Grants & Contract Associate [****] hours @ [****] Sr. Grants & Contract Associate [****] hours @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] Manager, (PM) (NA) [****] hours @ [****] Manager, (PM) (NA) [****]hours @ [****] Manager, (PM) (NA) [****][****]hours @ [****] Manager, (PM) (NA) [****]hours @ [****] Manager, DM (NA) - [****]hours @ [****] Manager, DM (NA) - [****][****]hours @ [****] Manager, DM (NA) - [****] hours @ [****] [****] hours PM NA @ [****] - Obtaining quotes to print of hard copy protocols, mini-protocols, IWRS Manuals Protocol v9, mini-protocols, received by sites Sr CRA (API) hours ([****] hr for IP replacement @ [****] Sr CRA (API) hours ([****] hr for IP contingency replacement @ [****] Sr CRA (NA) [****] hours ([****] hrs for IP replacement @ [****] Sr CRA (NA) [****] hour IP contingency at [****] CMPL (LCRA) (NA) [****] hrs ([****] hrs for lab manual and replacement kits FUP & [****] Hours for IP replacement @ [****] CMPL (LCRA) (NA) [****] hr for IP contingency replacement @ [****] Manager (PM) (NA) [****] hours @[****] Manager (PM) (NA) [****][****] hours @[****]
Data Management				
Database Archiving	$[****]	$[****]	No change	No change
Data Cleanup (DM)	$[****]	$[****]	Increased the number of total eCRF pages from[****] to [****]by increasing the number of unique pages from [****]to [****]. Also includes extensive clean-up of reworked CDAI entries related to new eCRF CDAI pages;	Sr. Database Programmer (API) - [****] for [****] hrs Sr. Database Programmer (API) - [****] for [****] hrs Sr. Database Programmer (API) - [****] - [****] hrs Manager DM (NA) - [****] - [****] hrs Manager DM (NA) - [****] - [****] hrs Manager DM (NA) - [****] - [****] hrs Sr. Database Programmer - [****] - [****] hrs Sr. Database Programmer - [****]- [****] hrs

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
				Sr. Database Programmer - [****] - [****] hrs Data Analyst (API) [****] hrs @ [****] Data Analyst (API) [****] hrs @ [****] Data Analyst (API) [****][****] hrs @ [****]
Data Management: Database Quality Control Inspection	$[****]	$[****]	Revisions to the CDAI eCRF and addition of new eCRF, increasing the number of pages from [****]to [****][****]in 2015 required QC.	Data Analyst (API) [****] hrs @ [****]
Database Design	$[****]	$[****]	Adding [****]NA and [****] [****]sites. Unused site additions to the database will be credited to the client at the end of recruitment. Updating the CDAI eCRF and adding another eCRF page. Israeli Site Transfer to Cato-Israel. Study site updates for Study Coordinator turnover in 2014, 2015, 2016, 2017, and 2018. Programming updates for central lab results integration into the database for CDAI calculations in 2016, 2017, & 2018. Annual reviews by Data Manager and Database Programmer	Sr. Database Programmer (API) - [****] hours at [****] Sr. Database Programmer (API) - [****] hours for [****] Sr. Database Programmer (API) - [****] hours for [****] Sr. Database Programmer (NA) [****] hrs to add [****] NA sites at [****] DM Manager (NA) [****] hours at [****] DM Manager (NA) [****] hours at [****] DM Manager (NA) [****] hours at [****] Sr. Database Programmer (API) [****] hours @ [****] Manager (DM) - [****] hour @ [****] Database Programmer API - [****] hours @ [****] Sr. D/B Programmer (NA) [****] hrs - Unique Pages @ [****] Sr. D/B Programmer (NA)- [****] hrs @ [****] Sr. Database Programmer (API) - [****] hrs @ [****] Manager (DM)(NA)- [****][****] hour @ [****] Sr. DB Programmer (API)- [****] hrs @ [****] Sr. DB Programmer (API)- [****] hrs @ [****] Sr. DB Programmer (API)- [****] hrs @ [****] Sr. DB Programmer (API)- [****] hrs @ [****] Sr. DB Programmer (API)- [****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****][****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] Manager (DM) = [****] hrs @ [****] Manager (DM) = [****] hrs @ [****] Manager (DM) = [****] hrs @ [****] Sr DB Programmer (API) [****][****] hrs @ [****] Sr DB Programmer (API) .[****] hrs @ [****] Sr DB Programmer (API) [****] hrs @ [****]
Dictionary Coding	$[****] [****]	$[****]	Increased number of terms from [****] to [****][****]	Sr Medical Director [****] hrs at [****] Sr Medical Director [****] hrs at [****] Sr Medical Director [****] hrs at [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
				Manager, DM (NA) - [****][****] hrs Manager, DM (NA) - [****] [****] hrs Manager, DM (NA) - [****][****] hrs Sr. Database Programmer (API) [****] hrs @ [****] Sr. Database Programmer (API) [****] hrs @ [****] Sr. Database Programmer (API) [****] hrs @ [****] Sr. Data Analyst (API) - [****][****] hrs; Sr. Data Analyst (API) [****][****] hrs Sr. Data Analyst (API) [****][****] hrs Sr. Database Programmer (API) [****] hrs @ [****] Sr. Database Programmer (API) [****] hrs @ [****] Sr. Database Programmer (API) [****][****] hrs @ [****] Manager, Medical Coding (NA) [****] hours @ [****] Manager, Medical Coding (NA) [****] hours @ [****] Manager, Medical Coding (NA) [****] hours @ [****] D/B Programmer (NA) - [****] [****] hrs D/B Programmer (NA) [****],[****][****] hrs Sr. Medical Coding Specialist (NA) - [****], [****] hrs Sr. Medical Coding Specialist (NA) [****], [****] hrs Sr. Medical Coding Specialist (NA) [****],[****][****] hrs
Edit Check Programming	$[****]	$[****]	Edit checks to generate CDAI listings; for updates to the CDAI eCRF page and additional page; and integration of central lab data to the clinical database	Manager (NA) DM = [****] hr @ [****] Sr Database Programmer (NA) [****] hrs @ [****] Sr Database Programmer (NA) [****] hrs @ [****] Sr. Data Analyst (API) - [****][****] hrs Sr. Data Analyst (API) - [****] - [****] hrs Database Programmer API - [****] hours @[****] Sr. D/B Programmer (NA) - [****] hours @ [****] Sr. D/B Programmer (NA) - [****][****] hours @ [****] Principal Statistician (NA) - [****] hours @ [****] Principal Statistician (NA) - [****] hours @ [****] Manager, (PM) (NA) [****] hours @ [****] Manager, (PM) (NA) [****] hours @ [****] Lead Statistical Programmer (NA) [****] hrs @[****] DM Stats Programmer, (NA) [****] hrs @[****] Lead Statistical Programmer (NA(= [****] hrs @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
				Principal Stats programmer (NA) = [****] hrs @ [****] Principal Stats programmer (NA) = [****]hrs @ [****] Principal Stats programmer (NA) = [****]hrs @ [****] Lead Stats programmer (NA) [****] hrs @ [****] Lead Stats programmer (NA) [****] hrs @ [****] Lead Stats programmer (NA) [****] hrs @ [****] Principal Statistical Programmer (NA) = [****] hrs @ [****] Manager-DM (NA) = [****] hrs @ [****]
Electronic Data Import	$[****]	$[****]	Increasing the length of the study will increase the number of monthly imports from vendors	Sr Database Programmer (API) [****] hrs at [****] Sr Data Analyst (API) [****] hrs at [****]
Case Report Form Data/Document Transfers	$[****]	$[****]	No change	
Statistical Analysis and Table Generation				
Electronic Data Transfer	$[****]	$[****]	Database transfers to Bioforum from [****]to [****], occurring [****]a month; [****] transfers in total and includes the test transfer in [****]	Sr Data Programmer (NA) [****] hrs @ [****] Sr Data Programmer (NA) [****] hrs @ [****] Sr Data Programmer (NA) [****] hrs @ [****] Sr Med Coding Specialist (NA) [****] hrs @ [****] Sr Med Coding Specialist (NA) [****] hrs @ [****] Manager (PM) (NA) [****] hr @ [****] Manager (PM) (NA) [****][****] hr @ [****] Manager (PM) (NA) [****] hr @ [****]
Interim Analysis/Report Preparation and Review	$[****]	$[****]	No change	Pending finalized Protocol v9
Statistical Analysis Plan Preparation/Review	$[****]	$[****]	No change	Pending finalized Protocol v9
Table Generation	$[****]	$[****]	No change	Pending finalized Protocol v9
Table/Listings Review	$[****]	$[****]	No change	Pending finalized Protocol v9
Clinical Study Report				
Clinical Study Report Preparation/Review	$[****]	$[****]	Increased timelines increase the possibility for more SAEs from [****]to [****]. Medical Writing will need to prepare [****]more narratives.	Director (NA), Pharmacovigilance - [****] hrs @ [****] Safety Associate II - [****] hrs @ [****] Medical Writer II (NA) - [****] hrs @ [****] Manager, Medical Writing (NA) - [****] hrs @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Team Meetings				
Project Team Meetings - Internal Meetings	$ [****]	$[****]	Protocol v9 and increased timelines lead to increases in the number of meetings from [****]to [****]	Sr. Medical Director (APA) [****][****] hrs at [****] Sr. Grant & Contracts Associate (NA) [****] hrs @ [****] Manager (NA)(PM) [****] hrs @ [****] Sr. Medical Director (NA) [****] hrs @ [****] Sr. Medical Director (NA) [****] hrs @ [****] Sr. Medical Director (NA) [****] hrs @ [****] Sr. Medical Director (NA) [****] hrs @ [****] Sr. Director (NA)[****] hrs @ [****] Sr. Director (NA)[****] hrs @ [****] Sr. Director (NA)[****] hrs @ [****] Sr. Director (NA)[****] hrs @ [****] Manager(NA)(PM) [****] hrs @ [****] Manager(NA)(PM) [****][****] hrs @ [****] Manager(NA)(PM) [****] hrs @ [****] Manager(NA)(PM) [****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****][****] hrs @ [****] SR.CRA (NA) [****] hrs @ [****] SR.CRA (NA) [****] hrs @ [****] SR.CRA (NA) [****] hrs @ [****] SR.CRA (NA) [****][****] hrs @ [****] CRA II (NA) [****] hrs @ [****] CRA I (NA) [****] hrs @ [****] CRA I (NA) [****] hrs @ [****] CRA I (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] Sr. Medical Director (WE) [****] hrs @ [****] Sr. Medical Director (WE) [****] hrs @ [****] Sr. Medical Director (WE) [****] hrs @ [****] Sr. Medical Director (WE) [****] hrs @ [****] GSSU Manager (NA) [****] hrs @ [****] Manager (NA) PM [****][****] hrs @ [****]s Manager (NA)(DM) [****]hrs @ [****] Manager (NA)(DSPM) [****] hrs @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
Project Team Meetings - Client Teleconferences	$[****]	$[****]	Protocol v9, dCRA teleconferences, CRA – Vendor teleconferences; CRO and site training teleconferences, monthly Medical Monitor teleconferences; Patrick and Randy's (iVH Sr. Director) Weekly conference calls; DSUR conference calls; Bioforum conference calls, and increased timelines lead to increases in the number of meetings from [****]to [****] ([****]client teleconferences completed as of 21Aug2016)	[****] hrs for Medical Director (NA) @ [****] [****] hrs Manager (N/A) (PM) @ [****] [****] hrs Manager (NA) (DSPM & DM) @ [****] [****] hrs LCRA (NA) @ [****] [****] hrs Sr. Director (NA)(Weekly team call and Thursday call with RHB) @ [****] [****] hrs for TA (NA) @ [****] [****] [****]hrs Regulatory Associate (NA) @ [****] [****] hrs Safety Associate (NA) @ [****] Sr. Medical Director (NA) [****] hrs@ [****] Sr. Medical Director (NA) [****] hrs@ [****] Sr. Medical Director (NA) [****] hrs@ [****] [****] hrs Manager (N/A) (PM) @ [****] [****] hrs Manager (N/A) (PM) @ [****] [****] hrs Manager (N/A) (PM) @ [****] CMPL (LCRA)(NA) [****] hrs@ [****] CMPL (LCRA)(NA) [****] hrs@ [****] CMPL (LCRA)(NA) [****] hrs@ [****] [****] hrs Sr. Director (NA) (Weekly team call and Thursday call with RHB) @ [****] [****] hrs Sr. Director (NA) (Weekly team call and Thursday call with RHB) @ [****] [****] hrs Sr. Director (NA) (Weekly team call and Thursday call with RHB) @ [****] [****] [****]hrs TA (NA) @ [****] [****] [****]hrs TA (NA) @ [****] [****] [****]hrs TA (NA) @ [****] [****] hrs Regulatory Director (NA) @[****] [****] hrs Regulatory Director (NA) @[****] [****] hrs Regulatory Director (NA) @[****] [****] hrs Regulatory Associate (NA) @ [****] [****] hrs Regulatory Associate (NA) @ [****] [****] hrs Regulatory Associate (NA) @ [****] [****] hrs Safety Associate (NA) @ [****] [****] hrs Safety Associate (NA) @ [****] [****] hrs Safety Associate (NA) @ [****] Sr Medical Director (WE) [****] hrs @ [****]

Task	Current (US Dollars)	Change Order 7	Assumption Changes influencing the change in the budget	Additional comments
				Sr Medical Director (WE) [****] hrs @ [****] Sr Medical Director (WE) [****] hrs @ [****] Sr Medical Director (WE) [****] hrs @ [****] Manager (PM) (NA) [****] hr @ [****] Manager (PM) (NA) [****] hr @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] TA (NA) [****] hrs @ [****] Sr. Safety Associate (NA) [****] hrs @ [****] Sr. Safety Associate (NA) [****] hrs @ [****] Sr. Safety Associate (NA) [****] hrs @ [****] CMPL (LCRA) (NA) [****]hours @ [****] Sr. CRAs (NA) [****] hours @ [****] Sr. CRA (API) - [****] hrs @ [****] Manager (PM) (NA) [****] hours @ [****] (CMPL) LCRA (NA) [****] hours @ [****] Sr. CRA (NA) [****]hrs @ [****] Manager (PM)(NA) [****] hrs @[****] CMPL (LCRA) (NA) [****] hrs @[****] (DCRA calls) CMPL (LCRA) (NA) [****] hrs @ [****](DCRA calls) CMPL (LCRA) (NA) [****] hrs@ [****] CMPL (LCRA) (NA) [****] hrs @ [****] Manager (PM) (NA) [****] hrs@ [****] Manager (PM) (NA) [****] hrs @ [****]
Project Team Meetings - Kick-off Meeting	$[****]	$[****]	No change	No change
Total Direct Costs	**$**[****]	[****]		

Total Costs

			Total Costs($)
Category	**Current Contract (USD)**	**Change in Scope #7 (USD)**	**Revised Total (USD)**
Pass-Through Costs	$[****]	$[****]	$[****]
Investigator Grants Costs	$[****]	$[****]	$[****]
Professional Fees	$[****]	$[****]	$[****]
Fee Discount	($v)	$[****]	($[****])
Revised Professional Fees	**$**[****]	**$**[****]	**$**[****]
DCRA Overpayment Credit	**$**[****]	**($**[****]**)**	**($**[****]**)**
Grand Total	**$**[****]	**$**[****] **[****]**	**$**[****]

Exhibit B Payment Schedule

7810962 Canada Inc. (11ISB001)

Milestone	Original Agreement	CO#2 with Discount	CO#3 with Discount	CO#4 with Discount	CO#5	CO#6	CO#6.1	CO#7	Total (USD) with Discount	Invoice #	Invoice Amount	Paid Amount
Upon Execution of Contract	250,249								250,249	11ISB001-001	250,249	250,249
Upon Execution of CO#3			904,042						904,042	11ISB001-064	904,042	904,042
Upon Execution of CO#4				119,480					119,480	11ISB001-065	119,480	119,480
Upon Execution of CO#5					349,419				349,419	0030018998	349,419	349,419
Upon Execution of CO#6						424,093			424,093	0030025408	424,093	424,093
Upon Execution of CO#7								2,205,858	2,205,858	0030028750	1,000,000	1,000,000
Completion of Investigator Meeting									0			
50% of Site Initiation Visits completed									0			
Last Site Initiation Visits completed									0			
Database Release (eCRF release) to Production									0			
First Patient In US Trial	250,249	-250,249							0			
First Patient In European Trial	250,249	-250,249							0			
Last Patient In US Trial	344,865	-344,865							0			
Last Patient In European Trial	344,865	-344,865							0			
First Patient In		421,712							421,712	11ISB001-034/11	421,712	421,712
Last Patient in		576,327	300,000						876,327	0030022105	876,327	876,327
	1,440,477	**-192,189**	**1,204,042**	**119,480**	**349,419**	**424,093**	**0**	**2,205,858**	**5,551,180**			
26-week Subject Treatment Period Ends:									0			
DBL for all patients completing 26-weeks completed		412,620	280,000						692,620			
Study Unblinded after analysis of efficacy part completed									0			
Delivery of Draft Tables, Listings and Graphs									0			
Delivery of Final Tables, Listings and Graphs									0			
Delivery of Final 26 CSR US Trial	750,746	-750,746							0			
Delivery of Final 26 CSR European Trial	750,746	-750,746							0			
	1,501,492	**-1,088,872**	**280,000**						**692,620**			
52-week Subject Treatment Period ends:									0			
DBL for all patients completed		232,364	200,000						432,364			
Delivery of Draft Tables, Listings and Graphs									0			
Delivery of Final Tables, Listings and Graphs									0			
Delivery of Final 52 CSR US Trial	261,441	-261,441							0			
Delivery of Final 52 CSR European Trial	261,442	-261,441							1			
Delivery of Final CSR		124,981							124,981			
Database Lock									0			
Delivery of Draft CRF US Trial	261,432	0							261,432	11ISB001-023	261,432	261,432
Delivery of Draft CRF European Trial	261,432	-261,432							0			
	1,045,747	**-426,969**	**200,000**	**0**	**0**	**0**	**0**	**0**	**818,778**			
Total Milestones	**3,987,716**	**-1,708,030**	**1,684,042**	**119,480**	**349,419**	**424,093**	**0**	**2,205,858**	**7,062,578**		**4,606,754**	**4,606,754**

Quarterly Project Management Fee (10 Quarters starting June 16, 2011, ending December 15, 2013: 183,590 USD per quarter) Only Invoiced for 7 quarters	1,835,894	-598,157							1,237,737	See below	1,237,737	1,237,737
Monthly Fees for Hold Period: (9 Monthlies starting April 2012, ending December 2012: 15,000 USD per month) Only Invoiced for 6 months		90,000							90,000	11ISB001-017	90,000	90,000
Quarterly Project Management Fee: (8 Quarterly Payments starting January 2014: $173,477.50 USD per quarter) Only invoiced for 4 quarters		1,387,820	-693,909						693,911	See below	693,911	693,911
Quarterly Project Management Fee: (4 Quarterly Payments starting January 2015: $244,147.50 USD per quarter)			976,590						976,590	See below	976,590	976,590
Quarterly Project Management Fee: (8 Quarterly Payments starting January 2017: $295,633.24 USD per quarter)[2]								2,365,066	2,365,066			
Monthly Site Management Fee: ($910.35 USD per active site month starting November 2016 through September 2018; estimated 1049 active site months[3])								954,957	954,957			
Quarterly Fees for Dedicated CRA Program (4 Quarters Starting July 2016: $141,364.29 USD per quarter)						565,457			565,457	See below	342,714	342,714
Quarterly Fees for Dedicated CRA Program (3 Quarters Starting July 2016: $59,985 USD per quarter)							179,955		179,955	See below	59,985	59,985
Credit for double payment of DCRA time								-113,582	-113,582			
Total Milestone Payments[1]	**5,823,610**	**-828,367**	**1,966,723**	**119,480**	**349,419**	**989,550**	**179,955**	**5,412,299**	**14,012,669**		**7,947,705**	**7,947,705**

[1] - Professional fees are net of the 5% discount applied to Original Agreement and CO#1-#4
[2] - Quarterly Project Management Fees will be invoiced at the beginning of each quarter
[3] - Site Management fee will vary from month to month as it is based on the number of sites active for the month.

Quarterly Payments			
3rd Quarter 2011	11ISB001-002	183,590.00	183,590
4th Quarter 2011	11ISB001-006	183,590.00	183,590
1st Quarter 2012	11ISB001-008	183,590.00	183,590
1st Quarter 2012(Reconciled for Amendment #1)	11ISB001-017 &	(47,393.00)	(47,393)
1st Quarter 2013	11ISB001-022	183,590.00	183,590
2nd Quarter 2013	11ISB001-027	183,590.00	183,590
3rd Quarter 2013	11ISB001-032	183,590.00	183,590
4th Quarter 2013	11ISB001-032	183,590.00	183,590
1st Quarter 2014	11ISB001-042	173,477.50	173,478
2nd Quarter 2014	11ISB001-045	173,477.50	173,478
3rd Quarter 2014	11ISB001-053	173,477.50	173,478
4th Quarter 2014	11ISB001-058	173,478.00	173,478
1st Quarter 2015	11ISB001-064	244,147.50	244,148
2nd Quarter 2015	0030014002	244,147.50	244,148
3rd Quarter 2015	0030017725	244,147.50	244,148
4th Quarter 2015	0030017726	244,147.50	244,148
2nd Quarter 2016	0030025949	201,349.29	201,349
2nd Quarter 2016	0030026160	141,364.29	141,364
3rd Quarter 2016	0030027609	59,985.00	59,985
4th Quarter 2016			
1st Quarter 2017			

Pass Through Costs:

(a) CO#2: Twenty percent (20%) of the average estimated expenses as set forth in the Expenses Estimate (exclusive of funds for investigator grants), totaling $
[****]
, 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: Twenty percent (20%) 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) 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.

(d) CO#5: This is a one-time payment of $
[****]
(exclusive of funds for investigator grants), that will be due and payable upon execution of this Agreement.

(e) CO#6: This is a quarterly payment of $
[****]
[****]for (4) Quarters beginning with 1st payment invoiced on or after [****]. First payment invoiced on [****].

(f) CO#6.1: This is a quarterly payment of $
[****]
for (3) Quarters beginning with 1st payment invoiced on or after [****]or upon execution of this Agreement if the executed date is later than [****]
(f) CO#7: This is a one-time payment of $
[****]
(exclusive of funds for investigator grants), that will be due and payable upon execution of this Agreement.

(g) Actual pass-through expenses, as provided in the expenses estimate, will be billed as incurred by inVentiv Health Clinical

(g) Any unused funds will be returned within ninety (
[****)) days from the date of the final reconciliation

Investigator Grants:

(a) Twenty percent (20%) of the estimated total of the grant payments of the study, totaling $
[****]
, will be invoiced upon commencement of services. Prepayment for Investigator Grants (to be drawn down once paid and replenished once 75% depleted). This process to continue until the end of the study.

(b) inVentiv Health Clinical will submit invoices in advance for estimated amounts to be paid to investigators during the next quarter to ensure that adequate funds are available to pay investigator grants

(c) inVentiv Health Clinical will not make payments to investigators without having sufficient funds available in advance.

(d) Any unused funds will be returned within ninety (90) days from the date of the final reconciliation

4. Payment Conditions:

(a) For all Services, pass through expenses and investigator grants invoiced, payments are due net thirty (30) days from invoice date as set forth in Terms, Item 2 of the Clinical Services Agreement. In the event of a dispute, all undisputed portions of the invoice(s) are due within the above stated terms

(b) Payments shall be made in the currency identified above and shall be made free of any applicable local withholding taxes, charges or remittance fees. Invoices will be inclusive of applicable taxes as determined by local laws and regulations

(c) inVentiv Health Clinical reserves the right to charge interest against any unpaid overdue balance at the rate of one and a half percent (1.5%) per month

(d) All services and pass-through payments should be sent via wire or ACH

Exhibit 4.24

STRICTLY CONFIDENTIAL - EXECUTION VERSION

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

EXCLUSIVE COMMERCIALIZATION AGREEMENT

THIS EXCLUSIVE COMMERCIALIZATION AGREEMENT (the "**Agreement**") is made and entered into as of December 30, 2016 (the "**Effective Date**"), by and between **CONCORDIA PHARMACEUTICALS INC.**, a société à responsabilité limitée (private limited liability company) duly continued and validly existing under the laws of the Grand-Duchy of Luxembourg, having its registered office at 8-10 Avenue de la Gare – L-1610 Luxembourg, Grand-Duchy of Luxembourg, and registered with the Registre de commerce et des sociétés, Luxembourg (register of trade and companies) under number B 200 344, by way of its Barbados branch, carrying on business at 5 Canewood Business Centre, St. Michael, Barbados, BB 11005 ("**Concordia**") and **REDHILL BIOPHARMA LTD.**, an Israeli company, having a place of business at 21 Ha'arba'a Street, Tel-Aviv, Israel (" **RedHill**"). RedHill and Concordia each may be referred to herein individually as a "**Party**," or collectively as the "**Parties**".

WHEREAS, Concordia owns, develops, markets and manufactures Donnatal® and wishes to appoint RedHill, and RedHill wishes to accept such appointment, as the exclusive Promoter of the Product for the Field of Use in the Territory (as those terms are defined below);

NOW THEREFORE, THE PARTIES HERETO AGREE AS FOLLOWS:

1. DEFINITIONS

For purposes of this Agreement, the following terms shall have the following meanings:

1.1 "**Act**" means the Federal Food, Drug and Cosmetic Act, as amended from time to time, and the rules, regulations, guidelines and requirements of the FDA as may be in effect from time to time**.**

1.2 "**Affiliate**" of a person means any other person that, directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with such first person. For purposes of this definition only, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" will mean the possession, directly or indirectly, of the power to direct the management or policies of an entity, whether through the ownership of fifty percent or more of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or

other similar entity, its general partner or controlling entity) of the other organization or entity or by contract relating to voting rights or corporate governance, or otherwise.

1.3 "**Applicable Laws**" means all federal, state and local laws, and the rules, regulations, guidance, guidelines and requirements of Governmental Authorities (as hereinafter defined) in effect from time to time, including those relating to the manufacture, marketing, promotion (including, but not limited to the *Telephone Consumer Protection Act*), distribution (including storage, handling and transportation) and sale of the Product in the Territory including the Act, the FDA Guidance for Industry – Supported Scientific and Educational Activities, "fraud and abuse", anti-kickback, consumer protection and false claims statutes and regulations.

1.4 "**Applicable Percentage**" means [****] percent ([****]%). Notwithstanding the foregoing, the Applicable Percentage for [****] shall, in all cases, decrease [****] percent ([****]%) to [****] ([****]%) at such time when the [****].

1.5 **Bankruptcy Event**" means a company: (i) becomes insolvent or admits its inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within [****] or is not dismissed or vacated within [****] after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; or has a receiver, trustee, custodian or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

1.6 [****].

1.7 "**Business Day**" means a day that is not a Saturday or Sunday or any other day on which banks in New York, NY, Barbados and/or Israel are authorized or required by law to be closed.

1.8 "**Calendar Year**" means each one-year period beginning January 1st and ending on December 31st.

1.9 " **Calendar Quarter**" means each period of three consecutive months starting on January 1st, April 1st, July 1st or October 1st.

1.10 **Commercialization Fee**" has the meaning set forth in Section 9.1 of this Agreement.

1.11 "**Commercialization Plan**" means the Commercialization Plan to be annexed hereto as **Annex A-1**, as may be amended from time to time by the Parties. The Commercialization Plan shall include [****].

1.12 "**Detail**" means any in-person sales presentation of the Product to physicians in a manner that is in compliance with Applicable Laws and customary in the industry for promoting a prescription pharmaceutical product. When used as a verb, "Detail" shall mean to engage in a Detail, also known as "Detailing".

1.13 "**Excess Units Sold**" in any period means: [****].

1.14 "**FDA**" means the United States Department of Health Food and Drug Administration.

1.15 "**Field of Use**" means all labeled indications for the Product.

1.16 "**Governmental Authorities**" has the meaning set forth in Section 2.3 of this Agreement.

1.17 "**Net Sales Price**" shall mean, with respect to the Product, [****].

1.18 "**PIRs**" means, collectively, Product Labels and Inserts and Promotional Materials.

1.19 "**Product**" means Donnatal® (phenobarbital and belladonna alkaloids) in all formulations, including the currently available bottles of 100 and 1,000 tablets and 4oz and one pint bottles of elixir, and/or any other additional product(s) determined by the Parties to be subject to this Agreement following the Effective Date. Any reference to "Product" shall mean and be deemed to refer to each Product subject to this Agreement at any time.

1.20 "**Product Copyright**" shall mean all copyrightable subject matter included in the PIRs and the Product training programs and materials developed and produced in accordance with this Agreement, whether or not such copyright has been registered and whether or not such materials have been published.

1.21 "**Product Label and Insert**" means (a) all labels and other written, printed or graphic matter affixed to any container, packaging or wrapper utilized with the Product or (b) any written material physically accompanying the Product, including Product package inserts.

1.22 "**Product Trademarks**" means the (a) Trademark "Donnatal" and the registrations thereof, (b) any other Trademarks relating to the Product and the registrations thereof, (c) any pending or future Trademark registration applications relating to the Product, (d) any unregistered Trademark rights relating solely to the Product as may exist through use prior to or as of the date hereof, (e) any current or future modifications or variants of any of the foregoing Trademarks, and (f) any future Trademarks adopted by Concordia for use solely in connection with the Product, in each case excluding the Concordia Trademark and tradename.

1.23 "**Promotion**" and "**Promotional Activities**" means those activities conducted in compliance with Applicable Laws and customary in the industry by a pharmaceutical company's sales force to implement marketing plans and strategies aimed at encouraging the use of a prescription pharmaceutical product, including Detailing. When used as a verb, "Promote" or "Promoting" means engagement in such activities. When used as a noun, "Promoter" means a person or entity engaged in such activities.

1.24 "**Promotional Materials**" has the meaning set forth in Section 3.3 of this Agreement.

1.25 "**Regulatory Approval**" means the obtaining of all necessary regulatory approvals (including the obtainment of pricing and reimbursement approval) required from all applicable Regulatory Authorities in the Territory in order to commercially sell or market

the Product for human consumption in such Territory, and satisfaction of any related applicable regulatory and notification requirements (if any).

1.26 "**Regulatory Authority**" means any applicable Governmental Authority regulating or otherwise exercising authority with respect to the manufacture, development and commercialization of the Product in the Territory.

1.27 "**Sample**" means a standard sample unit of Product consistent with industry practices, subject to the provisions of Section 3.6.

1.28 **"Tax"** means, except as otherwise addressed herein, all federal, state, local, foreign and other income, gross receipts, sales, use, value added, production ad valorem, transfer, franchise, registration, profits, license, lease, service, service use, withholding, payroll, employment, unemployment, estimated, excise, severance, environmental, stamp, occupation, premium, property (real or personal), real property gains, or windfall profits, together with any interest, additions or penalties with respect thereto and any interest in respect of such interest, additions or penalties determined or assessed by a Governmental Authority.

1.29 "**Term**" shall be as defined in Section 19.1.

1.30 "**Territory**" shall mean the geographical territories [****] within the United States as set out in the Commercialization Plan.

1.31 "**Third Party(ies)**" means any party other than Concordia, RedHill and their respective Affiliates.

1.32 "**Trademarks**" means any trademark, servicemark, trade dress, brand mark, certification marks, internet domain names, trade name, brand name, corporate name, logo, business symbol, and other indicia of source, whether or not registered, and all registrations and applications therefor including all extensions, modifications, divisions and renewals of the foregoing.

1.33 "**Unit**" means a base unit of measure such as tablet, milliliter, or other individual dosage of Product.

1.34 **Interpretation**. As used in this Agreement, any reference to gender shall include all genders and any reference to the plural shall include the singular, and the singular shall include the plural. When a reference is made in this Agreement to a section, such reference shall be to a section of this Agreement, unless otherwise clearly indicated to the contrary. Whenever the words "include," "includes" or "including" are used in this Agreement they shall be deemed to be followed by the words "without limitation." The words "hereof," "herein" and "herewith" and words of similar import shall, unless otherwise stated, be construed to refer to in this Agreement as a whole and not to any particular provision of this Agreement, and annex, article, section, paragraph, exhibit, annex and schedule references are references to the annex, articles, sections, paragraphs, exhibits, annexes, and schedules of this Agreement, unless otherwise specified. The captions contained in this Agreement are for convenience only and shall not be deemed a part hereof or affect the interpretation or construction of any provision hereof.

2. APPOINTMENT AND GRANT OF RIGHTS

2 . 1 **Appointment; Grant of Rights**. Subject to the terms and conditions hereinafter set forth, Concordia hereby appoints RedHill, together with its Affiliates, as the exclusive (including as to Concordia) Promoter of, and grants to RedHill and its Affiliates, the exclusive (including as to Concordia) right to Promote and commercialize the Product for the Field of Use in the Territory. To the extent that an Affiliate of RedHill performs any of the responsibilities and obligations of RedHill hereunder, RedHill shall remain liable for such performance as if RedHill performed the responsibilities and obligations itself subject to the terms and conditions set forth in this Agreement.

2.2 **Limitations on Grant of Other Rights**. Concordia shall not permit or authorize any Third Party to market, commercialize or otherwise Promote the Product in the Territory. The foregoing notwithstanding, Concordia or its Affiliates may: [****].

2 . 3 **Governmental Authorities**. As between the Parties, all regulatory matters regarding the Product, including without limitation, all filings in connection therewith, shall be the obligation and responsibility solely of [****], subject to the participation by [****] as requested by the [****].[****] shall not without the consent of [****] or unless so required by Applicable Laws (and then only pursuant to the terms of this Section 2.3), correspond or communicate with any applicable governmental and Regulatory Authorities (including the FDA) (collectively, "**Governmental Authorities**"), whether within the Territory or otherwise, concerning the Product or otherwise take any action concerning any authorization or permission under which the Products are sold or any application for the same. Furthermore, [****] shall, immediately upon receipt of any communication from any Governmental Authority relating to the Product, forward a copy or description of the same to [****] and respond to all inquiries by [****] relating thereto. If [****] is advised by its counsel that it must communicate with any Governmental Authority, then [****] shall so advise [****] immediately and, unless prohibited by Applicable Laws, provide [****] in advance with a copy of any proposed written communication with any Governmental Authority and comply with any and all reasonable direction of [****] and the [****] concerning any meeting or written or oral communication with any Governmental Authority. Notwithstanding the foregoing, [****] shall promptly provide [****] with copies of all communications received from any Governmental Authority concerning the Product and shall promptly submit to [****] copies of all communications and filings concerning the Product made to any Governmental Authority during the Term.

2.4 **Additional Products**. The Parties shall discuss in good faith the addition of other existing or future products of Concordia to be included in the definition of "Product" under this Agreement.

3. COMMERCIALIZATION PLAN; PROMOTIONAL ACTIVITIES

3 . 1 **Commercialization Plan**. The Parties have developed the initial outline of a commercialization plan annexed hereto as **Annex A** (the "**Initial Commercialization Outline**"). [****].

3.2 **Promotional Activities**. During the Term of the Agreement, RedHill accepts the appointment in Section 2.1 and shall be responsible at all times during the Term for the Promotion and commercialization of the Product for the Field of Use in the Territory and shall use its commercially reasonable efforts to Promote the Products for the Field of Use in the Territory. RedHill shall recruit and deploy sales professionals in the Territory in accordance with the Commercialization Plan. RedHill shall not be prohibited from undertaking Promotional Activities with respect to the Product that are in excess of those for which RedHill is responsible under the then current Commercialization Plan, provided that such excess Promotional Activities are consistent with the Commercialization Plan, are in compliance with Applicable Laws and prior notice of such excess Promotional Activities is provided to Concordia. In implementing the Commercialization Plan, Promoting the Product in the Territory and otherwise exercising its rights and fulfilling its obligations under this Agreement, [****].

3.3 **Promotional Materials**. Concordia shall, at its own expense, provide RedHill in a timely manner with the necessary quantities of electronic and physical advertising, promotional, educational, training and communication materials for marketing, advertising and Promotion of the Product to Third Parties ("**Promotional Materials**") that are consistent with the then current Commercialization Plan and that are consistent with any such materials provided to Concordia sales personnel. Concordia shall own all rights, including copyrights in such Promotional Materials. Concordia shall ensure that all Promotional Materials are in strict compliance with all Applicable Laws. The Parties may mutually agree on the transfer to RedHill of responsibilities related to Promotional Materials.

3.4 **Statements**. Each Party shall make, and shall permit its representatives to make, only such statements and claims regarding the Product, including as to efficacy and safety, as are consistent with the PIRs. Without limitation to the foregoing, each Party shall not, and shall not permit its representatives, to make any untrue or misleading statements or comments about the Product, and/or take any action that jeopardizes or could reasonably be expected to jeopardize the goodwill or reputation of the other Party or its products, including the Product.

3.5 **Training**. Concordia shall train RedHill's sales managers and trainers to assist RedHill in the fulfillment of its obligations under this Agreement. Such training provided by Concordia shall comply with all Applicable Laws. In connection therewith, Concordia shall provide such trainers and lecturers as RedHill may deem reasonably necessary. RedHill shall have the right to review and comment on training materials from medical, legal and regulatory perspectives. Concordia shall, in addition to the aforementioned training of RedHill's sales managers and trainers, designate and make available during regular business hours at least one (1) individual to respond to inquiries from RedHill's sales managers and trainers. Concordia shall provide RedHill with such training materials as is reasonably required to adequately train RedHill's sales managers and trainers to Promote the Product and in such quantities as RedHill shall reasonably require and request.

3 . 6 **Samples**. Concordia shall initially supply RedHill with types and quantities of Samples of the Product consistent with its supply of Samples to representatives in the Territory prior to the Effective Date and in territories other than the Territory. Thereafter, Concordia shall supply Samples to RedHill in accordance with the Commercialization Plan. RedHill shall store, secure, handle, transport, distribute, destroy and account for Samples in accordance with the Commercialization Plan and with Applicable Laws.

3.7 **Transparency Reporting/Compliance.**

3.7.1 RedHill shall provide Concordia or its designee with the following information in a mutually acceptable format on a monthly basis to enable Concordia to comply with federal and state aggregate spend reporting obligations: [****].

3.7.2 RedHill shall provide Concordia or its designee with the following information in a mutually acceptable format on a monthly basis to enable Concordia to comply with the Prescription Drug Marketing Act of 1987 and applicable state accountability obligations: [****].

3.8 Neither Party shall be required to perform any obligation under this Agreement or the Commercialization Plan, or use any Promotional Materials or otherwise engage in any activity, to the extent that such Party believes, in its reasonable judgment and in good faith, that such obligation, use of Promotional Materials or other activity: (i) violates any Applicable Law; (ii) violates a written corporate policy of such Party; or (iii) would have a material adverse effect on the business, assets, properties, liabilities (actual or contingent), operations, condition (financial or otherwise) or prospects, of such Party. Each Party shall promptly notify the other Party if and when it formulates such a belief and the Parties shall discuss, in good faith, how best to alter the relevant obligation, Promotional Material or other activity so that it does not have the effect described in item (i), (ii) or (iii) above.

4. Trademark License.

4.1 Concordia hereby grants RedHill the royalty-free right to use the Product Trademarks and Product Copyrights in the Territory solely in connection with the Promotion of the Product, subject to the provisions of this Agreement. RedHill shall, subject to relevant laws and regulations, market the Product throughout the Territory under the Product Trademarks.

4.2 Whenever RedHill uses the Trademarks in advertising or in any other manner in connection with the Product, RedHill shall, subject to relevant laws and regulations, clearly indicate Concordia's ownership of the Trademarks. When using the Trademarks under this Agreement, RedHill undertakes to comply with all laws and regulations pertaining to trademarks in force at any time in the Territory. RedHill shall not at any time do, cause to be done, or permit any act or thing inconsistent with, contesting or in any way impairing such ownership. RedHill agrees that all use of the Trademarks shall inure to the benefit of and be on behalf of Concordia. RedHill acknowledges that nothing in this Agreement shall give RedHill any right, title or interest in or to the Product Trademarks or Concordia

Trademarks other than the right to use the Product Trademarks in accordance with Section 4.1 hereof.

4.3 RedHill shall, to the extent permitted by Applicable Law, ensure that the Product Trademarks appear in marketing materials, in such manner as is reasonably determined by the Parties.

4.4 RedHill shall not use any Trademark other than the Product Trademarks to identify the Product in connection with its activities under this Agreement.

5. JOINT COMMERCIALIZATION COMMITTEE

5.1 Within [****] following the Effective Date, the Parties shall establish a joint commercialization committee (the "**JCC**") comprised of up to [****] with up to [****] being appointed by Concordia, of which [****] shall be the "**Concordia Project Leader**" based in Barbados, and up to [****] being appointed by RedHill, of which one shall be the "**RedHill Project Leader**". All such representatives shall be individuals of suitable authority and seniority with significant and relevant experience and expertise. Each Party may remove any member appointed by it for any reason or no reason and appoint another member in his or her stead. Any appointment or removal shall be notified to the other Party in writing.

5.2 The JCC shall be responsible for ensuring full cooperation between the Parties in implementing this Agreement and for [****] .

5.3 The Concordia Project Leader and the RedHill Project Leader (collectively, the "**Project Leaders**") shall facilitate the flow of information and otherwise promote communications and collaboration within and among the Parties, the JCC, and any other sub-committees or teams that the JCC may appoint or constitute.

5.4 The JCC shall hold meetings at such times and places as agreed between the members of the JCC, but in no event less frequently than following every [****] to examine the [****]. The JCC may conduct meetings in person or by teleconference or videoconference or other means. Meetings shall be chaired by the [****] Project Leader in [****]. Each Party shall only be responsible for its own costs related to the JCC and meetings. The Project Leader conducting the meeting also will be responsible for taking and distributing the minutes. At and between meetings of the JCC, each Party shall keep the other fully and regularly informed as to its progress with its respective tasks and obligations under the Agreement and shall make themselves available to the other members of the JCC for communication purposes.

5.5 At each JCC meeting, at least [****] appointed by RedHill and [****] based in [****] for Concordia present in person, by teleconference or videoconference or by other means shall constitute a quorum. Each Party shall have equal voting power, whether represented by one or two committee members, on all matters before the JCC and, unless specifically determined otherwise herein, with [****] having a final vote; provided, however, that in the case of a tie-vote on [****] issues as described in **Annex C** hereto, such matter shall, at the request of either Party, be referred to a designated senior executive

of each Party for resolution. In the event that such senior executives are unable to reach agreement within thirty (30) days of the date of referral, then the matter shall, upon written notice of either Party to the other Party, be resolved by final, binding arbitration in accordance with Section 20.4.

5.6 Each Party shall be entitled to appoint up to [****] non-voting observers to the JCC. Furthermore, by mutual consent of the members appointed by both Parties, such consent not to be unreasonably withheld, conditioned or delayed, either Party may invite other personnel to attend appropriate meetings of the JCC.

5.7 The JCC may act without a meeting if prior to such action the JCC members agree regarding such action and a written consent thereto is signed by all members of the JCC.

5.8 The JCC may amend or expand upon the foregoing procedures for its internal operations by unanimous written consent.

5.9 The JCC shall not have any power to amend this Agreement or bind or incur liability on behalf of either Party hereto without such Party's express prior written authorization, and shall have only such powers as are specifically delegated to them hereunder.

5.10 Notwithstanding the regular meeting schedule of the JCC, a meeting of the JCC may be called by either Party on ten (10) days written notice to the other, unless such notice is waived by the other Party. In the event of any meeting called pursuant to a notice under this Section 5.10, the Party calling the meeting shall provide with the notice an agenda for the meeting together with the information that such Party believes is relevant for the items to be discussed. Neither Party shall call more than [****] additional meetings per Calendar Year for the JCC under this Section 5.10 without the other Party's consent.

5.11 The JCC shall, among its other authorities, have the authority to establish and appoint sub-committees, as the JCC deems necessary. All decisions of a subcommittee are subject to approval by the JCC. The JCC may prescribe rules of procedure for the foregoing subcommittees. In the event that any such other subcommittees fail to reach agreement on an issue within its respective area of oversight, the matter shall be referred to the JCC.

5.12 Unless otherwise expressly stated, nothing contained in this Agreement may be deemed to make any member of the JCC a partner, agent or legal representative of the other, or to create any fiduciary relationship for any purpose whatsoever. No member of the JCC shall have any authority to act for, or to assume any obligation or responsibility on behalf of, any other member of the JCC, or the other Party.

6. SALE, MANUFACTURE AND SUPPLY OF PRODUCT

6.1 During the Term, Concordia shall continue to be responsible for:

6.1.1 Manufacturing, packaging, labeling, warehousing and distributing the Product in the Territory.

6.1.2 Accepting orders, invoicing customers, compliance with reimbursement systems, and collecting receivables.

6.1.3 Preparing training materials, Territory sales reports and Promotional Materials for RedHill's field sales force.

6.1.4 Providing customer service activities, pharmacovigilance services, medical information services and regulatory filings and activities.

6.2 [****].

6.3 All terms of sale, including policies concerning pricing, credit terms, cash discounts and returns and allowances shall be set by Concordia consistent with its normal internal selling and past practices; provided that [****]. Without derogating from the foregoing, Concordia will not, without RedHill's prior written consent, [****].

6.4 RedHill shall not [****]. All [****] for the Product shall be received and executed by Concordia or its designee. If RedHill receives [****], it shall promptly refer such to Concordia.

6.5 Concordia shall supply the Product during the Term in sufficient quantities to timely satisfy orders for the Product in the Territory. Concordia shall maintain reasonable inventory levels of the Product in order to ensure its ability to fulfill its obligations hereunder. All orders for Product shall be subject to acceptance by Concordia, which acceptance shall not be unreasonably withheld. [****]. Any such request received by RedHill shall be forwarded by RedHill to Concordia for consideration, and in Concordia's sole discretion, processing.

6.6 In the event that Concordia fails to supply the Product as required pursuant to this Agreement for any reason or no reason, which failure results in lost sales in the Territory, the Parties shall meet and attempt to negotiate a mutually agreeable and commercially reasonable solution. If the Parties cannot reach such an agreement within a reasonable period, the issue will be dealt with as contemplated in respect of major issues under Section 5.5 of this Agreement.

6.7 Concordia shall have the sole responsibility and right to accept any returned Product in accordance with Concordia's returns policy. RedHill shall not solicit the return of any Product and shall not receive or accept any returned Product. In the event that any such Product is inadvertently returned to RedHill, RedHill shall promptly ship such Product to Concordia, along with any documentation or explanation RedHill receives regarding the reason for the return, at Concordia's cost and expense.

6.8 Concordia shall be responsible for all aspects of [****] in connection with the Product, including [****]. Concordia shall communicate with RedHill sales management on a Calendar Quarterly basis regarding such [****] activities.

6.9 For the avoidance of doubt, and unless otherwise set forth herein, each Party shall be responsible for all costs and expenses of its performance under this Agreement.

6.10 If there is a change in market conditions, which materially affects the economics of this Agreement, the Parties will discuss modifications to this Agreement in good faith to address such changed market conditions. [****].

7. INFORMATION; REPORTING; RECALLS

7.1 **Information**. Each Party shall promptly notify the other Party of receipt of information from a Governmental Authority that: (i) raises any material concern regarding the safety or efficacy of the Product, or would affect the Product Label and Insert, Promotion and/or sale of the Product; (ii) indicates a potential material liability for either Party relating to the Product; (iii) is reasonably likely to lead to a recall or market withdrawal of the Product; or (iv) is reasonably likely to impact the manner in which a Party satisfies its obligations hereunder. Concordia shall promptly provide RedHill with copies of all material communications received from any Governmental Authority concerning the Product.

7.2 **Adverse Experience Reporting**. RedHill shall give Concordia notice of any Product complaint it receives, including but not limited to any adverse drug experience (as defined in 21 CFR 314.80 or any successor provision thereto) of which RedHill obtains information in accordance with the following procedure:

7.2.1 Information concerning any adverse drug experience associated with the Product shall be reported to Concordia's call center which can be reached at medicalinformation@concordiarx.com or (877) 370-1142 within one (1) Business Day after initial receipt of such information;

7.2.2 RedHill's report to Concordia shall contain: (i) the date the report was received by RedHill; (ii) the name of the reporter; (iii) the address and telephone number of the reporter; and (iv) an indication of the adverse drug experience; and

7.2.3 All other Product complaints not covered by 7.2.1 above shall be reported to Concordia in writing within [****] Business Days after initial receipt of such information.

7.3 Concordia shall be responsible for all activities relating to [****]within the Territory, including [****], preparation and filing of [****] reports, conducting [****],[****]. Without derogating from the foregoing, Concordia shall investigate all [****] and [****] associated with the Product, including those reported to Concordia by RedHill, and, as appropriate, report such information to [****]. In addition, Concordia shall provide RedHill with a summary of all [****] and [****] received by Concordia, during each Calendar Quarter and all material comments [****] with respect thereto within thirty (30) days after the end of such Calendar Quarter; provided, however, that Concordia shall provide RedHill prompt written notice of any [****] experienced in response to the use of the Product.

7.4 **Product Recall and Withdrawal**. Concordia shall have the sole responsibility with respect to any recall or withdrawal of the Product, and shall bear all costs and expenses relating thereto, except to the extent such recall or withdrawal is as a result of a breach by RedHill of the terms of this Agreement, or by the gross negligence, willful misconduct, bad faith or fraud of Redhill. At Concordia's request, where the Product has been recalled or withdrawn from the market, RedHill shall, as soon as reasonably practical and in accordance with Applicable Law, assist Concordia in obtaining the return of any Product

not in the direct possession or control of Concordia by notifying physicians who have received Samples from RedHill and by returning to Concordia Samples still in the possession of RedHill, and Concordia shall reimburse RedHill for all documented costs and expenses incurred in taking such actions.

7.5 **Product Medical Inquiries**. Concordia shall have the exclusive right and obligation, consistent with Applicable Law, to [****] for information about the Product made by any [****] or any other [****] to RedHill's representatives that warrant a response beyond the information included in the PIRs (all such questions or requests being referred to as "**Product Medical Inquiries**"). RedHill shall direct its representatives to direct all Product Medical Inquiries to Concordia's call center which can be reached at medicalinformation@concordiarx.com or (877) 370-1142.

7.6 **Third Party Actions and Communications**. Concordia shall be solely responsible for: (i) taking all actions and conducting all communication with all Third Parties in respect of the Product (other than Promotional Activities performed by RedHill in accordance with the terms hereof), including responding to all Product quality complaints in respect thereof, including complaints related to tampering or contamination; and (ii) investigating all Product quality complaints, adverse events, and field alerts in respect of the Product. Moreover, Concordia shall timely, and in good faith, respond to all Product complaints and investigate any such Product quality complaints, adverse events, and field alerts in respect of the Product.

8. REPORTS

8.1 **Reports.** On a [****] basis, within five (5) days following the end of each of [****], Concordia shall deliver to RedHill a report in the English language with respect to the relevant [****] (each, a "[****]") showing: (i) [****].

8.2 **Final Report and Payment**. Upon termination of this Agreement for any reason, Concordia shall deliver a final report, in the English language and the associated [****] after the end of the then current Calendar Quarter.

9. FINANCIAL PROVISIONS

9.1 **Commercialization Fee Payments**. In respect of each [****], or part thereof, during the Term, [****] shall pay [****] an amount equal to the product of: (i) [****] *multiplied* by (ii) [****] *multiplied* by (iii) [****] (the "**Commercialization Fee**"). To the extent any measuring period is less than a [****], the Commercialization Fee shall be based on the [****].

9.2 **Quarterly Reports and Payments**. All payments due pursuant to the provisions of this Section 9 shall be due and payable [****] on a [****] basis within [****] following the date for submission of the relevant [****], all against the receipt of an appropriate invoice from [****] for same. [****].

9.3 **Payment Method**. Any amounts due to [****] under this Agreement will be paid in US Dollars, by wire transfer in immediately available funds to an account designated in writing in an appropriate invoice at least [****]in advance by [****], as the case may be.

9.4 **Currency; Foreign Payments**. If any currency conversion will be required in connection with the calculation of any payment hereunder, such conversion will be made by using the average exchange rate for the purchase of the relevant currency as published in *The Wall Street Journal*, Eastern Edition, on the date of the payment.

9.5 **Taxes**. Any Tax in respect of the payments due hereunder shall be the sole responsibility of and paid by [****]. Notwithstanding the foregoing, [****] shall be responsible for and shall pay to [****] any sales, value-added or similar tax determined by a U.S. Governmental Authority ("**Sales Tax**") in respect of the Commercialization Fee. Unless required by Applicable Law, any Sales Tax shall be paid directly by [****]. To the extent that [****] has an obligation under Applicable Law to collect and remit any such Sales Tax (in which case [****] shall invoice [****] for such amount), any penalties and interest determined or assessed by a Governmental Authority for the failure or late withholding, collection or remittance of such Sales Tax by [****] is the sole responsibility of [****]. For greater certainty, except for Sales Tax and Tax in respect of the Commercialization Fee, [****] will not be responsible for collection or payment of any Tax in connection with [****] receipts or earnings arising from [****] interest in the Product.

10. RECORDS RETENTION AND AUDIT

10.1 **Record Retention**. Throughout the Term and for a term of [****]thereafter, Concordia will maintain (and will ensure that its Affiliates maintain) complete and accurate books, records and accounts that fairly reflect sales of the Product in the Territory, in sufficient detail to confirm the accuracy of Quarterly Reports and Commercialization Fee payments made hereunder, which books, records and accounts will be retained [****] after the end of the period to which such books, records and accounts pertain.

10.2 **Audit**. RedHill will have the right to have an independent certified public accounting firm of nationally recognized standing, reasonably acceptable to Concordia and who agrees to be bound by a customary undertaking of confidentiality, have access during Concordia's normal business hours, and upon reasonable prior written notice, to Concordia's records as may be reasonably necessary to verify the accuracy of Concordia's Quarterly Reports in respect of any period; *provided, however*, that except as set forth in Section 10.3, RedHill will not have the right to conduct more [****] in any Calendar Year. The accounting firm shall not in any way be compensated (in whole or in part) contingent on the outcome of the audit. Any such audit shall be completed within a reasonable time. The costs of the audit are the responsibility of RedHill provided that in the event that there is a shortfall of more than [****] in the payment due, the audit costs and all related travel costs will be covered by Concordia within [****]of billing.

10.3 **Payment of Additional Amounts**. If the audit report shows that additional payments are owed by [****] under this Agreement, [****] shall make such additional payments plus interest at the rate prescribed in Section 10.4 hereof within thirty ([****] after [****] demand. [****] shall have the right to conduct additional follow-up audits in the same Calendar Year to ensure that there are no further shortfalls.

10.4 **Interest.** All late payments under this Agreement shall bear interest from the date due until paid at a rate equal to [****] per month as of the date that such payment was due, or, if lower, the highest rate permitted under Applicable Law, calculated on the number of days such payment is delinquent.

10.5 **Confidentiality**. RedHill will treat all information subject to review under this Section 10 in accordance with the confidentiality provisions of Sections 15 and 16 below.

11. REPRESENTATIONS AND WARRANTIES

11.1 **By the Parties**. Each Party hereby represents, warrants and covenants to the other Parties as of the Effective Date as follows:

11.1.1 Such Party (a) has the power and authority and the legal right to enter into this Agreement and perform its obligations hereunder, and (b) has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party and is enforceable against it in accordance with its terms subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity, whether enforceability is considered a proceeding at law or equity.

11.1.2 Such Party has obtained all necessary consents, approvals and authorizations of all Governmental Authorities and other parties required to be obtained by such Party in connection with the execution and delivery of this Agreement and the performance of its obligations hereunder, except to the extent that the failure to have such consents, approvals and authorizations would not materially impair or delay the ability of the applicable Party to perform its obligations hereunder.

11.1.3 The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of Applicable Law or any provision of the articles of incorporation, bylaws or any similar instrument of such Party, as applicable, in any material way and (b) do not conflict with, violate, or breach or constitute a default or require any consent not already obtained under, any contractual obligation or court or administrative order by which such Party is bound, except in the case of (b), such matters that would not reasonably be expected to materially impair or delay the ability of the applicable Party to perform its obligations hereunder.

11.2 **By Concordia**. Concordia hereby further represents, warrants, and covenants to RedHill as follows:

11.2.1 It has the sole legal and/or beneficial title to and ownership of the Product, all as is necessary to fulfill its obligations under this Agreement and to grant all rights granted to RedHill pursuant to this Agreement. Other than as disclosed in Concordia's public filings on the System for Electronic Document Analysis and Retrieval ("**SEDAR**"), Concordia is not aware of any FDA communication or action suggesting its ability to

market or sell the Product in the Territory can or will be diminished or compromised or eliminated.

11.2.2 Other than as set forth in Annex B, it has not and during the Term shall not grant any new rights to Third Parties, or renew any existing rights that expire or terminate in the Field of Use in the Territory (and those [****] territories occupied by RedHill or stated in the Commercialization Plan as being assigned to RedHill) that conflict with the rights granted to RedHill hereunder.

11.2.3 The manufacture, use and sale of the Product by Concordia, and the exercise by RedHill of its rights granted under this Agreement, do not, and during the Term, will not infringe or otherwise violate any patent, trademark, copyright, trade secret or other intellectual property right of a Third Party in any material respect.

11.2.4 It has and shall maintain throughout the Term, all Regulatory Approvals necessary for the performance of its obligations hereunder.

11.2.5 Product: (i) shall be manufactured in conformance with all applicable federal, state and local statutes, ordinances and regulations, (including the Act), as the same may be amended from time to time; (ii) at the time of shipment by Concordia shall not be adulterated or misbranded within the meaning of the Act; and (iii) at the time of shipment by Concordia shall not be a product which would violate in any material respect any section of the Act if introduced into interstate commerce.

11.2.6 It has not received any written notice from any Third Party asserting or alleging that any research or development of the Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party.

11.2.7 There are no pending, and to Concordia's knowledge, no threatened, adverse actions, suits or proceedings against Concordia or its Affiliates involving the Product other than as disclosed in Concordia's public filings on SEDAR.

11.2.8 The Product Trademarks have been properly filed and registered with the U.S. Patent and Trademark Office and are valid and in full force and effect, and Concordia has the right to use and license the Product Trademarks, free and clear of any liens or encumbrances (other than such liens and encumbrances provided to Concordia's and/or its Affiliates' lenders).

11.2.9 To Concordia's knowledge, there are no pending legal suits or proceedings involving the Product; and to there are no threatened legal suits or proceedings in the Territory involving the Product other than as disclosed in Concordia's public filings on SEDAR.

11.2.10 There are no current pending, or to Concordia's knowledge, threatened in writing, material product liability, warranty or other similar claims by any Third Party (whether based in contract or tort and whether relating to personal injury, including death, property damage or economic loss) arising from the marketing or sale of the Product.

11.2.11 It will not act in a manner that is intended to and has the effect of materially and detrimentally affecting the operations, prospects, or reputation of RedHill.

11.3 **By RedHill**. RedHill hereby further represents, warrants, and covenants to Concordia that:

11.3.1 RedHill will conduct any activities under this Agreement in compliance with all Applicable Laws.

11.3.2 RedHill and any RedHill personnel performing RedHill's obligations hereunder will be professionally trained and duly qualified and have the experience and expertise to perform RedHill's obligations hereunder in a manner commensurate with professional standards generally applicable in this industry.

11.3.3 RedHill and any RedHill personnel have not been, and will not knowingly use in any capacity in the performance of this Agreement, the services of any person or entity, currently or ever debarred under 21 U.S.C. § 335a or convicted of a felony for conduct relating to the regulation or handling of any drug product.

11.3.4 It shall notify Concordia promptly if, during the term of this Agreement, it becomes aware that RedHill or any RedHill personnel comes under investigation by the FDA for debarment or disqualification or is debarred or disqualified.

11.3.5 It will not act in a manner that is intended to and has the effect of materially and detrimentally affecting the operations, prospects, or reputation of Concordia.

11.4 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

12. [****]; MUTUAL COLLABORATION

12.1 **Sale of Product**. [****].

12.2 **Mutual Collaboration**. Throughout the Term, the Parties shall discuss in good faith potential collaboration with respect to [****].

13. LIMITATION OF LIABILITY

EXCEPT IN THE CASE OF A FRAUD OR WILLFUL MISREPRESENTATION, BREACH OF APPLICABLE LAWS, BREACH OF CONFIDENTIALITY, INTELLECTUAL PROPERTY INFRINGEMENT, PRODUCT LIABILITY, RECALL, CONTAMINATION OR EXTORTION AS WELL AS ANY CRIMINAL, CIVIL OR ADMINISTRATIVE PROCEEDING INVOLVING THE PRODUCT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT,

WARRANTY, NEGLIGENCE OR TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT.

14. Intellectual Property

14.1 **The Product**. RedHill shall Promote the Product under the trademark "Donnatal", or such other Product Trademark as Concordia may direct in writing. RedHill may include its name on Promotional Materials in coordination with Concordia.

14.2 **No Rights or License**. Nothing in this Agreement shall give RedHill a license to any right, title or interest in or to the Product, the Product Trademarks, Product Copyrights, or other intellectual property of Concordia, its Affiliates or licensors related to any other property of Concordia, its Affiliates or licensors, except for the rights granted to RedHill in connection with Product sales under this Agreement as specified herein.

14.3 **Ownership of Intellectual Property Rights**.

14.3.1 RedHill acknowledges and agrees that Concordia or its Affiliates, as the case may be, are the owners of all rights, title and interest in and to the Product Trademarks and the Product Copyrights and all other intellectual property relating to the Product, including any form or embodiment thereof, and the goodwill now and hereafter associated therewith.

14.3.2 RedHill shall not, or knowingly cause another Person to, contest or dispute or otherwise impair or endanger the validity of, or the rights of Concordia, or any of its Affiliates, as the case may be, in and to, the Product Trademarks, the Product Copyrights, or, any other intellectual property rights relating to the Product, any part thereof, or the registrations thereof.

14.3.3 RedHill (upon written request of Concordia) shall assist Concordia in safeguarding its full rights, title and interest in and to the Product Trademarks, Product Copyrights and all other intellectual property relating to the Product.

14.3.4 RedHill shall not undertake any action to register or renew any of the Product Trademarks (or any Trademark similar thereto) or Product Copyrights. RedHill shall not use or adopt any Trademark that is confusingly similar to or a colorable imitation of, or that dilutes, any Product Trademark.

14.4 **Enforcement**

14.4.1 **Infringement Notice**. If either Party determines that a Third Party is wrongfully marketing, promoting or selling the Product or infringing any intellectual property of Concordia or its Affiliates or licensors relating to the Product, including actual, potential or suspected wrongful marketing, promoting or selling of the Product or infringement, and that such activities could affect the exercise of the rights granted under this Agreement by the other Party, it will notify the other Party in writing without undue delay.

14.4.2 **Enforcement**. Concordia will have the sole, exclusive and first right, but not the obligation, to remove such wrongful marketing, promotion, selling, infringement

and/or misappropriation and to control all litigation to remove such wrongful marketing, promotion, selling, infringement and/or misappropriation, all as it shall deem appropriate in its sole discretion, and to settle or compromise any such possible infringement by taking such action as Concordia or its Affiliates may determine in their sole and absolute discretion; provided, however, that Concordia shall not settle any such potential infringement in a manner that materially adversely affects the rights granted to RedHill hereunder, except with RedHill's prior written consent (which consent shall not be unreasonably withheld). Concordia shall be solely responsible for all costs and expenses of such litigation. In the event Concordia does take any action to remove such wrongful marketing, promotion, selling, infringement or misappropriation activity, Concordia will keep RedHill informed of the progress of such action. If Concordia decides not to take any action to remove such wrongful marketing, promotion, selling, infringement or misappropriation activity, it shall notify RedHill in writing and RedHill shall be entitled to do so at its own cost and expense upon giving written notice to Concordia within [****] days of the date of Concordia's notice. In the event RedHill does, at its discretion, undertake any action to remove such wrongful marketing, promotion, selling, infringement or misappropriation activity, RedHill will provide Concordia with copies of all relevant documentation so that Concordia will be informed of the continuing action and may comment upon such documentation sufficiently in advance of any initial deadline for filing a response, provided, however, that if Concordia has not commented upon such documentation in a reasonable time for RedHill to sufficiently consider Concordia's comments prior to a deadline, or RedHill must act to preserve the action, RedHill will be free to act without consideration of Concordia's comments, if any.

14.4.3 **Co-operation**. The Parties will provide reasonable assistance to each other (at no charge or expense, other than with respect to reasonable out-of-pocket expenses), including providing access to relevant documents and other evidence, making its employees available at reasonable business hours, and joining the action to the extent necessary to allow the prosecuting Party to maintain the action.

14.4.4 **Recovery**. Any amounts recovered in connection with or as a result of any action contemplated by Section 14.4.2, whether by settlement or judgment, will be used to reimburse the Parties for their reasonable documented costs and expenses in such action (which amounts will be allocated pro rata in accordance with the respective costs and expenses if insufficient to cover the totality of such expenses), [****].

14.5 **Infringement of Third Party Rights**. In the event that either Party is sued by a Third Party alleging that the Promotion, manufacture, marketing, use or offer to sell of the Product in the Territory infringes upon any intellectual property rights of such Third Party, the Party being so sued shall immediately give the other Party notice of same and the Parties shall thereafter proceed as provided in Section 17.

15. CONFIDENTIALITY

15.1 **Disclosure and Use Restriction**. The Parties agree that, during the Term and thereafter, each Party will keep completely confidential and will not publish, submit for

publication or otherwise disclose, and will not use for any purpose except for the purposes contemplated by this Agreement, any Confidential Information (as such term is defined below) received from the other Party. This Article 15 replaces and supersedes the Confidentiality Agreement entered into by the Parties dated [****].

15.2 **Confidential Information**. "**Confidential Information**" shall mean all information, intellectual property and know-how and any tangible embodiments thereof provided by or on behalf of one Party to another Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing this Agreement, which may include data; knowledge; practices; processes; ideas; research plans; engineering designs and drawings; research data; manufacturing processes and techniques; scientific, manufacturing, marketing and business plans; and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business. Notwithstanding the foregoing, Confidential Information shall not include information that:

(i) was already known to the receiving Party as evidenced by written records, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party;

(ii) was part of the public domain, at the time of its disclosure to such receiving Party;

(iii) became part of the public domain, after its disclosure to such receiving Party through no fault of the receiving Party;

(iv) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation not to disclose such information or know-how to others; or

(v) was independently discovered or developed by such receiving Party, as evidenced by their written records, without the use of Confidential Information belonging to the disclosing Party and prior to any subsequent disclosure by the receiving Party.

15.3 **Authorized Disclosure**. Notwithstanding the provisions of Section 15.1 above, a Party shall be entitled to disclose the Confidential Information of another Party hereto to the extent that such disclosure is:

(i) made in response to a valid order of a court of competent jurisdiction; *provided,* however, that such Party will first (to the extent practicably possible and permitted by such order) have given notice to such other Party and given such other Party a reasonable opportunity to quash such order, at such Party's sole cost and expense, and to obtain a protective order, at such Party's sole cost and expense, requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided further* that if a disclosure order is not quashed or a protective order

is not obtained, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order;

(ii) otherwise required by Applicable Law or the rules of a stock exchange on which such Party or such Party's parent company's securities are listed or traded; *provided, however*, that the receiving Party will provide the disclosing Party with notice of such disclosure in advance thereof to the extent practicably possible, and to the extent permitted seeks confidential treatment of the information disclosed and reasonably cooperates with any efforts of disclosing Party to seek confidential treatment of the information disclosed and discloses only that portion of the Confidential Information required;

(iii) made by such Party, in connection with the performance of this Agreement and on a need to know basis only in connection therewith, to Affiliates, directors, officers, employees, consultants, representatives or agents, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Agreement; or

(iv) made by such Party in the course of submitting financial accounts to relevant Governmental Authorities as per local statutory requirements or to existing or potential acquirers; existing or potential investment bankers; existing or potential investors, merger candidates, venture capital or private equity firms or other financial institutions or investors for purposes of obtaining financing; or, bona fide strategic potential partners; each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least equivalent in scope to those set forth in this Agreement.

16. PRESS RELEASES

Press releases or other similar public communication by any Party relating to the terms of this Agreement (but not, for the avoidance of doubt, unless reference is made to any of the other Parties or the terms of this Agreement, with respect to activities in exercise of its rights under this Agreement) will be approved in advance by the other Party, which approval will not be unreasonably withheld, conditioned or delayed, except for those communications required by Applicable Law, regulation or securities exchange rules on which such Party or such Party's parent company's securities are listed or traded, disclosures of information for which consent has previously been obtained, and information of a similar nature to that which has been previously disclosed publicly with respect to this Agreement, each of which will not require advance approval but will be provided to the other Party as soon as practicable after the release or communication thereof. For the avoidance of doubt, the Parties may issue press releases regarding the fact that this Agreement has been signed and the nature of the agreement so long as they do not describe the specific economic provisions hereof without approval from the other Party, unless required under Applicable Law, regulation or securities exchange rules on which such Party or such Party's parent company's securities are listed or traded, as aforesaid.

17. INDEMNIFICATION

17.1 **Indemnification Concordia**. Concordia will defend and hold RedHill, its respective Affiliates, and their respective directors, officers, employees and agents ("**RedHill's Indemnified Persons**") harmless, from and against any and all liability, damages, suits, investigations, claims, demands, actions, judgments, costs and expenses (including reasonable and documented attorneys' fees and expenses) ("**Losses**") to which the RedHill Indemnified Persons may become subject arising from any third party claim, demand, suit, action or proceeding to the extent arising out of or in connection with this Agreement or otherwise in connection with any actions taken by RedHill hereunder after the date of this Agreement; except that Concordia shall not be required to indemnify RedHill to the extent any Loss arises from or occurs as a result of the: (i) relevant negligence, willful misconduct, bad faith or fraud on the part of a RedHill Indemnified Person; or (ii) breach by a RedHill Indemnified Person of any relevant representations, warranties or covenants set forth in this Agreement. Without derogating from the foregoing, Concordia shall be responsible for all the costs, fees, expenses and control in connection with any litigation instituted by a Third Party relating to a claim or claims of infringement of intellectual property against either of the Parties, relating to or arising from the manufacturing, marketing, use, sale or offer to sell of the Product in the Territory and shall indemnify RedHill and its Indemnified Persons in respect of all Losses in connection therewith, subject to the foregoing clauses (i) and (ii).

17.2 **Indemnification RedHill**. RedHill will defend and hold Concordia, its respective Affiliates, and their respective directors, officers, employees and agents ("**Concordia's Indemnified Persons**", and, together with "**RedHill Indemnified Persons**", **"Indemnified Persons"**) harmless, from and against any and all Losses to which the Concordia Indemnified Persons may become subject arising from any third party claim, demand, suit, action or proceeding to the extent arising out of or in connection with this Agreement or otherwise in connection with any actions taken by Concordia hereunder after the date of this Agreement to the extent arising from or occurring as a result of or in connection with: (a) the negligence, willful misconduct, fraud or bad faith on the part of RedHill in performing any activity contemplated by this Agreement; and/or (b) any breach by a RedHill Indemnified Person of any representations, warranties, or covenants set forth in this Agreement.

17.3 **Conditions to Indemnity**. Each Party's agreement to indemnify and hold the other harmless is conditioned upon the Indemnified Person: (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within [****] days after the Indemnified Person has knowledge of such claim, demand or action; (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand; and (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation of and defense of any such claim or demand. The indemnifying Party shall not compromise or settle such claim or demand without the indemnified Party's prior written consent, unless such settlement includes as an unconditional term thereof the giving

by the claimant or plaintiff to such indemnified Party a complete release from all liability in respect of such claim or litigation. If the Party entitled to indemnification fails to notify the indemnifying Party without undue delay pursuant to the foregoing clause (i), the indemnifying Party shall only be relieved of its indemnification obligation to the extent it is materially prejudiced by such failure and provided further that the indemnified Party is not obligated to notify the indemnifying Party of claims, demands and/or actions made directly against the indemnifying Party only. Notwithstanding the foregoing, if in the reasonable judgment of the indemnified Party, such suit or claim involves an issue or matter which could have a materially adverse effect on the business, operations or assets of the indemnified Party, the indemnified Party may waive its rights to indemnity under this Agreement and control the defense or settlement thereof, but in no event shall any such waiver be construed as a waiver of any indemnification rights such indemnified party may have at law or in equity.

17.4 **Participation in Defense**. If the indemnifying Party defends the suit or claim, the indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense; provided, however, that the indemnifying Party shall pay the reasonable and documented fees and costs of any separate counsel to the extent such separate representation is due to a conflict of interest between the Parties.

17.5 **Settlement**. No Party shall, without the consent of the other Party, which shall not be unreasonably withheld, conditioned or delayed, enter into any settlement or compromise or consent to any judgment in respect of any claim related to the rights and liabilities under this Agreement, unless such settlement, compromise or consent includes an unconditional release of the other Party from all liability arising out of the claim and does not otherwise limit or impair the other Party's rights.

18. INSURANCE

18.1 Each Party hereto shall maintain, for the Term and thereafter, insurance sufficient to cover its obligations under this Agreement and under law as it customarily maintains for similar activities in the regular course of its business.

18.2 Without derogating from the generality of the aforesaid, [****].

19. TERM AND TERMINATION

19.1 **Term**. Unless earlier terminated in accordance with the provisions of this Article 19, the term of this Agreement (the "**Term**") shall be for the period of three (3) years commencing upon the Effective Date, following which the Term shall be renewed for an additional [****] upon mutual agreement between the Parties.

19.2 **Termination for Cause**. Without derogating from any other remedies that either Party may have under the terms of this Agreement or at law, each Party hereto shall have the right upon [****] prior written notice to terminate this Agreement forthwith upon the occurrence of any of the following:

19.2.1 the commission of a material breach by any other Party hereto of its obligations hereunder, and such other Party's failure to remedy such breach to the reasonable satisfaction of the other Party within [****] after being requested in writing to do so; or

19.2.2 the occurrence of a Bankruptcy Event in respect of another Party.

19.3 **Termination for** [****].

19.3.1 After [****] (the "**RedHill Initial Term**"), RedHill shall be entitled, in its sole discretion, to terminate this Agreement in its entirety [****] if, in RedHill's good faith judgment, [****] . RedHill may effect such termination at any time after the RedHill Initial Term by providing [****] prior written notice to Concordia. Furthermore, RedHill shall be entitled, at any time, in its sole discretion, to terminate this Agreement [****] if, Concordia has [****].

19.3.2 After [****] (the "**Concordia Initial Term**"), Concordia shall be entitled, in its sole discretion, to terminate this Agreement [****] if RedHill is not, in Concordia's good faith judgment, [****] in accordance with the terms of this Agreement.

19.3.3 The terminating Party shall not incur any liability and shall not be required to pay any compensation in respect of such termination for convenience, other than for any amounts properly owing to the effective date of termination.

19.4 **Continuation following Concordia's Bankruptcy**. The Parties agree that in the event that Concordia becomes insolvent or makes a filing under bankruptcy or similar laws in any jurisdiction, RedHill shall have the protection afforded to the licensee under the United States Bankruptcy Code, including but not limited to, the protections set forth in 11 U.S.C §365(n) or its equivalent in any other jurisdiction which allows the licensee, upon rejection of the license agreement by the debtor-licensor or its representative, the option to either retain the licensee's rights in the intellectual property under the existing contract while continuing to pay royalties, or to treat the executory contract as terminated.

19.5 **Consequences of Termination**

19.5.1 **License**. Upon termination of this Agreement, all rights granted to RedHill under Section 2 will automatically terminate and all such rights shall automatically revert to Concordia.

19.5.2 **Return of Information and Materials**. Upon termination of this Agreement, each Party will return to the other all Confidential Information of the other Party (except one copy of which may be retained for archival and compliance purposes), provided that any such retained copy shall continue to be subject to the confidentiality provisions of this Agreement.

19.5.3 **Accrued Rights**. Termination or expiration of this Agreement for any reason will be without prejudice to any rights or financial compensation that will have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration will not relieve a Party from obligations that are expressly indicated to survive

the termination or expiration of this Agreement, whereas "accrued" shall mean the creation and/or maturity of a claim.

19.5.4 **Survival**. Sections 1, 8.2, 10, 13, 14.3, 15, 16, 17, 18, 19 and 20 of this Agreement will survive expiration or termination of this Agreement for any reason.

20. MISCELLANEOUS

20.1 **Assignment**. Without the prior written consent of the other Party, neither Party shall 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 a Party may assign or transfer this Agreement and its rights or obligations hereunder without the consent of the other Party to any Affiliate and to any Third Party successor in interest with which it has merged or consolidated, or to which it has transferred all or a substantial part of its assets or stock to which this Agreement relates; provided such Third Party assumes and agrees, in advance, to assume the obligations of the transferring party under this Agreement.

20.2 **Severability.** Should any term or provision of this Agreement be or become invalid or unenforceable or should this Agreement contain an omission, the validity or enforceability of the remaining terms or provisions shall not be affected. In such case, subject to the next following sentence, the Parties shall immediately commence to negotiate in good faith in order to replace the invalid or unenforceable term or provision by such other valid or enforceable term or provision which comes as close as possible to the original intent and effect of the invalid or unenforceable term or provision, or respectively, to fill the omission by inserting such term or provision which the Parties would have reasonably agreed to, if they had considered the omission at the date hereof. In the event that any term or provision as aforesaid is invalid, void or unenforceable by reason of its scope, duration or area of applicability or some similar limitation as aforesaid, then the court making such determination shall have the power to reduce the scope, duration, area or applicability of the term or provision so that they shall be enforceable to the maximum scope, duration, area or applicability permitted by Applicable Law which shall not exceed those specified in this Agreement or to replace such term or provision with a term or provision that comes closest to expressing the intention of the invalid or unenforceable term or provision.

20.3 **Governing Law.** This Agreement will be governed by and construed in accordance with the substantive laws of the State of New York, USA, without reference to any rules of conflicts of laws.

20.4 **Dispute Resolution**. Subject to Section 5.5 with regard to JCC disputes, all disputes regarding this Agreement shall be finally settled by arbitration conducted under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with the said Rules. The place of arbitration shall be New York City. The language of the arbitration shall be English and all correspondence between the Parties related to the arbitration shall also be in English. The arbitration award shall be final and binding on both parties. The arbitrator shall be liable to give written grounds for its

decision. The arbitrator shall determine what discovery will be permitted, consistent with the goal of reasonably controlling the cost and time that the Parties must expend for discovery, provided that the arbitrator shall permit such discovery as he or she deems necessary to permit an equitable resolution of the dispute. The arbitration proceedings and the decision of the arbitrator shall be deemed Confidential Information of both Parties. Judgment upon any award rendered may be entered in any court having jurisdiction, or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be. Each Party shall pay its own expenses of arbitration, and the expenses of the arbitrator shall be equally shared between the Parties, unless the arbitrator assesses as part of his or her award all or any part of the arbitration expenses of a Party (including reasonable and documented attorneys' fees) against the other Party. Notwithstanding the foregoing, any Party may apply to any court of competent jurisdiction and seek interim, provisional, injunctive or other equitable relief until the award is rendered or the controversy is otherwise resolved.

20.5 **Notices**. All notices or other communications that are required or permitted hereunder will be in writing and delivered personally with acknowledgement of receipt, sent by electronic mail (provided receipt is acknowledged), facsimile (and promptly confirmed by personal delivery, registered or certified mail or overnight/express courier as provided herein), sent by nationally-recognized overnight courier or sent by registered or certified mail, postage prepaid, return receipt requested, addressed as follows:

If to Concordia, to:

Concordia Pharmaceuticals Inc., S.à.r.l. Barbados Branch,
Canewood Business Centre
5 Canewood Industrial Park
St. Michael, Barbados, BB11005
Attention: [****]
Telephone: [****]
Fax: 246-621-1860
[****]
With a copy to [****]

If to RedHill, to:

RedHill Biopharma Ltd.
21 Ha'arba'a Street
Tel-Aviv 64739
Israel
Fax: +972 (3) 541 3144
Email: [****]

or to such other address as the Party to who notice is to be given may have furnished to the other Party in writing in accordance herewith. Any such communication will be deemed to have been given: (i) when delivered, if personally delivered; (ii) on the Business Day (on the receiving end) after dispatch, if sent by nationally-recognized overnight/express courier (third Business Day if sent internationally); (iii) on the third Business Day

following the date of mailing, if sent by mail (fifth Business Day if sent internationally); and (iv) on the first Business Day (on the receiving end) after being sent by facsimile or electronic mail. It is understood and agreed that this Section 20.5 is not intended to govern the day-to-day business communications necessary between the Parties in performing their duties, in due course, under the terms of this Agreement.

20.6 **Entire Agreement; Modifications.** This Agreement sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understanding, promises and representations, whether written or oral, with respect thereto are superseded hereby, including the [****]. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth herein. No amendment, modification, release or discharge will be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties; this shall also apply to any change of this clause.

20.7 **Relationship of the Parties**. It is expressly agreed that the Parties will be independent contractors of one another and that the relationship between the Parties will not constitute a partnership, joint venture or agency.

20.8 **Waiver.** Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver will be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. Any such waiver will not be deemed a waiver of any other right or breach hereunder.

20.9 **Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument, and shall become effective when counterparts have been signed by each of the Parties and delivered to the other Parties; it being understood that all Parties need not sign the same counterparts. The exchange of copies of this Agreement and of signature pages by facsimile transmission, by electronic mail in "portable document format" (".pdf") form, or by any other electronic means intended to preserve the original graphic and pictorial appearance of a document, or by combination of such means, shall constitute effective execution and delivery of this Agreement as to the Parties and may be used in lieu of the original Agreement for all purposes. Signatures of the Parties transmitted by facsimile shall be deemed to be their original signatures for all purposes.

20.10 **No Third Party Beneficiaries.** The representations, warranties, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns, and they will not be construed as conferring any rights on any other parties.

20.11 **Expenses**. Except as expressly provided herein, each party shall each bear its own legal, accounting, brokerage and other costs and expenses in connection with this Agreement and the transactions contemplated hereby.

20.12 **Further Assurances.** Each Party will duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further

acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary to carry out the provisions and purposes of this Agreement.

20.13 **Force Majeure**. No party shall be responsible to the other for failure or delay in performing any of its obligations under this Agreement or for other non-performance hereof but only to the extent that such delay or non-performance is occasioned by a cause beyond the reasonable control and without fault or negligence of such party, including earthquake, fire, flood, explosion, discontinuity in the supply of power, court order, or governmental interference, act of God, general strike or other general labor trouble, act of war or terrorism and provided that such party will inform the other party as soon as is reasonably practicable and that it will entirely perform its obligations immediately after the relevant cause has ceased its effect. If any such force majeure event continues for a continuous period of three (3) months, a Party whose performance is not prevented by such event may terminate this Agreement thereafter so long as the force majeure event continues, with immediate effect by providing the other Parties with written notice.

[*Signature Page Follows*]

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

RedHill Biopharma Ltd.

By: /s/ Dror Ben-Asher
Name: Dror Ben-Asher
Title: CEO
Date: Dec. 30, 2016

By: /s/ Adi Frish
Name: Adi Frish
Title: Senior VP Bus. Dev. and Licensing
Date: Dec. 30, 2016

Concordia Pharmaceuticals Inc., S.à.r.l., Barbados Branch

By: /s/ [****]
[****]
Title: [****]

STRICTLY CONFIDENTIAL

ANNEX A

COMMERCIALIZATION PLAN

[****]

STRICTLY CONFIDENTIAL

ANNEX B

[****]

30

ANNEX C

[****]

[****]

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 23, 2017

/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, Micha Ben Chorin 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 23, 2017

/s/ Micha Ben Chorin
Micha Ben Chorin
Chief Financial Officer

Exhibit 13

CERTIFICATION BY CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUAN 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, 2016 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 23, 2017

/s/ Dror Ben-Asher
Dror Ben-Asher
Chief Executive Officer

/s/ Micha Ben Chorin
Micha Ben Chorin
Chief Financial Officer

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. 333-209702), and the Registration Statements on Form S-8 (file No. 333-207654 and file No. 333-188286) of RedHill Biopharma Ltd. of our report dated February 22, 2017, relating to the financial statements which appears in this Form 20-F.

Tel-Aviv, Israel
February 22, 2017

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

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